

FINAL REPORT OF THE JOINT STUDY COMMITTEE ON THE PRESCRIPTION OF MEDICAL CANNABIS FOR SERIOUS MEDICAL CONDITIONS

Committee Members:

Senator Renee Unterman, Co-Chairperson District 45

Senator Dean Burke District 11

Senator Butch Miller District 49

Senator Curt Thompson District 5

Mr. Charles Spahos, Executive Director Prosecuting Attorneys' Council of Georgia

Representative Allen Peake, Co-Chairperson District 141

Representative Rich Golick
District 40

Representative Micah Gravley
District 67

Representative Margaret D. Kaiser District 59

Dr. Matthews W. Gwynn, M.D. Medical Association of Georgia

Report prepared jointly by:

Senate Research Office

House Budget and Research Office

December 31, 2014

TABLE OF CONTENTS

Introduction
Summary of Testimony
Committee Recommendations
U.S. Department of Justice Memorandum on Guidance Regarding Marijuana Enforcement
Letter from Representative Rich Golick
Letter from Senator Curt Thompson
Letter from Mr. Charles SpahosAppendix [

INTRODUCTION

The Joint Study Committee on the Prescription of Medical Cannabis for Serious Medical Conditions (the "Committee") was created by Senate Resolution 981 during the 2014 Legislative Session of the Georgia General Assembly. The Committee was charged with undertaking a study of the issues relating to the potential prescriptive use of medical cannabis for serious medical conditions to determine whether it would be appropriate to enact legislation making new provisions or changing provisions of current law with regard to such prescriptive use. Senate Resolution 981 expressed the sense of the Senate that the state's purpose in desiring to study this matter is the compassionate, potentially life-saving use of medical cannabis, and that it is not the state's intent to sanction, encourage, or otherwise be construed as a movement in the direction of legalization of the recreational use of cannabis or other controlled substances.

Senator Renee Unterman of the 45th and Representative Allen Peake of the 141st co-chaired the Committee, which held five public meetings at locations throughout the state. Committee hearings were held as follows:

- August 27, 2014, at the State Capitol, Atlanta, Georgia;
- September 10, 2014, at Mercer University, Macon, Georgia;
- October 1, 2014, at Georgia Gwinnet College, Lawrenceville, Georgia;
- November 12, 2014, at Georgia Regents University, Augusta, Georgia; and
- December 3, 2014, at the State Capitol, Atlanta, Georgia.

In addition to the co-chairpersons, the Committee was comprised of the following individuals:

- Senator Dean Burke of the 11th;
- Senator Butch Miller of the 49th;
- Senator Curt Thompson of the 5th;
- Representative Rich Golick of the 40th;
- Representative Micah Gravley of the 67th;
- Representative Margaret D. Kaiser of the 59th;
- Mr. Charles Spahos, Executive Director, Prosecuting Attorneys' Council of Georgia; and
- Dr. Matthews W. Gwynn, M.D., Specialist in Neurology, Medical Association of Georgia.

SUMMARY OF TESTIMONY

The Committee received testimony from the medical community, law enforcement agencies, and patient advocates on issues related to potentially legalizing and regulating the possession, cultivation, and distribution of cannabidiol (CBD) oil in Georgia. This testimony built and expanded upon the significant volume of testimony presented on House Bill 885, sponsored by Representative Peake, during the 2014 Legislative Session. The following summarizes the testimony presented to the Committee at its five meetings held throughout the state.

First Meeting: Wednesday, August 27, 2014

The first meeting of the Committee was held at the State Capitol in Atlanta, Georgia, where testimony was given by the following individuals:

- Paige Figi. Ms. Figi is the mother of a Colorado child with intractable epilepsy. Ms. Figi treats her child with an oil derived from cannabis known as "Charlotte's Web," which has significantly reduced her daughter's incidence of gran mal seizures.
- Matt D. Cook, Manager, Cook Consulting, LLC, and former Senior Director for Enforcement, Colorado Department of Revenue. Mr. Cook was instrumental in designing the regulatory and enforcement structures for the State of Colorado's initial medical cannabis program.
- James Bell, Georgia Campaign for Access, Reform, and Education (Georgia CARE).

Paige Figi told the Committee the story of her seven year old daughter, Charlotte, who suffers from debilitating seizures brought on by a rare form of severe, intractable epilepsy. Ms. Figi indicated to the Committee that Charlotte once suffered up to 1,200 gran mal seizures each month, with the various treatments she underwent providing little relief. After the treatments proved unworkable, the Figi family explored the use of an oil derived from cannabis that, at the time, was rumored to have significant effects on reducing seizures. Ms. Figi told the Committee that, after starting the cannabis oil treatment, Charlotte's seizures fell to only three in total over an eight-month period, almost entirely eliminating them. She noted that Charlotte, during the time since starting her treatments, has shown considerable improvement in her autonomy and less dependence on her other medicines and equipment.

Ms. Figi noted that Colorado's programs and state laws which permit the use of cannabis oil for serious medical conditions have created numerous "medical refugees" from other states who have come to Colorado to use these medications to treat their children. She noted that hemp is largely an industrial waste product and that the strains bred in Colorado for treating pediatric conditions are designed to be specifically high in CBD and low in tetrahydrocannabinol (THC)—generally with a THC content of less than 0.3 percent. This reduces most psychoactive effect from the THC component. Ms. Figi suggested that low-THC/high-CBD products, such as Charlotte's Web and similar strains, should be removed from Schedule I in the Georgia Controlled Substances Act so that testing and clinical trials can be conducted in Georgia without fear of prosecution.

Ms. Figi is currently working with non-profit partners to treat roughly 400 children in Colorado with the Charlotte's Web product. She noted anecdotal evidence she had collected suggesting that 78 percent of the patients treated with the product had seen at least a 50 percent reduction in seizure activity with no side effects. She stated that her organization guarantees an unlimited supply of the product to patients regardless of their ability to pay.

Matt Cook testified regarding his experience as the head of enforcement for the Colorado Department of Revenue when the state's medical cannabis program was enacted by the legislature and brought online in the following months. Mr. Cook offered his opinion that the best way to promote a robust medical cannabis program in the state is to allow closely regulated cultivation and distribution of legalized forms of cannabis. In response to questions from Representative Rich Golick, Mr. Cook indicated that Missouri provides an example of several best practices security requirements for cultivation facilities, and requires testing and detailed labeling of all products produced for sale. Given his experience, Mr. Cook indicated that regulatory structures based on alcoholic-beverage control structures offer the best model for states to build from in designing medical cannabis regulatory programs.

With regard to cultivators, Mr. Cook recommended that a lottery system not be used to issue licenses. Instead, he stated that a detailed application and investigation process should be used, with applicants being required to post a sizeable cash bond. He indicated that it might make sense to divide cultivation licenses among pre-established regions or districts to ensure access in all areas of the state. He also suggested that limiting cultivation to academic institutions only (rather than licensed cultivators) may present some issues in terms of creating a sizeable supply of products, because many universities have been reluctant to engage in clinical research projects involving cannabis, as doing so in violation of current federal law could jeopardize the universities' federal funding.

Mr. Cook stressed that buy-in from cannabis industry participants, cooperation between state and local agencies, and implementing tested regulatory elements (including those described above) have been the key elements of success in other states that have started medical cannabis programs.

James Bell of Georgia CARE indicated that his organization wants to see a medical cannabis program in place that can help children and adults with glaucoma, Crohn's disease, post-traumatic stress disorder, cancer, HIV/AIDS, and patients with severe seizures. He stated his view that, in order to enable treatment of people with these conditions, patients, as well as their caregivers, need access to approved cannabis products.

Second Meeting: Wednesday, September 10, 2014

The second meeting was held at Mercer University in Macon, Georgia. At this meeting, the Committee heard testimony from the following individuals:

- Aaron Klepinger: parent of child with seizure disorder; in Colorado;
- Chris Clark: parent of child with seizure disorder; wife in Colorado;
- Blaine & Shannon Cloud: parent of child with seizure disorder;
- Christina Cusack: suffers from multiple sclerosis;
- Katie Crosby: suffers from chronic pain;
- Daryl Hayes: parent of child with autism and seizure disorder;
- David Garrison: cancer patient;
- Sebastien Cotte: parent of child with mitochondrial disease; in Colorado;
- Katherine Bailey Lynch: parent of child with seizure disorder;
- Joshua Littrell: Air Force veteran suffering from chronic pain;
- Corey Lowe: parent of child with seizure disorder; moved to Colorado;
- Brian Cox: parent of child with seizure disorder; mom and child in Colorado;
- Perry Parks: veteran suffering from PTSD; and

 Jason Cranford: Grower from Colorado who has provided cannabis oil to Georgia families.

Individuals suffering from seizure disorders, chronic pain, and mitochondrial disease testified in favor of cannabis oil with a high-CBD and low-THC concentration, whereas individuals suffering from multiple sclerosis, cancer, and PTSD testified in favor of full legalization of medical marijuana with higher THC concentrations.

Additionally, Jason Cranford, a Colorado citizen who cultivates cannabis oil, testified about his experience growing and distributing this drug to patients. In early 2010, Cranford began researching and analyzing cannabis with high CBD concentrations using an analytics lab in Colorado to test the drug. After five years of breeding this strain of marijuana, Cranford was able to reduce the amount of THC in the plant from 7 percent to 1 percent. Cranford was then hired by a pharmaceutical company and granted access by the National Institute of Health for the exclusive use of the government issued 507-patent to study cannabinoids. Cranford continued to study the drug and found that medical cannabis with high CBD concentrations was not toxic, even in high amounts. Cranford now treats patients with cannabis oil in Colorado through his non-profit organization, Flowering Hope Foundation.

Seizure Disorder

Aaron Klepinger's son, Hunter, suffers from a seizure disorder and is currently being treated with cannabis oil in Colorado. Prior to using cannabis oil, Hunter was treated with FDA approved seizure medications which caused pain, rapid weight gain, and extreme insomnia, and did not help to reduce the seizures. After moving to Colorado and using cannabis oil, Hunter has shown an increased awareness of his environment, increased eye contact with others, ability to track items visually, ability to tolerate movement better, and increased purposeful arm movement to interact with and explore his environment. Further, according to Mr. Klepinger, Hunter is calmer, happier, and less agitated.

Sergeant Chris Clark's son suffers from Lennox-Gastaut syndrome, a form of seizure disorder that is characterized by frequent and different types of seizures. Prior to using cannabis oil, Sgt. Clark tried twenty different FDA approved seizure medications that caused "horrible" side effects, including the inability to walk. Sgt. Clark's son also underwent brain surgery twice that helped reduce "drop attack" seizures, but did not reduce the frequency and number of seizures. After moving to Colorado and using cannabis oil, Sgt. Clark has noticed a large reduction in his son's seizures.

Testimony was also provided by Blaine and Shannon Cloud, Katherine Lynch, Daryl Hayes, Corey Lowe, and Brain Cox, all of whom have children with seizure disorders and advocate for cannabis oil.

Chronic Pain

Katie Crosby experiences chronic pain and has not been able to manage her pain effectively with the current pain medications on the market. Crosby testified that roughly 20 percent of Americans experience chronic pain and 10-15 percent of those people cannot work because of their pain. Although Crosby has not tried medical marijuana due to its illegality, she testified that cannabis oil helps reduce inflammation and pain. Additionally, the Committee heard testimony from Joshua Littrell who lives in Vermont, a state with legalized whole plant medical marijuana. Littrell grows marijuana and uses it to treat his chronic pain.

Mitochondrial Disease

Sebastien Cotte's son suffers from mitochondrial disease. Cotte testified that he treats his son with cannabis oil in Colorado and has noticed a 30 percent reduction in seizures. In addition, Cotte has noticed that his son is more alert and vocal.

Post-Traumatic Stress Disorder (PTSD)

Perry Parks, a veteran suffering from PTSD, testified that he uses medical marijuana every day to help manage his PTSD.

Cancer

David Garrison, a cancer patient, advocates for whole plant marijuana in a smokeable form. To deal with the enduring effects of chemotherapy, Garrison first tried to use narcotics (both hydrocodone and oxycodone). Garrison then chose to try marijuana, which has greatly minimized his anxiety, nausea, and pain.

Multiple Sclerosis

Christina Crusack suffers from multiple sclerosis causing severe pain her in back. Crusack advocates for a whole plant marijuana in a smokeable form with a high THC concentration. Crusack uses marijuana (illegally) to manage her pain. She testified that after years of experiencing pain, marijuana was the first drug that helped reduce her pain, help her appetite, and increase her happiness.

Third Meeting: Wednesday, October 1, 2014

The third meeting of the Committee was held at Georgia Gwinnett College's Student Center in Lawrenceville, Georgia, where testimony was given by the following individuals:

- Dennis Troughton, Deputy Director, Georgia Drugs & Narcotics Agency;
- Terry Norris, Executive Director, Georgia Sheriff's Association;
- Frank V. Rotondo, Executive Director, Georgia Association of Police Chiefs;
- John Cary Bittick, Monroe County Sherriff;
- Major Neil Franklin, Executive Director, Law Enforcement Against Prohibition;
- Jack Killorin, Director, Atlanta HIDTA, GBI;
- Chief Dennis Bell, Georgia Peace Officers Association;
- Ellen Gerstein, Gwinnett Coalition for Health;
- Danny Porter, Gwinnett County District Attorney;
- Chuck Spahos, Executive Director, Prosecuting Attorney's Council; and
- Dr. Greg Raduka, Georgia Marijuana Abuse Prevention Collaborative.

At the third meeting, law enforcement showed support for the legalization of CBD oil that would be grown, processed, and regulated in Georgia for the purpose of providing a treatment option for patients suffering from seizure-related disorders. Testimony indicated that there is a consensus among law enforcement agencies that their support of the legalization of CBD oil in Georgia is contingent upon the development and implementation of reliable and strict cultivation, regulation, and distribution processes. Georgia law enforcement agencies made it clear to the Committee that they did not support the legalization of marijuana for recreational use.

Decatur County Sheriff Wiley Griffin, president of Georgia Sheriff's Association, reported that Georgia's sheriffs are extremely concerned about the cultivation of cannabis. He further added

that there must be strict security measures in place for cultivation and distribution. Mr. Terri Norris, Executive Director of Georgia Sheriff's Association, joined Sheriff Griffin in providing testimony to the Committee. Sherriff John Cary Bittick of Monroe County shared his support of regulating CBD oil in Georgia and briefly shared that Haley Cox moved from Monroe County to Colorado so her family could obtain CBD oil to treat her seizure disorders.

Mr. Frank Rotondo, Executive Director of the Georgia Association of Police Chiefs, urged that no one in his organization would ever want to deny children relief from pain. He further added that a mechanism for proper dispensing of CBD oil should be part of any bill that is drafted. Mr. Rotondo also suggested that "caretakers" of patients prescribed CBD oil should be vetted and dispensation to these caretakers should be limited and narrowly construed in future legislation. Like those who spoke before him, Mr. Rotondo expressed concern for the high market value for any cannabis-derived product on the black market. Dr. Gwynn, a member of the Committee, added that he is concerned about the standardization of CBD oil products and wants people to receive the medication they are supposed to receive, reminding the Committee that the efficacy and dosages of CBD oil is yet to be determined by clinical trials.

Ms. Ellen Gerstein of the Gwinnett Coalition for Health provided testimony to the Committee that reflected a strong concern regarding substance abuse in youth. She acknowledged that her organization does not want to prevent sick adults and children from receiving FDA-approved treatments, but reminded the Committee that there is "big money" behind medical cannabis and that the financial impact of dispensing it in Georgia should be considered.

Mr. Jack Killorin, Atlanta HIDTA Director for GBI, echoed the statements of those who provided testimony before him and added that any crop grown in Georgia must be strictly controlled to ensure that it does not end up on the black market. He told the Committee that there is an ongoing epidemic of pharmaceutical abuse and that he supports compassionate distribution.

Chief Dennis Bell of the Georgia Peace Officers' Association reminded the Committee that the American Medical Association (AMA) recommends that marijuana remain classified as a Schedule I controlled substance. He supports keeping an open mind while considering CBD oil as treatment option. However, Georgia should be careful to not start a slippery slope that leads to the legalization of marijuana for recreational use.

Mr. Danny Porter, chair of the Prosecuting Attorney's Council (PAC), told the Committee that he feels strongly that CBD oil be viewed as a medication made from cannabis and that we move away from using the term "medical marijuana." State prosecutors have been clear that they have no interest in depriving the citizens of this state from legitimate medical care. They also will not support a law that conflicts with federal law; doing so would result in a professional ethics issue. Mr. Porter told the Committee that the burden is on the medical community to enable CBD oil to be available to patients as a medication by certifying a patient's condition. Mr. Porter has also agreed to assist in determining the appropriate levels of THC to be included in any future legislation. Mr. Chuck Spahos, Executive Director of PAC and Committee member, echoed the statements made by Mr. Porter, adding that nothing prevents a physician from classifying a condition that would authorize possession of a medication.

Major Neil Franklin, Executive Director of Law Enforcement Against Prohibition, told the Committee that resources related to education and treatment are very low and people in need of CBD oil should not be forced to obtain it from dangerous and non-regulated markets. He stressed that Georgia must regulate this medication.

Dr. Gregg Raduka of the Georgia Marijuana Abuse Prevention Collaborative provided a PowerPoint presentation to the Committee that applauded Georgia legislator's desires to help children and showed support for the Governor's Epidiolex® program at Georgia Regents University. He explained to the Committee that legalizing medical marijuana can create a "slippery slope" that could lead to the legalization of marijuana for recreational use. He reported that legal marijuana is currently a \$3 billion industry in the United States and this figure is expected to double in size by 2018. Dr. Raduka also stressed the importance of protecting Georgia's children from harm and ensuring that medical ingredients derived from marijuana are safe for consumption.

Fourth Meeting: Wednesday, November 12, 2014

The fourth meeting was held at Georgia Regents University (GRU) in Augusta, Georgia, where testimony was provided by the following individuals:

- Dr. Michael Diamond, Interim Senior Vice President, Research, Georgia Regents University;
- Dr. Yong Park, Principal Investigator, Department of Neurology, Georgia Regents University and Health System;
- Dr. Cynthia Wetmore, Director, Innovative Therapy/Phase I Program, Aflac Cancer and Blood Disorders Center; Director, Center for Clinical and Translational Research, Emory, Children's Pediatric Research Center;
- Dr. Terry M. Himes, Neurologist, Medical Center of Centerra;
- Jason Cranford, Colorado Grower, Flowering Hope Foundation; and
- Dr. Peter Buckley, Dean, Medical College of Georgia, Georgia Regents University.

GRU partnered with Governor Deal in April of 2014 to organize and conduct a scientific study for treating children with medication-resistant epilepsy with CBD. Since then, GRU has initiated a "fact finding mission" to identify feasible options for acquiring pharmaceutical grade CBD to conduct clinical trials and determine necessary steps for initiating the State of Georgia Clinical Study for medication resistant epilepsy.

The CBD product to be used in the State of Georgia Clinical Study is Epidiolex®, which is manufactured by GW Pharmaceuticals (GW Pharma) and has an "orphan designation" with the FDA in the treatment of Dravet Syndrome and Lennox-Gastaut Syndrome.¹ This orphan designation does not alter the standard regulatory requirements and process for obtaining marketing approval. Specifically, the safety and effectiveness of a drug must still be established through adequate and well-controlled studies. GW Pharma has six years of pre-research into cannabinoids in epilepsy, and Epidiolex® is classified as an anti-inflammatory, anti-convulsant, anti-oxidant, neuroprotective. The FDA recently granted Fast Track designation to GW's Epidiolex®, in the treatment of Dravet syndrome, a rare and catastrophic treatment-resistant

 $\underline{http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm.}$

¹ The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product ("drug") to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation, which requires that both the drug and the disease or condition must meet certain criteria specified in the ODA and FDA's implementing regulations at 21 CFR Part 316. *See*

form of childhood epilepsy.² This affords greater access to the FDA for the purpose of expediting the Epidiolex®'s development, review, and potential approval to get the drug to patients earlier.

Dr. Michael Diamond provided the Committee with an update and overview of the clinical trial plans at GRU. He shared with the Committee that Epidiolex® is being provided at no cost by GW Pharma. Thus far, the study has cost about \$400,000.00, which GRU has absorbed with hopes that the outcome will be positive. The cost to conduct the clinical trial study on 50 children for one year is estimated by GRU to be about \$8 million.

The Committee then heard discussion from a panel of physicians including Dr. Diamond, Dr. Cynthia Wetmore and Dr. Yong Park. The panel weighed in on issues surrounding conducting clinical trials on Epidiolex® and how the efficacy of the drug will be measured. Senator Unterman inquired about whether anyone is concerned or looking into the prolonged effect of CBD on the development of the brain. Dr. Diamond indicated that the research will not examine long-term effects, given constraints on resources, but he stated that long-term effects are an important part of studying the efficacy of the medication. Senator Burke also stated that the medical community should carefully weigh whether CBD oil has a place in children's healthcare. In response, Dr. Cynthia Wetmore agreed that any drug that is given to children should be carefully examined and screened for its potential effects on a developing child's brain. Dr. Wetmore stressed to the Committee that she would not give this drug to her own child without confirming its safety and efficacy through clinical trials.

Senator Unterman asked the panel whether the children in the study would remain on their current medications. The panel answered by explaining that the FDA has given guidelines on this issue and that it is preferable that the children selected for the study are on at least two medicinal agents while still presenting with high frequency seizures.

Dr. Terry Himes, a neurologist form the Medical Center of Centerra emphasized to the Committee the importance of providing parents of children with seizure disorders adequate guidance, support, and assistance in monitoring for potential toxicity as a result of receiving Epidiolex®.

Jason Cranford, a grower from Colorado who previously provided testimony at the second meeting, shared with the Committee the patient data he has collected through his non-profit Flowering Hope Foundation. The Committee expressed its appreciation that Mr. Cranford followed up with this information and indicated so during his presentation. Dr. Gwynn pointed out that Mr. Cranford did not have as much data on as many patients as he had hoped to see. While Mr. Cranford kept records on the patients receiving CBD oil, these records lacked consistency in how efficacy was measured. Mr. Cranford explained that this information is difficult to standardize because the parents of the children receiving the CBD oil cannot be controlled. Representative Peake asked Mr. Cranford how many patients he has treated. Cranford indicated that he has seen over 200 patients and has been breeding strains of CBD oil for five years.

At the end of the meeting, Senator Thompson commented on the quality of life for patients and suggested that multiple tracts in addition to clinical trials should be pursued for very severe, low

9

-

² FDA's Fast Track program facilitates the development and review of drugs intended to treat serious conditions and fill an unmet medical need. *See* http://www.orphan-drugs.org/2014/06/13/gw-pharmaceuticals-announces-epidiolex-receives-fast-track-designation-fda-treatment-dravet-syndrome/.

quality of life scenarios. He added that "clinical only" access to CBD derivatives will not address the issues relating to people wanting to move to other states where CBD oil can be legally prescribed and possessed. Representative Peake also asked the Committee to consider whether the business model for CBD oil in Georgia would work, noting his view that a for-profit model would be sustainable.

Fifth Meeting: Wednesday, December 3, 2014

The final meeting of the Committee was held at the State Capitol in Atlanta, Georgia, where testimony was provided by the following individuals:

- Dr. James Smith, physician and former member of the Medical Association of Georgia.
 Dr. Smith is also the parent of a child with seizure disorders. Dr. Smith's daughter lives in Colorado and is currently being treated with cannabis oil.
- Rick Allen, Director of Georgia Drugs & Narcotics Agency.
- Virginia Galloway, Southern Regional Director for the Faith and Freedom Coalition.

Dr. James Smith provided testimony about his daughter, Marlow, and the effect of cannabis oil on treating her seizures. Marlow developed a seizure disorder at age six. She experiences "drop attack" seizures which result in a loss of muscle control that cause the individual to "drop" to the ground when the seizing begins, which often results in physical injuries as individuals hit objects as they fall. Prior to Marlow's treatment with cannabis oil, she was on the maximum dosage of three anti-seizure pharmaceutical drugs that, according to her father, made her into a "zombie." Additionally, prior to her treatment with the oil, Marlow experienced up to 30 seizures per day.

Dr. Smith's wife and daughter moved to Colorado and begin treating Marlow with Charlotte's Web, a strain of marijuana in the form oil that is high in CBD and low in THC, five months ago. Now Marlow can go several days without experiencing any seizures, and on bad days she will experience one or two seizures. Additionally, Marlow has been weaned off of one pharmaceutical drug thus far, and Dr. Smith testified that he has witnessed dramatic, positive results in her behavior.

Dr. Smith also provided testimony regarding the guidelines in place for administering oil. He testified that every batch of the oil extracted from the plant is sent to independent lab for testing. The results from those tests are sent to the parents and doctors, and doctors base their recommended dosages off of results. Those results indicate whether there are pesticides or fungicides in that strain in addition to the bacterial count and concentrations of CBD to THC in the strain. Finally, Dr. Smith testified that there are currently 17 families that have moved to Colorado from Georgia for the purpose of treating their children with the Charlotte's Web oil.

Rick Allen testified regarding his experience as the director of the Georgia Drugs and Narcotics Agency. In an effort to learn more about medical cannabis, Rick Allen spoke with members from the U.S. Drug Enforcement Administration (DEA). Allen testified that cannabis is and will likely remain a federally controlled Schedule I substance. In order for it to be removed from this category, the FDA would need to change its stance or Congress would need to pass a law decriminalizing it. Currently, the federal prosecutors have been instructed not to prosecute individuals for cultivating medical marijuana if they are in compliance with the guidelines set

forth in the U.S. Department of Justice's current guidance on prosecution of marijuana offenses, a document known as the "Cole Memorandum."

Additionally, Mr. Allen reiterated that, under federal law, a physician cannot write or issue a prescription for a Schedule I Controlled Substance. Therefore, as is done in Colorado and other states, practitioners recommend that patients can benefit from the use of medical cannabis but do not issue a formal prescription.

Allen also testified about the methods for producing cannabis oil. The current method for production used in states like California and Colorado is known as the Butane Gas Extraction method. This method involves running butane gas through a pipe that contains the marijuana leaves in order to create the oil. The oil must then sit out until the butane gas is released. Allen testified that this has caused a rise in the number of lab explosions, sometimes resulting in as many as one per day. A more reliable and effective method for extracting CBD oil from the cannabis plant is the method utilized by GW Pharmaceuticals in Great Britain. This costly method of extraction requires the use of a centrifuge to extract the oil. Allen testified that this method produces pharmaceutical-grade CBD oil.

Allen also testified about the issues Florida has faced administering its medical marijuana program. Although legislation moved in Florida last year, the state does not currently have a seed source to begin production and no farms to produce cannabis. Allen testified that Colorado is willing to supply Florida with the seeds; however, transportation across state lines will prove difficult for Florida due to existing trafficking laws. Additionally, Allen testified that if Florida started the grow cycle today it would take 150 days before the crop would be ready for processing into oil.

Further, Florida has no administrative rules in place to oversee cannabis production. Each time the overseeing agency proposes a rule regarding cannabis production an administrative law judge rejects the rule. Allen's advice for Georgia was to write legislation regarding medical cannabis in a manner that contains details and standards by which a viable rule can be adopted, so as to avoid the issues Florida is facing.

Finally, Allen testified that GBI Crime Lab does not currently possess the equipment or have trained personnel to test for percentage levels of THC in cannabis. Instead, the lab can only test that for the presence of THC in the cannabis oil. Allen testified that in order to purchase the necessary equipment and personnel required for this kind of testing, the crime lab will need a substantial increase in appropriations.

Virginia Galloway, the Southern Regional Director for the Faith and Freedom Coalition, provided testimony regarding concerns and issues for legislators to address as the upcoming bill is drafted. Galloway's first concern is the lack of a formal, double-blind study to determine the long-term effects of THC in small dosages. Additionally, Galloway questioned the monitoring and evaluation of the program, the scope of the bill, and the conditions that will be treatable with the cannabis oil. Further, Galloway voiced concerns regarding the process for children after they are released from the study as to whether they continue receiving medication. Galloway

entirety in Appendix A.

³ The "Cole Memorandum" is a memorandum issued by Deputy Attorney General James M. Cole on August 29, 2013 in which he issued guidance to federal prosecutors regarding enforcement priorities of the U.S. Department of Justice with respect to marijuana in light of actions taken by numerous states to provide for medical and/or recreational use of marijuana within their borders. The Cole Memorandum has been reproduced in this Report in its

asked the Committee who will be eligible for the oil and how much it will cost to research, regulate, and enforce the law. Finally, Galloway requested that the legislators address the issue of civil forfeiture in the bill.

COMMITTEE RECOMMENDATIONS⁴

The Committee recommends that the General Assembly adopt the following measures:

1. <u>Changes to existing Georgia statutes on controlled substances to accommodate use</u> of certain specific strains of marijuana for treatment of medical conditions.

- The General Assembly should leave unamended any statute that prohibits the use of marijuana and all unlawful products and activities associated with marijuana crimes.
- However, the General Assembly should amend the provisions of the Georgia Controlled Substances Act which ban possession of marijuana by creating a narrow exception allowing a defined set of qualified patients with specified medical conditions to register with the state and be issued a patient registry card to purchase, possess, and use an oil-based, non-smokeable form of marijuana that is low in THC and contains an appropriate ratio of CBD to THC. Such marijuana should only be used by such qualifying patient to treat his or her specified medical condition(s).
- The General Assembly should also create a definition in the Georgia Controlled Substances Act for such oil-based, non-smokeable form of marijuana that is low in THC and contains an appropriate ratio of CBD to THC.

2. <u>Support of clinical research efforts in Georgia regarding use of certain strains of marijuana for treatment of medical conditions.</u>

- The General Assembly should create statutory authorization for state-approved medical research to be conducted in state facilities with funds other than those provided by the federal government.
- Such statute(s) should also prohibit any form of marijuana from being unlawfully present
 in any medical facility or teaching hospital in this state unless the federal government
 has issued approval for research or other clinical study in accordance with federal
 regulations or if the lead administrator of a medical facility issues written approval for an
 exception for the holder of a patient registry card.
- The General Assembly should also continue to support Georgia Regents University in its pursuit of approval for conducting clinical trials on Epidiolex®. Specifically, the General Assembly should (a) place the line item for funding of this trial in a section of the budget other than that pertaining to the Board of Regents; (b) prohibit the charging of money for participation in these trials; and (c) encourage GW Pharma to contribute to the costs of the study.

_

⁴ Additional statements from some Committee members have been included as appendices to this report.

In addition to the recommendations listed above which were agreed upon by the Committee as a whole, some individual members of the Committee have suggested additional measures for the General Assembly's consideration. Such members feel that the General Assembly should establish a strictly regulated system of cultivating, processing, and dispensing certain strains of marijuana with the following elements:

- Full repeal the Controlled Substances Therapeutic Research Act, which became law in Georgia in 1980.
- Legislation should contain a requirement that approved medical marijuana products shall not be smoked:
- Such program must exceed the guidelines issued by the U.S. Department of Justice in the Cole Memorandum regarding marijuana enforcement;
- Such program should require licensing and registration of medical marijuana businesses and the owners, managers, employees, and contractors for such businesses at the Georgia Department of Revenue for fees sufficient to offset program costs;
- Such program should require use of a secure, real-time inventory tracking system to be managed by the Georgia Department of Revenue, with software designed to track every cannabis plant in this state "from seed to sale" using radio-frequency identification (RFID) tagging;
- Legislation should authorize state and local law enforcement agencies to access tracking system information, enter the premises of any medical marijuana business at any time, with or without prior notice, for a bona fide law enforcement purpose, and increase drug trafficking penalties for any medical marijuana business licensee convicted for criminally diverting medical marijuana cultivated in this state;
- Legislation should provide immunity from prosecution for crimes including, but not limited to, crimes under the Georgia Controlled Substances Act for holders of patient registry cards or their identified caregivers in possession of medical marijuana obtained in Georgia from a retail medical marijuana business or obtained lawfully from another state;
- Legislation should direct the Georgia Department of Public Health to establish and utilize a confidential patient registry database with software designed to interface with the Georgia Department of Revenue tracking system referenced above. Such software should permit access to real-time information about qualifying patients and the validity of a qualified patient's registration;
- Legislation should set strict guidelines to implement statutory requirements for a physician to be permitted to recommend medical marijuana to a patient in this state;
- Legislation should create a Physician Advisory Board to counsel the Georgia Department of Public Health and issue findings for reporting to the Commissioner of Public Health and/or to the General Assembly on patient and physician issues; and

• Such program should employ the most stringent and broad independent laboratory testing requirements in the United States for medical marijuana both upon harvest of the plant and after processing into a product.

The Members of the Committee agree that their overriding consensus is to care for Georgia children who suffer from epileptic seizures and their families and to ensure that such children have access to safe and timely medical care in the State of Georgia.