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CANNABIS POLICIES FOR THE NEW DECADE

WEDNESDAY, JANUARY 15, 2020

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:01 a.m., in Room 2123, Rayburn House Office Building, Hon. Anna G. Eshoo [chairman of the subcommittee] presiding.

Present: Representatives Eshoo, Engel, Butterfield, Matsui, Castor, Sarbanes, Lujan, Schrader, Kennedy, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Rush, Pallone (ex officio), Burgess, Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Hudson, Carter, Gianforte, and Walden (ex officio).

Also Present: Representatives Schakowsky and Rodgers.

Staff Present: Joe Banez, Professional Staff Member; Jeff Carroll, Staff Director;

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Waverly Gordon, Deputy Chief Counsel; Tod Guidry, Health Fellow; Meghan Mullon, Policy Analyst; Lino Pena-Martinez, Staff Assistant; Tim Robinson, Chief Counsel; Rebecca Tomilchik, Staff Assistant; Kimberlee Trzeciak, Chief Health Advisor; C.J. Young, Press Secretary; Madison Wendell, Intern; S.K. Bowen, Minority Press Assistant; Jordan Davis, Minority Senior Advisor; Theresa Gambo, Minority Human Resources/Office Administrator; Tyler Greenberg, Minority Staff Assistant; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; Brannon Rains, Minority Legislative Clerk; Kristin Seum, Minority Counsel, Health; and Kristen Shatynski, Minority Professional Staff Member, Health.

Ms. Eshoo. Good morning, everyone. The Subcommittee on Health will now come to order. Welcome to everyone who is here in the hearing room. The chair now recognizes herself for 5 minutes for an opening statement.

According to the Department of Health and Human Services' National Survey on Drug Use, 44 million Americans reported using cannabis in the last year. Thirty-three States now allow the medicinal use of cannabis and 11 States in the District of Columbia have legalized cannabis for adult use.

But State laws and Federal policy are a 1,000 miles apart. As more States allow cannabis, the Federal Government still strictly controls and prohibits it, even restricting legitimate medical research.

Given the widespread availability of cannabis, the purpose of today's hearing is to examine the pressing need for medical research about cannabis and its chemical compounds with CBD being one of them.

A half century ago, Congress listed cannabis as a highly controlled schedule I substance. Other schedule I drugs include heroin, LSD and ecstasy. Schedule I drugs have no medical value and high potential for abuse. Schedule II drugs, such as cocaine and Vicodin through schedule V drugs, such as Robitussin, all have some medical value but differ in ranking depending on their potential for abuse.

The schedule I designation restricts legitimate medical research about cannabis. Today scientists who wish to study cannabis must seek approval from three Federal agencies: the NIH, the FDA and the DEA. Once scientists are federally approved, which can take more than a year, they are allowed to only research cannabis grown by a

government-authorized farm at the University of Mississippi.

This cannabis lacks the properties and potency of commercially available cannabis and leads to inadequate research. So researchers are in a catch-22, they can't conduct cannabis research until they show cannabis has a medical use, but they can't demonstrate cannabis as a medical use until they can conduct research. It doesn't make sense, at least to me.

So why is it concerning that research about cannabis is blocked by Federal law? First, cannabis has therapeutic potential for chronic pain, nausea, and the treatment of neurological disorders such as seizures. In 2018, the FDA approved the first cannabis-derived medication, Epidiolex, which treats seizures in patients 2 years of age or older. Second, the restrictions on cannabis research has led to unanswered questions about the safety and quality of products containing CBD.

In December 2018, the farm bill removed hemp, including CBD derived from hemp, from the Controlled Substances Act. The farm bill explicitly preserved the FDA's authority over CBD products, but the FDA has yet to issue regulations due to its unanswered questions about the intrinsic safety of the CBD. The FDA says it will take 3 to 5 years to finalize CBD regulations. And in the meantime, the CBD market is predicted to reach $20 billion in sales by 2024. Meanwhile, CBD is now available in everything from fast food hamburgers, to scented lotions, to over-the-counter pills.

Today, we are considering six bills that offer a range of solutions to update Federal policy to advance research on cannabis and its compounds. I want to thank the leaders of the bills. Representatives Barbara Lee and Congressman Earl Blumenauer who have joined us. They are sitting in the front row. Thank you for being here and for your

work. Congressman Jerry Nadler, Hakeem Jeffries, Matt Gaetz, and our fellow subcommittee member Congressman Morgan Griffith: Thank you to each one of you for your good work.

Now I would like to yield to Mr. Kennedy for the remainder of my time.

[The prepared statement of Ms. Eshoo follows:]

******** COMMITTEE INSERT ********

Mr. Kennedy. Thank you, Madam Chair. I want to thank you for the time for yielding.

This is a critical debate and it is long overdue. Federal prohibition has failed, from our criminal justice system, to our healthcare system, to our State and local governments that are forced to navigate an impossible landscape. To that end, government officials and elected representatives are important witnesses and bring an important perspective to this conversation.

But there are also critical stakeholders who are missing, those who lives have been directly touched by our broken marijuana policies. The people unjustly incarcerated, patients who rely on medical cannabis, and researchers with expertise yearning to learn more, small businesses owners trying to find fair footing in a new industry.

I am grateful for the chairwoman who is committed to continue working with us on a second hearing that will center those voices in this debate.

Thank you, Madam Chair. I yield back.

[The prepared statement of Mr. Kennedy follows:]

******** COMMITTEE INSERT ********

Ms. Eshoo. The gentleman yields back. It is a pleasure to recognize Dr. Burgess, the ranking member of our subcommittee for his opening statement.

Mr. Burgess. And I thank the chair. I appreciate -- and thanks to our witnesses who are here with us today to help advise us in this important matter. I appreciate that we are holding the hearing today to discuss this policy. It is a topic that is of interest to many members of this subcommittee. In fact, that was evidenced when we had our discussion on the smokeless tobacco products. At the end of last year, some of the Republican members of the full Energy and Commerce Committee and myself sent a letter to request a hearing on three of the bills before us today that focus on easing pathways to marijuana research. So I am glad that we followed through with that. It included H.R. 171, the Legitimate Use of Medical Marijuana Act; H.R. 601, The Medical Cannabis Research Act of 2019; and H.R. 3797, the Medical Marijuana Research Act of 2019 in this hearing.

States and localities across the country have moved forward, they have different policies to address marijuana, including both recreational and medicinal. I am concerned that there is a lack of available research on the benefits and the risks of the medical and recreational use of this product and that we really don't justify the actions that some of the States have taken. Thus far the Food and Drug Administration, the National Academies have found that there is a lack of evidence to demonstrate effective medical use for marijuana. So certainly we need more research.

It is concerning that there are arguments over what may or may not be a great medicinal use for marijuana, but we don't have any data. So it is time to get the data

and let the decision be driven by the data. Additionally, some of the data that we do have includes some concerning results. For example, a study conducted by researchers at Kaiser Permanente in northern California found that cannabis use among pregnant mothers nearly doubled between 2009 and 2016. Research has also found that prenatal marijuana may impair fetal growth and neural development but added that more studies are necessary as the THC potency continues to vary, but appears to be continuing to rise. So, as someone who has practiced obstetrics for a number of years, I worry about the health of the mothers and their babies that could be at risk.

So one of the key hurdles to research is that researchers require DEA approval. And for decades they have only been allowed to obtain marijuana from one source, the University of Mississippi, which is the only contract that the National Institute on Drug Abuse has for research-grade cannabis.

In the past, it may have made some sense to have this single source for research purposes. Certainly if there are variations in quality or gradation, that could be minimized by having that single source. But because of the diversity now of the quality potency and other aspects of the marijuana that is available for individuals to obtain from medical and recreational purposes, and it does vary across the United States, research using the single-source marijuana may not adequately assess what the current landscape represents. Not to mention, it is difficult to obtain the quantity necessary to conduct research in the existing structure.

To that point, the Drug Enforcement Agency -- we are grateful that you are with us this morning -- announced in 2016 that it would establish a new policy to increase the number of approved sources of research grade marijuana, but I don't think that has quite

gotten across the finish line. Maybe we can hear about that today. I hope that we will get an update on the administrative efforts to streamline the research process today. I hope that we can identify ways to work together to achieve that goal.

While three of the bills before us today aim to enhance research efforts, there are two that may go a step too far. H.R. 2843 and H.R. 3884 completely remove marijuana from the controlled substances list. It is worth noting and I believe the Food and Drug Administration will explain this in more detail, that in order for the Drug Enforcement Agency to reschedule a drug, doing it administratively without congressional direction, the Food & Drug Administration must conduct a medical evaluation of the drug and provide a recommendation to the Drug Enforcement Agency as to what the scheduling should be. This recommendation is binding; therefore, the DEA must do what the FDA recommends. My opinion, completing descheduling marijuana using or congressional authority, which can override this scenario, could possibly be a dangerous move, especially given the lack of research to back up the decision.

So it is critical that the American public, the medical community understands what marijuana does to our bodies and our brains at different potencies throughout our lifecycle. We have a way to go before we have a full understanding of all of these factors. Some of the bills before us are a step in the right direction. Some go a step too far, but I look forward to learning more about the issues of our Federal agencies and the efforts they are taking to work on this problem.

Thank you all for being here, and I yield back my time.

[The prepared statement of Mr. Burgess follows:]

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Ms. Eshoo. The gentleman yields back.

It is a pleasure to yield 5 minutes to the chairman of the full committee, Mr. Pallone, for his opening statement.

The Chairman. Thank you, Chairwoman Eshoo.

Today the subcommittee will have an important hearing about Federal cannabis policies. While State laws and public perception around cannabis and its derivatives have evolved over the years, much of the Federal framework that regulates cannabis has stayed the same. In my home State of New Jersey, for example, State law allows for the use of medical cannabis, and at the end of last year, State lawmakers passed a referendum that will put the question of legalizing adult cannabis use to New Jersey voters on the 2020 ballot this coming November.

New Jersey is not alone in its State-level changes, in fact the National Conference of State Legislatures reports that 33 States, as well as Puerto Rico, Guam, the U.S. Virgin Islands, and the District of Columbia approved medical cannabis programs while 11 States, D.C., Guam, the Northern Mariana Islands approved adult-use cannabis. And although some States have changed their own policies, national laws, such as the Controlled Substances Act, have yet to change in the same way. And that is why we are looking forward to this hearing from a panel of agency witnesses who agreed to appear before the subcommittee today. The Drug Enforcement Agency, the FDA, the National Institute on Drug Abuse all play crucial roles on the Federal cannabis policy. From researching its benefits and harms to protecting the American public from bad actors. And I hope that we can learn about what the agencies believe works and what needs to

be changed.

We will discuss six bills offered by both Democrats and Republicans, some bipartisan. These bills propose various policy changes, such as rescheduling or descheduling marijuana, providing a safe harbor for patients and veterans who use medical marijuana, and streamlining cannabis research processes.

Given the evolving landscape in the States, these bills are worthy of further discussion. And I am particularly interested in hearing about how Federal agencies are reducing barriers to research and enabling research on cannabis to thrive. I am also interested in how the agencies are working together to regulate a cannabis derivative recently removed from the Controlled Substances Act, and that is CBD or cannabidiol, I guess is how it is pronounced.

Before I conclude, I did want to recognize, as Ms. Eshoo did, Representatives -- first -- Blumenauer and Representative Barbara Lee. I know they have talked to many us on a regular basis, and we are pleased to see that you are here in the audience today. And they are the co-chairs of the bipartisan Cannabis Caucus with Representatives Young and Joyce. Together they foster a continued dialogue on cannabis issues and both have offered bills before us today. And I thank them for joining us and commend them for their ongoing leadership in this area.

Thank you again, Madam Chair. I don't know if anybody are -- I have 2 minutes left if anybody wants it. If not, I yield back.

[The prepared statement of The Chairman follows:]

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Mr. Griffith. Mr. Chairman, will take it.

I appreciate that. As one of the sponsors of the bills, a lot of times people think, why does a conservative Republican get into this and champion it?

Well, let me tell you a story. When I was a young man in the 1980s, some of my friends were smuggling marijuana into the hospital in our community there in the Roanoke Valley because there was an individual whom I did not know who was dying of cancer, but he wanted to spend every day he could with his son who was about 2 at the time. And that formed my policy that we need to have a rational medical marijuana policy; thus the LUMMA bill.

But I decided when I got to Congress that, you know, well, it is kind of controversial, and maybe I shouldn't do that. But I would talk about it. And when I was at a high school townhall as I call them -- I go to the high schools and talk to students -- they ask about marijuana policy. I told them my position on medical marijuana, which I went public with in 1998 on the floor of the Virginia House of Delegates. And I was standing there, and I thought -- all the hands went up, and I thought one of the kids was going to say to me, "Well, what about for just for recreational use or for fun?" And I will never forgot it: I was in Wise, Virginia, and a young man on this side of the room raised his hand, and I went to him expecting to get the recreational question. And he said, "They did that for my daddy, too." Now my district is a big district. These two communities, 20 years apart -- 30 years apart, and hours apart from one another. And yet doctors were turning a blind eye to allow marijuana to be brought into the hospital because they recognized for those patients who were dying, this was the

only way they could have a little bit of relief and get the nutrients that they needed to stay alive a little bit longer to spend a little bit more time with their children. I came back to D.C., and I said: You know what? I am in Congress now. I can do something about the DEA and the FDA not making marijuana available for patients who need it. And today is that day.

I yield back.

[The prepared statement of Mr. Griffith follows:]

******** COMMITTEE INSERT ********

The Chairman. And I yield back, Madam Chair.

Ms. Eshoo. The gentleman yields back. There is nothing like a real-life story.

It is a pleasure to recognize the ranking member of the full committee, my friend Mr. Walden, for 5 minutes for his opening statement.

Mr. Walden. Thank you, Madam Chair.

We appreciate the hearing today because we will finally have an opportunity to review initiates aimed at improving federally sanctioned research on cannabis. Representatives Burgess, Griffith, Rodgers, and others, we sent a letter asking for this hearing. We appreciate your willingness to have it, Madam Chair.

Federally sanctioned reached on cannabis is challenging. It is a schedule I controlled substance under the

Controlled Substances Act. This means that researchers seeking to investigate cannabis must work with the Food & Drug Administration, the National Institute of Drug Abuse and the drug enforcement administration just to meet the Federal guidelines, requirements specified in the CSA to conduct research. In addition, international obligations set forth in the United Nations drug control treaties impose additional requirements on the substance impacting the supply of research-grade cannabis.

So researchers now can only use cannabis for products sourced through the NIDA's drug supply program single DEA licensee, the University of Mississippi.

Now, unfortunately, that cannabis is distinct from what is commercially available from State legal dispensaries, such as in my home State of Oregon, meaning that we have little to no data on the health impacts of products in States that have legalized cannabis

for medical or recreational use.

Now, in Oregon, you can purchase a range of THC-infused products, like these cookies we have a photo of right there. If you look up on the screen behind you, I guess, it is sort of stereo on this other side, but right there. And each of you, by the way, has a cookie in front of you. I have a pizza stand opening in an hour out in a hallway. Don't worry; I didn't get that carried away. You can actually eat these, as far as I know. Unless Safeway inserted something beyond the normal ingredients, it is just a cookie.

The question is, how do you know if your child stumbled upon it? So serious side. Oregon, these cookies in this photo are limited to 5 milligrams of THC per serving, 50 milligrams per package. Now, if you go across the Columbia River to Washington State, you find they have a different limit, 10 milligrams and 100 milligrams per package. The difference is arbitrary. You see we lack data. We do not know -- what we do know is there have been an elevated number of cannabis-related poison center calls, emergency room visits, and impaired driving incidents. But we need the research that reflects the reality of what is on today's market.

Additionally, products containing CBD derived from the hemp plant have become commonplace across the country in pharmacies, food health stores, even fast food chains since hemp was removed from the CSA in 2018 farm bill. Now these products often contain claims they can effectively treat depression, inflammation, and even cancer or Alzheimer's. However, none of these claims have been evaluated or approved by the Food and Drug Administration, which means patients may be relying on the unsubstantiated claims of CBD products and foregoing other proven medical treatments.

And while there is potential for CBD to provide real patient benefit, the research

and science lags far behind the market, and the agencies are struggling to catch up.

So nationwide exposure in youth is increasing. From 2006 to 2013, children's exposure to marijuana products rose 147.5 percent nationwide. And in States that have legalized medical marijuana, exposure has risen 610 percent. And while alcohol use is going down in teens, last month, NIDA reported record numbers of eighth through twelfth grade students regularly vaping marijuana, a subject we have talked about before this committee.

So we need more research, and we need more data. Americans are consuming more cannabis, and policy decisions on this substance has been made in a virtual information vacuum. States that have legalized marijuana, such as my State, have done so with far less information than they have on legal substances that are easily abused, such as alcohol or tobacco. Rescheduling cannabis may help improve the research landscape and allow for more medical treatments. However, administrative rescheduling necessitates robust data on potential medical uses, and the current research restrictions on fully studying cannabis have effectively created a catch-22 in this rescheduling debate. Evaluations by the FDA and the National Academies have both concluded that lack of research was a significant factor in denying previous rescheduling petitions.

So I would like to note that two of the six bills we are reviewing today completely descheduled cannabis, removing it from the Controlled Substances Act, even though we do not have the necessary data to justify doing so, in my opinion. Descheduling cannabis is a step too far and a step I cannot support because descheduling removes it from the Controlled Substances Act and cuts the DEA completely out of the picture. So

any discussion of descheduling must be preceded by a fuller understanding of the potential risks associated with cannabis use, which we currently do not have.

Research is the first step in making it easier to get our research on cannabis. It is common ground we should pursue as we improve the Federal-State relationship and the marijuana policy gap.

And, with that, Madam Chair, I yield back.

And you can eat your cookies now.

[The prepared statement of Mr. Walden follows:]

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Ms. Eshoo. The gentleman yields back. The chair would like to remind members that, pursuant to committee rules, all members' written opening statements shall be made part of the record.

Now I would like to introduce our witnesses for today's hearing and to thank each one of you for being with us today. Dr. Nora Volkow is the director of the National Institute of Drug Abuse at the National Institutes of Health.

Thank you to you.

Dr. Douglas Throckmorton is the deputy director for regulatory programs at the Center for Drug Evaluation and Research at the FDA, at the Food & Drug Administration.

And Mr. Matthew Strait is senior policy adviser for the Diversion Control Division of the Drug Enforcement Administration.

So welcome to each one of you. Thank you for essentially your life's work that brings you to the table to testify today. We look forward to the testimony that each one of you are going to offer.

I think you are familiar with the lights. It is like a traffic system. Green is go. Yellow is caution, and when red turns up, it is time to stop.

So we will start with Dr. Volkow.

You are recognized for your 5 minutes of testimony. And, again, thank you not only for your work, but for being here with us today. Turn your microphone on.

**STATEMENTS OF NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH; DOUGLAS C. THROCKMORTON, M.D., DEPUTY DIRECTOR FOR REGULATORY PROGRAMS, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION; AND MATTHEW J. STRAIT, SENIOR POLICY ADVISOR, DIVERSION CONTROL DIVISION, DRUG ENFORCEMENT ADMINISTRATION.**

**STATEMENT OF NORA D. VOLKOW, M.D.**

Dr. Volkow. I want to say good morning to everybody, and I want to than Chairwoman Eshoo, Ranking Member Burgess, and all of the members of the subcommittee for inviting us to discuss cannabis research.

Cannabis is the most widely used illicit drug in the world and in the United States. THC is responsible for cannabis rewarding and addictive effects. And it is content has tripled in the past two decades. On the other hand, the content of cannabidiol, or CBD, which is not rewarding but of interest because of its potential therapeutic effects, has decreased in cannabis plants while food, drinks, and other products containing it have proliferated it.

THC exerts its effects by interacting with cannabinoid receptors, which are part of our own endogenous cannabinoid system. The system is involved in brain development and multiple brain functions, memory, emotions, reward, among others. Cannabinoid receptors also modulate immune, inflammatory, hormonal, metabolic processes in our

body. Thus, it is not surprising that cannabis, which basically hijacks that systems can negatively affect health. Of particular concern are its effects on the developing fetal and adolescent brain. Cannabis exposure, as was mentioned before, during pregnancy has increased and is associated with fetal growth restriction, lower birth rate, and preterm delivery. In adolescents, cannabis use has been consistently associated with lower academic achievement, higher risk of dropping out of school, lower IQ, disruptions in brain connectivity and structure as the brain transitions into adulthood. Cannabis use at a young age increases the risk of addiction to cannabis and to other drugs.

Another area of major concern is the association of cannabis use with psychosis, the risk of which increases with consumption of high-content THC. The while most episodes of psychosis are short lasting, they can become chronic. Concerns have also emerged regarding higher risk for depression and suicide, though these associations have been less studied.

The availability of high-THC products has markedly increased emergency department visits and hospital admissions associated with cannabis exposures. Vehicle-related injuries while driving under the influence of THC are one of the main causes. Another frequent cause is severe cycles of nausea, vomiting, and abdominal pain referred to as cannabis hyperemesis syndrome.

However, our understanding of the adverse effects of cannabis is incomplete. This was made clearly evident by the outbreak of e-cigarette or vaping product use associated lung injury or EVALI, a condition reported in June 2019 predominantly associated with THC vaping that has, over 6 months, resulted in 2,500 more hospitalizations and 55 deaths.

Consumption of cannabis edibles packaged in food and drinks disproportionately accounts for cannabis-related emergency department visits. The slow absorption can prompt the user to take further doses, resulting in very high THC levels. Toxicity was frequently manifest as acute psychosis, severe anxiety, and cardiovascular complaints, and they also contribute increasingly to intoxication in children. Cannabis plants have been legalized for medical use for multiple indications in many States, even though FDA has not approved any of them for any indication.

Though not meeting FDA requirements, there is evidence though that cannabis may be effective for treating spasticity multiple sclerosis and for pain, but otherwise there is little evidence for other indications for which patients are using it.

NIH is helping to close this knowledge gap, including supporting stories to examine CBD for treating pain, inflammation, PTSD, and addiction. Understanding the effects of cannabis on brain development is a NIDA priority. And the adolescent brain cognitive development study will follow more than 11,000 children into early adulthood to investigate how cannabis affects their brains.

Despite the urgency for advancing research, the fact that cannabis is a schedule I substance proposes major challenges. NIDA's contract with the University of Mississippi is currently the only DEA source of research cannabis, and researchers are unable to access cannabis for research from dispensaries and other sources resulting in a gap in our understanding of their impact on health.

Cannabis research is urgently needed both to guide policy and to develop therapeutics; thus the importance of facilitating their ability to do so.

Thank very much.

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[The prepared statement of Dr. Volkow follows:]

******** INSERT 1-1 ********

Ms. Eshoo. Thank you, Doctor.

We will now recognize Dr. Throckmorton for his 5 minutes of testimony.

And thank you again for being here today. Do you have your microphone on?

Dr. Throckmorton. I do. Thanks.

Ms. Eshoo. You are recognized.

**STATEMENT OF DOUGLAS C. THROCKMORTON, M.D.**

Dr. Throckmorton. Chairman Eshoo, Ranking Member Burgess, and members of the subcommittee, I am Dr. Douglas Throckmorton Morton from the Center for Drug Evaluation and Research at the Food & Drug Administration. Thank for the opportunity to be here today to discuss the important role that FDA plays in research involving cannabis and cannabis-derived compounds for potential medical uses in the United States.

I would also like to discuss the recent work the FDA is doing to respond to the recent legislation affecting the availability of compounds derived from cannabis, such as cannabidiol.

First, with regards to drug development, FDA continues to believe that the drug approval process represents the best way to ensure that safe and effective new medicines, including medicines derived from cannabis, are available for patients. FDA stands ready today provide information to investigators on the progress and process and specific requirements needed to develop a human drug that is derived from plants such

as cannabis. For example, FDA has ways to speed drug development programs, including programs such as fast track, breakthrough therapy, accelerated approval, and priority review, all designed to facilitate the development of and to expedite the approval of novel and effective drug products.

We have also established a botanical review team to assist the development of plant-based drugs, including those derived from cannabis. Using these resources, the FDA has successfully approved one cannabis-derived drug product, Epidiolex, containing cannabidiol or CBD, and three synthetic cannabis-derived drug products: Marinol, Syndros and Cesamet.

While FDA is aware of the activities of States in this area, to date FDA has not approved any other cannabis, cannabis-derived, or CBD products currently available on the market. Turning our activities through recent work under legislation, in December of 2018, the farm bill removed hemp defined as cannabis and its derivatives with extremely low concentrations of THC from the definition of marijuana in the Controlled Substances Act. The farm bill explicitly preserved FDA's authorities over products derived from hemp, such as CBD, which means the products must still meet any applicable FDA requirements and standards just like any other FDA-regulated product. Because we understand the broad interest in making compounds found in cannabis more widely available to the public, FDA is working hard to respond to these changes quickly and appropriately.

For example, we have reached several conclusions about the use of CBD in nondrug products. First, it is prohibited under our statute to introduce into interstate commerce any human or animal food to which certain drug ingredients have been added.

In addition, drug ingredients are excluded from the definition of dietary supplement. Because CBD is an active ingredient of an approved drug, these restrictions apply to products made with CBD.

These provisions make sense. It is easy it to understand why we generally don't want blood pressure medicines or pain medicines in our food are in our dietary supplements. Additionally, FDA is concerned that the marketing of CBD in nondrug products could put consumers at risk, such as by making unsubstantiated claims to prevent or cure serious diseases such as cancer or Alzheimer's disease. The proliferation of such products may deter consumers from seeking proven, safe medical therapies for serious illnesses.

We also know that CBD can cause adverse effects, including drug interactions, sleepiness that could impair driving, and potential liver injury. There are many unanswered questions about the safety and quality of products containing CBD, and the agency has made it a priority to address these questions, including questions about the safety of long-term use of CBD by different populations. For example, we have very little information about the use of CBD by pregnant women, by children, and by the elderly. To address these gaps, FDA is in the process of systematically collecting all of the data that are available to us to make the best science based and public-health-focused decisions about the availability of the compounds in hemp.

To close, FDA understands the broad interest in making that compounds more available to the public and is considering the possibilities and new legal pathways for CBD products. However, it is important to maintain adequate incentives for drug development as we do so. Drugs have important therapeutic value and are approved

after rigorous scientific studies that provide important, new information about their safety and effectiveness. It is critical that we continue to do what we can to support quality science needed to develop new products in cannabis.

With that, I thank you and look forward to answering any questions I can.

[The prepared statement of Dr. Throckmorton follows:]

******** INSERT 1-2 ********

Ms. Eshoo. Thank you, Doctor.

Now it is a pleasure to recognize Mr. Matthew Strait for his 5 minutes of testimony.

And thank you again for joining us today.

**STATEMENT OF MATTHEW J. STRAIT**

Mr. Strait. Thank you. Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of committee, on behalf of the Administrator Dillon and 9,000 men and women of the Drug Enforcement Administration. I appreciate the invitation to be here today to discuss DEA's regulatory requirements for those who perform research with schedule I controlled substances, including marijuana.

Much like our partners at HHS, the Department of Justice and DEA fully support research into the effects of marijuana and the potential medical utility of its component. The procedures for evaluating an application for registration by statute is an interagency process. At HHS, the Food and Drug Administration conducts a review of the qualifications and competency of the researcher as well the merits of the scientific protocol. The DEA is charged with ensuring that adequate steps are in place to safeguard against diversion. These procedures have been in place for several decades, and in my 20 years, there has not been a single incident in which a researcher who has put forth a valid research protocol and has implemented safeguards to prevent diversion has been denied.

Given the public interest in marijuana research, DEA has taken a number of proactive steps to do its part in improving research with marijuana. First, in December 2015, DEA executed a change intended to ease the requirements to modify existing registrations in order to conduct research with cannabidiol or CBD, which at the time was being investigated for use in children with certain epilepsy disorders. I believe this action ultimately contributed to the 2018 approval of Epidiolex.

Second, in August 2016, the Department of Justice and DEA took steps to increase the number of entities registered under the Controlled Substances Act to grow marijuana to supply researchers. To ensure that this program is consistent with applicable laws and treaties, the Department, in consultation with other Federal agencies, continues to be engaged in a policy review process. In August 2019, DEA published a list of the 33 entities who have applied for registration and whose applications remain pending to grow marijuana pursuant to that policy. A forthcoming proposed rule, which has been drafted and submitted to the Office of Management and Budget, remains under development at this time.

Third, in February 2018, DEA announced its development of and implementation of an online portal for researchers to safely and securely submit their research protocol, curriculum vitae, and institutional approval, materials required by DEA regulations to be submitted for FDA and DEA review. This online portal has streamlined the process and improved the amount of time for obtaining a schedule I research registration. Presently the average time it takes to approve a new application is 52 days, while the time required to modify an existing registration is far less.

Finally, 2 months ago, DEA increased the aggregate production quota for

marijuana to 3,200 kilograms. The increase was based on a close collaboration with NIDA, who provides high-quality marijuana to NIH and non-NIH-funded researchers. The 2020 quota represents a 575-percent increase for marijuana since 2017.

I believe these efforts are working. Today DEA has 829 active researchers; 70 percent of those researchers, 605 in total, are performing research with marijuana or its constituent parts, making it far and away the most researched schedule I controlled substance in the United States.

Despite these efforts and our successes the multistep process for approving research with schedule I controlled substances is perceived as onerous by some of the research community. Unfortunately, this perception has translated into a false narrative that DEA does not support research. I am here today to tell you that this is simply not true. This belief has hampered efforts to pass practical commonsense legislation aimed at addressing the more than 30,000 overdose deaths in the United States from fentanyl and fentanyl-related substances. In just 23 days, DEA's temporary scheduling action which placed schedule I controls on substances chemically similar to fentanyl will expire unless Congress acts. DEA and the Department of Justice have worked with HHS and ONDCP to put forth a proposal that addresses this public health emergency while improving access for research. On behalf of the Department of Justice, I urge the committee to take up this important legislation.

In conclusion, DEA is fully committed to supporting research for schedule I controlled substance. We will continue to work with our partners within the administration to find commonsense approaches to improve and enhance research of marijuana.

Thank you and I look forward to your questions.

[The prepared statement of Mr. Strait follows:]

******** INSERT 1-3 ********

Ms. Eshoo. Thank you, Mr. Strait. Now we have concluded not only the opening statements of members but the testimony of the witnesses. We are going to move to members' questions now, and I recognize myself for 5 minutes.

I would like to ask a few foundational questions of the panel, and I think that the following can be answered with a simple yes or no. Is more medical research needed on the therapeutic effects and the health consequences of cannabis?

Dr. Volkow. Yes.

Dr. Throckmorton. Yes.

Mr. Strait. Yes.

Ms. Eshoo. Is the cannabis from the University of Mississippi, which is the only approved cannabis for Federal research, adequate for medical research?

Dr. Volkow. No.

Dr. Throckmorton. No.

Mr. Strait. We would like additional sources, but we also recognize that importation is allowed in certain circumstances.

Ms. Eshoo. Should legitimate researchers be able to access a wider array of cannabis products for their research?

Dr. Volkow. Yes.

Dr. Throckmorton. It would help drug development.

Mr. Strait. Yes.

Ms. Eshoo. Have there been, in your view, real-life consequences to researchers not being able to conduct research on a variety of cannabis products?

Dr. Volkow. Yes.

Dr. Throckmorton. Product development has been slow.

Ms. Eshoo. So there has been an effect because of that.

Dr. Throckmorton. Uh-huh.

Mr. Strait. I don't disagree with what my colleagues have said.

Dr. Volkow. I know one point that we haven't discussed enough, which has been hindered, is our ability to actually recognize when drugs may be particularly harmful. So that is another aspect of the limitations.

Ms. Eshoo. The main reason cannabis research is restricted is because cannabis is listed as a schedule I drug. Yet two active compounds in cannabis, THC and CBD, are both approved ingredients for drugs that are scheduled as schedule III and schedule V respectively. So how can cannabis be schedule I and considered to have no accepted medical use because that is part of the schedule I, but both of its major active ingredients can be considered to have medical use?

Dr. Volkow. I defer to my colleagues at the FDA for answering that.

Dr. Throckmorton. Separately those two compounds are safe and effective for intended uses and so meet the statutory standard for accepted medical use.

Ms. Eshoo. How do you pull them out and separate them?

Dr. Throckmorton. That is what the drug development process is meant to encourage. It is to have people --

Ms. Eshoo. So, if FDA decides to pull those out to be applied to and used and be part of a certain drug, you just automatically vanish -- schedule I vanishes as a result of that?

Dr. Throckmorton. When Congress defined what the schedules were to be, they said that there were tests to be applied for whether you had accepted medical use. There are five that we would be happy to talk in greater detail offline. When you apply those tests to marijuana, at least when the FDA and NIDA have applied those tests to marijuana three times in the recent 20 years or so, our conclusion, our recommendation to the DEA is that it did not meet the test for accepted medical use. It mostly has to do with whether you have identified a therapeutic value for the product and whether you can describe it.

Ms. Eshoo. It is more the trigger than anything else.

Dr. Throckmorton. Yes.

Ms. Eshoo. To Dr. Throckmorton, does the FDA have all the authorities it needs to regulate CBD products for consumer safety?

Dr. Throckmorton. I believe we do. When I talk to drug --

Ms. Eshoo. Are you sure?

Dr. Throckmorton. When I talk to drug developers that come in and talk to me and they say, "We are interested in studying a compound found in cannabis," whether it is CBD or it is one of the other 80 cannabinoids or the terpenes or whatever else, I say: If you can get me a legal source for that compound, a legal source for that compound, I am going to treat you exactly the same way I would treat any other drug in development.

Ms. Eshoo. Okay.

Dr. Throckmorton. Except I am going to give you some additional resources in the forms of --

Ms. Eshoo. I still have more questions. Now, the FDA has estimated that it will

take 3 to 5 years to complete rulemaking in relation to CBD products. Is this still accurate?

Dr. Throckmorton. We understand the --

Ms. Eshoo. Is it?

Dr. Throckmorton. It is unfortunately not a yes-or-no question, ma'am. We know that there is interest in moving quickly. We understand that 3 to 5 years is longer than people would like. We are looking --

Ms. Eshoo. What is the estimate today?

Dr. Throckmorton. We are looking at a full range of options. We are interested --

Ms. Eshoo. You don't want to tell me. It seems to me that maybe 3 to 5 is still in place, but you don't want to say.

In your testimony, you said the FDA knows of CBD products that may not contain the amount of CBD indicated on the label or may contain other potentially dangerous compounds. Has the FDA issued any labeling requirements for CBD? My time is -- you may answer.

Dr. Throckmorton. The labeling requirements would be imposed on the approved drugs, Epidiolex. That product is well manufactured, possesses -- we have no concerns like that that I am aware of. The products that the warning letters are subject to that that comment related to are the unapproved products that have been marketed in the States.

Ms. Eshoo. Thank you.

Well, my time has expired, and I recognize the ranking member now for his 5

minutes of questions.

Mr. Burgess. Thank you, Madam Chair.

And, Dr. Throckmorton, staying with you for just a minute on the Epidiolex question. When I look at my drug discount app, it is like $1,300 a month for a therapeutic course of that. So, if somebody didn't have $1,300, could they just go buy CBD oil and supplant the use of Epidiolex?

Dr. Throckmorton. Well, we always recommend that you use an approved product for a number of really good reasons. But what we learned when we did that sampling of unapproved products is that we don't know what will be in that oil if you choose to take it. It may contain things that would be dangerous to you. We also know it is reasonably likely that it could not contain the amount of CBD that you were looking to take for whatever condition.

Mr. Burgess. Just along the lines of the timeframe that Chairwoman Eshoo asked you about just, for point of reference, when we did the Cures for 21st Century bill, pretty much standard accepted lengths of time in FDA for approval of a new drug was 14 to 16 years, and about a billion and a half dollars. Do I remember that correctly? So 3 to 5 years actually sounds like you are moving with great dispatch, would that be a fair statement?

Dr. Throckmorton. The 3 to 5 years comes from our general experience with rulemaking rather than any specific --

Mr. Burgess. So it is not a recent --

Dr. Throckmorton. It is not related specifically to drug development or product development. It is just that rulemaking has steps that we have to use.

Mr. Burgess. We will move forward with the DEA with this. Has DEA ever done an administrative change in a scheduled drug without being prompted by Congress?

Mr. Strait. Oh, absolutely, yes. We initiate scheduling actions with some frequency. It could come through a petition received from a public citizen. It could come as a direct result of an approval of a new drug, a new molecular --

Mr. Burgess. Would that not come through the FDA, though?

Mr. Strait. Yes. In that circumstance, yes.

Mr. Burgess. So you couldn't just do that de novo and say, "We are going to change the schedule of this medication on an administrative basis"?

Mr. Strait. The agency retains the ability to initiate its own proposal as well. In that instance, we would put together --

Mr. Burgess. Initiate, but you can't complete it without input from the FDA.

Mr. Strait. No. As you say in your opening remarks quite correctly that we are tethered to the science that we are given by our colleagues over at HHS.

Mr. Burgess. Yeah, I don't know if that is inappropriate; being tethered to science can be a good thing.

Dr. Vokow, you actually mentioned in your written testimony about the risk of addiction with cannabis products. Presumably you are talking about marijuana. That is a thing? That is a real thing?

Dr. Volkow. It is a real thing, and it is THC, the active ingredient responsible for the addictiveness of marijuana. And the plants contain higher and higher content of THC.

Mr. Burgess. So is marijuana a gateway drug? Some people call it that. Is

that a fair statement?

Dr. Volkow. It decreases the likelihood that you are sensitive to the addictive effects of other drugs, and that is why it has coined the term of "gateway drug"; it makes you more sensitive.

Dr. Burgess. So yesterday we spent a full hearing in Oversight and Investigations on the scourge of opiate addiction. We do worry that, if we go too far in one direction or another, that 10 years from now, we will be having a hearing on perhaps we have gone too far with what we did with liberalizing marijuana laws. But let me just ask you this: You also mentioned the National Highway Traffic Safety Administration, the effects of driving under the influence. Our traffic laws and our State partners, have they kept up with all of the changes in marijuana policy that have occurred across the country?

Dr. Volkow. No. One of the major challenges in doing so is that it is very difficult to quantify whether someone is intoxicated with marijuana or not. With alcohol, you actually measure the alcohol content in plasma, but that measure does not guarantee for marijuana that you are under the influence of the drug or not. So you can have very high levels from having taken it 3 days ago in a regular user. So that has been a major challenge.

Mr. Burgess. So you can't really quantitate to the degree of behavioral disruption that may occur.

Dr. Volkow. That has been much harder to do

Mr. Burgess. And as a consequence for our law enforcement partners and our partners at the State that are writing State traffic laws, that becomes a difficulty. Is that correct?

Dr. Volkow. Correct. And that is an area that we are trying to bring up new strategies to identify intoxication with marijuana from NIDA.

Mr. Burgess. As a practical matter, that actually happened in my district: A pedestrian who was struck by an automobile, the driver of the automobile had under the 0.08 limit in their blood alcohol, but they also had a positive quantitative test for THC. That individual was no billed by the grand jury. I don't know whether that was right or wrong, but it seems to me that the potential for the additive effects should be something that law enforcement would bear in mind when deciding whether or not to bring a case like that. It was clearly a very tragic situation, young high school athlete who got hit. So it was a high-profile case in the community and something I will never forget.

Thank you, Madam Chair. I yield back.

Ms. Eshoo. The gentleman yields back.

It is an pleasure to recognize the gentlewoman from California, Ms. Matsui, for her 5 minutes of questions.

Ms. Matsui. Thank you very much, Madam Chair.

And I really appreciate the hearing we are having today. This issue really needs to be examined.

And thank you very much for the witnesses for being here today.

At the University of California, researchers are doing important work to study the health effects, public safety, and environmental impacts of marijuana. I would like to discuss how our existing Federal regulations may be limiting researchers from fully understanding cannabis' potential risks and benefits.

Now despite the fact that cannabis is being cultivated right in California to sell at

local dispensaries, under current law, UC researchers must obtain their study samples through the NIDA contracted site in Mississippi. In order to study what the public is purchasing in dispensaries, UC researchers have applied for a license to cultivate cannabis locally. However, these researchers have not heard back from the DOJ and DEA as to the status of their applications.

Mr. Strait, where is the Department of Justice in its process of granting or denying applications some researchers have put forth at a university to study to cultivate cannabis at a university?

Mr. Strait. As I said in my opening, we certainly support all research endeavors.

One of the challenges we see that often leads to this misperception about delays on the DEA side is we look for a complete application before we forward that application to our colleagues at the Department of Health and Human Services. So there are three things that we need: We need a protocol, which most researchers if they are federally funded or even State funded have; a CV for the researcher, which every researcher certainly has; but sometimes the delay is the result of the third piece, which is that institutional review approval. Sometimes, for purposes of timing, the researchers will submit an application, knowing that their State university or their State system, their university has not met to review their application.

Ms. Matsui. Well, I now the University of California, I think they pretty good about doing this. And so we would like to be able to expedite as much as possible because their research is going to be very important as far as all of this.

From the researcher's perspective I understand there is some ambiguity around the ability to conduct research with synthetic CBD for potential applications in humans.

For the panel, what is your agency's position on the current status of CBD? Is there a distinction between marijuana-derived CBD and hemp or synthetically derived CBD when it comes to regulating these products? Dr. Volkow?

Dr. Volkow. From our perspective, we are interested in understanding what are the effects of the chemical compound that goes by the name of CBD. With respect to actually its pharmacological actions, but the potential of negative effects and the potential of therapeutic actions. So, for all, the molecule is the one that is of interest. At the same time, though, we are doing research to try to investigate how, when it is mixed with other cannabinoids, that may influence its effects.

Ms. Matsui. Okay.

Dr. Throckmorton, do you agree?

Dr. Throckmorton. Yes. One of the things that happened in the results of the farm bill was that cannabidiol was removed from oversight from the Controlled Substances Act. In some sense that allows us to encourage its conduct -- studies and things using it without interacting --

Ms. Matsui. It opens it up.

Dr. Throckmorton. -- with DEA. We believe that is a powerful, potentially powerful, in terms of getting new studies done.

Ms. Matsui. Great. Mr. Strait?

Mr. Strait. Yeah, and Dr. Throckmorton is 100 percent correct. I think the passage of the farm bill created a little bit of a question mark as to the legal status of synthetic CBD versus that derived from natural sources. Very clearly that which is derived from natural sources, if it contains less than 0.3 percent THC, it is no longer

controlled under the CSA.

Ms. Matsui. Dr. Throckmorton, if a researcher wants to conduct clinical cannabis research that may lead to a new drug, what requirements need to be fulfilled with the FDA?

Dr. Throckmorton. When you say "cannabis," are you talking about farm-bill-compliant low-THC cannabis? It is important, when we talk to investigators, we think about it in sort of two tracks, an arrow going one way, and arrow --

Ms. Matsui. Right. Right. Right.

Dr. Throckmorton. One arrow, the farm-bill-compliant cannabidiol and other compounds extracted from hemp, we view as subject to the Food, Drug, and Cosmetics Act. They are able to be used for investigational use. Come in and talk to us; we will treat you as any other drug substance for study.

If it is high-THC cannabis, then that still applies, but in addition, we would want to make certain that they work with the DEA because there are other requirements under those circumstances.

Ms. Matsui. Okay. Fine. Thank you, and I have gone over my time.

I yield back.

RPTR GIORDANO

EDTR SECKMAN

[10:57 a.m.]

Ms. Eshoo. The gentleman yields back.

Mr. Strait, would you respond after you get back to your agency with Congresswoman Matsui on University of California's application, please?

Mr. Strait. Absolutely.

Ms. Eshoo. This is the greatest public university in the world. They know how to do applications. They know how to do applications. Well, it is causing a ruckus, but I will stand --

Mr. Upton. You do not have any right to object.

Ms. Eshoo. I will stand with my statement representing the greatest private university in the world, Stanford.

It is now a pleasure to recognize the gentleman from Michigan, Mr. Upton, for his 5 minutes of questions.

Mr. Upton. You are just lucky Pete Olson is not here this morning, but I do not have my jersey on.

Thank you, Madam Chair, for this hearing. I do have a couple of questions.

Dr. Throckmorton, you mentioned that Epidiolex is one of the three drugs that have been approved, and two others in addition to that. What are the illnesses or conditions that they were approved for?

Dr. Throckmorton. Right. So Epidiolex is approved for two genetic seizure disorders, severe seizure disorders in children, and that contains cannabidiol.

Mr. Upton. Is it injected? Is it oral? Is it shot? Is it --

Dr. Throckmorton. It is oral.

Mr. Upton. Oral?

Dr. Throckmorton. It is given in an oil form. It is fat soluble, and so it is a syringe basically.

The other compounds are all synthetic. They are not extracted from the cannabis plant, and they are approved for wasting diseases. There are nausea and vomiting associated with chemotherapeutics. We can get you a full list of those, but it is more general. Those compounds contain THC. So they have a different active ingredient than the Epidiolex does.

Mr. Upton. So Greg Walden talked about something. As consumers, 33 States now have approved medical uses. Eleven States -- Michigan is one -- that is both medical as well as recreational, or adult use. And I guess consumers are very interested in, you know, how much is in here? I mean, we know, when we drink a beer, different alcohol content, whether it is a craft beer, you know, maybe a State like -- that has a smaller threshold like Utah.

But, in addition, you have got the law enforcement issues. I was with one of my sheriffs last week. He, unfortunately, had -- we had a situation like Dr. Burgess had in his district with a student returning back to Michigan State, and, sadly, he was involved in a terrible auto accident, and, in fact, afterwards, they -- he survived, but they found out that he was -- had a high level of THC, as I understand it.

Where are we in terms of some visible standards or some review that folks can look at as it relates to the cookies or the brownies or whatever it is, the cereal that they

are going to eat and consume as relates to perhaps the safety of that, and where are we as relates to law enforcement who, as -- you know, it is not like the breathalyzer. They have got to do a variety of different cognitive exercises to try and determine whether or not that individual has taken too much, and it is a blood sample, but where are we in terms of trying to help the consumer know the right information if they choose to take, in these States, a legal substance?

Dr. Volkow. I can speak on the research perspective. We are interested in understanding what content of THC is associated with specific pharmacological effects, including side effects, and so research has been done to show that, if you consume anywhere between 2 and 8 milligrams, you are going to get high, but, in general, you do not have any adverse effects.

So what we would like to be able to do from the research perspective is to create a unit of marijuana that can be utilized consistently across research to help us understand how exposures of different content THC --

Mr. Upton. And how long -- when is that research going to be completed?

Dr. Volkow. The research on doses has been done. The research on creating a unit of THC that can be used consistently is something that we are working on to try to consolidate and get a perspective of what are the differences on the consumption by people --

Mr. Upton. Are we a year out? How long do you think that will take? What is --

Dr. Volkow. I would hope that we will be able to implement the standard dose for research purposes within one year, but that is very different from implementing a unit

dose for legal -- for products that are not legally accepted federally, and that is the States are trying to come themselves with standard doses, and you mentioned it for the cookies, or -- but that varies also between the States.

Mr. Upton. Yeah. Anybody else have a comment?

Dr. Throckmorton. I do, Mr. Upton. You raised an incredibly important point that is important to understand about the development of nondrug products containing things like CBD. So, as the FDA thinks about how to develop those products, one thing we remember is that there would be requirements on a product that we approved regarding accurate labeling, regarding dosing.

So, for instance, the cookie that we are discussing, if that packaging was approved, if we found a pathway that enabled us to allow CBD in a cookie, along with that packaging would come labeling that would say it contains 10 milligrams or a hundred milligrams or whatever else; could include other conditions of use that could help understand when it would appropriately be used and things like that. So part and parcel with the work we are doing is to think about the consequences, the important consequences, which would include that kind of labeling improvement. We would have more understanding. People would have a better understanding. They would also have more assurance that the product actually contained the CBD --

Mr. Upton. I know my time has expired, but just a "yes" or "no." Do you have authority for that labeling now?

Dr. Throckmorton. It is -- absolutely, we have that authority. What we need is to determine the pathways to take --

Mr. Upton. Right.

Dr. Throckmorton. -- for those nondrug-containing CBD products.

Mr. Upton. I yield back.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the Chairman of the full committee, Mr. Pallone, for his 5 minutes of questions.

The Chairman. Thank you, Chairwoman Eshoo.

As I said in my opening statement, the cannabis policy landscape is evolving across the States and territories. Yet, at the Federal level, the policy has remained largely the same, and one issue that researchers across the Nation have raised with the committee is the fact that they are not able to conduct research on cannabis products available through State cannabis dispensaries.

Dr. Volkow notes in her testimony that the cannabis available in States to consumers is much more potent than what has been available in the past, and that means that Federal researchers cannot adequately study the health potential or adverse health consequences of products that are more readily available.

So this poses a legitimate public health challenge as it impedes the ability for researchers to truly understand the impact of products regularly used by consumers and prevents us from advancing sound science.

So, Dr. Volkow, you noted in your testimony that having only a single domestic source of research of cannabis limits the diversity of products and formulations available to researchers and slows the development of cannabis-based medications, so let me ask, yes or no, Dr. Volkow, do you believe Federal researchers should have access to cannabis has State-authorized dispensaries?

Dr. Volkow. Yes.

The Chairman. And, Dr. Throckmorton, yes or no, would access to cannabis outside of the University of Mississippi be beneficial to drug developers in the U.S.?

Dr. Throckmorton. Yes.

The Chairman. And, Mr. Strait, as you mentioned in your testimony, DEA is actively working to consider applications for additional cannabis growers. What is the status -- this is not yes or no -- what is the status of this effort, and when can we expect that the agencies would finalize rulemaking?

Mr. Strait. So we actually have a draft regulation in place. In August of 2019, we were able to get to the point of our policy review process where we were able to publicly acknowledge, consistent with our regulations, who our pending applicants were as of August 27th, 2019.

We know that we have to probably do notice-and-comment rulemaking to implement regulations on two matters. One is how we are going to evaluate all of our pending applications; and then, two, what additional types of regulations might need to be in place in order to -- you know, in order to impose on those that would grow. So that regulation is in a draft form. I cannot talk too much about it, but rest assured we have submitted it to OMB. It has been drafted, and, tomorrow, many of us will be getting on a call to talk through it.

The Chairman. All right. Thank you.

I want to switch to CBD. A Google search can lead any consumer to websites that offer CBD-infused gummies, cereal cookie. This is in addition to personal care products and dietary supplements. One recent estimate by an independent company

suggested that the CBD market can bring in as much as $15 billion by 2025.

So, Dr. Throckmorton, I understand your agency is working to regulate CBD products. However, FDA has suggested that it could take 3 to 5 years before rulemaking to clarify the regulatory pathway work to be completed.

Can you explain to the committee the scientific and regulatory activities the agency believes are needed to ensure the safety of CBD in other products, such as food and dietary supplements?

Dr. Throckmorton. Sure. And I want to start by saying that 3 to 5 years was an estimate, that we understand the importance that people have in identifying in a rapid process to a pathway for nondrug CBD products.

Having said that, rulemaking is the one pathway that is identified in statute for an exception to the prohibition against the use of drug substances in foods and dietary supplements. So that prohibition, as I just -- you know, as I mentioned in my opening remarks, exists, and, for the agency to change, we need to find a mechanism to allow a path forward for nondrug CBD products to be developed.

We are in the process of doing that. The rulemaking is one thing that is under consideration. As has been mentioned, there are a number of legislative ideas that people have had. We have had other meetings where people have raised other suggestions regarding this as well.

Bottom line is we get it. Bottom line is we understand that we need to identify a path as quickly as we can, but we need to be grounded in science. You mentioned yourself -- many of us have mentioned -- fundamentally, there are many unknowns about cannabidiol. There are things that we know that it can do, adverse effects that I

mentioned in my testimony related to liver jury, related to potential male reproductive injury that we need to know more about.

We need to know more about its uses in vulnerable populations and for long periods of time because, if it is placed in a nondrug product, there will be no learned intermedia. There will not be a doctor or a nurse or anyone that will talk to the patient or to help them make their choices about the use of that product.

You could get up in the morning, take your CBD -- to get started -- in your coffee, take another dose of CBD for lunch when you have your sandwich, and then end in the late afternoon with an alcoholic beverage containing CBD; and the aggregate amounts of CBD then matter. We need to decide how to do that safely.

Our fundamental focus for foods and dietary supplements is safety, and we need to have more data than we do available at present in order to make that determination, in order to help inform what the right, best steps are.

The Chairman. All right. Thank you.

Thank you, Madam Chair.

Ms. Eshoo. And, in the appropriations bill that was passed last year, there were moneys that go directly to FDA to move up the work on CBD, correct?

Dr. Throckmorton. That is correct.

Ms. Eshoo. Yes. All right.

Dr. Throckmorton. And focused, I believe, in the --

Ms. Eshoo. Yes.

Dr. Throckmorton. -- nondrug space --

Ms. Eshoo. Yes. So you have the money, and now you have got to get it going.

It is a pleasure to recognize Mr. Guthrie for his 5 minutes of questioning, the gentleman from Kentucky.

Mr. Guthrie. Thank you very much. Thank you for being here.

And, Dr. Volkow, we have heard that it can take up to a year to get a schedule I registration. That process of adding new cannabinoids to an existing registration, and getting approval for protocol modifications is time consuming, and how does the DEA registration processes for modifying a schedule I registration to conduct research of cannabis impact ability to do research? But I also understand, Mr. Strait, you said -- oh, actually, I wanted to ask you something first, if that is okay.

Mr. Strait. Sure.

Mr. Guthrie. Before I get to answer your questions, last October, myself and others sent a letter asking about the implementation and recommendations included in the committee staff report on the opioid distribution. To date, we have not received DEA's response, and I would ask that, after the hearing, that we follow up together to see if we can get DEA's responses to that report.

Mr. Strait. I would be happy to follow up with that.

Mr. Guthrie. Okay. Thank you. So, getting to my other question, just the time-consuming process in ability to do research, and I do believe, Mr. Strait, you said it was like 52 days to get a registration, and it seems like we are hearing different than that. Can both of you, both Dr. Volkow, you talk about the time-consuming process for that?

Dr. Volkow. Yeah. And there are two issues with it. One of them has to do with the process of how lengthy it is to get an approval to do a human subjects protocol, and, if it is schedule I, that is much longer. And, on average, about 52 days by the DEA

actually counts the moment that that protocol has been deemed complete and moves forward, but what we have heard from the researchers is that it is not so straightforward to get the protocol in a way that the DEA can work with it, because it is complex.

And another issue that becomes -- makes it harder is that the DEA State local agents interpret the rule differently, and, as a result of that, that further hinders the problem. So those are the issues that we see.

The other aspect where we are also seeing an impact on schedule I is that there are certain scientists that do not even want to go there because they say, "I do not want to go there; it is going to take too much effort to do research on a schedule I," and so we lose potentially-valuable scientists into looking at things that are important.

Mr. Guthrie. Okay. Mr. Strait, do you have any comment on that, or --

Mr. Strait. Yeah. Thank you. Thank you for giving me the opportunity.

You know, this is a common refrain we have heard from our partners over at HHS. One of the challenges that they have is that, when we try to get information from them about who the concerns are being raised by, maybe it plays into the fear of DEA, but we are kind of cited with PII, that they cannot disclose information to us, that they are prohibited from doing it. So we struggle to try to understand who the people are that are having these difficulties so that we can give them some special attention, and we are happy to give them that special attention.

The other point I wanted to make is the inconsistent applicability of our DEA regulations across our 23 field divisions or the concerns of that, and, as I mentioned to some staff before we started this call, we are actually getting ready to host a management conference across our entire division from all across the country, and we

are going to actually invite Dr. Volkow or her designee to come in and address this because I think that is something that we can solve easily. That is not anything that we need Congress' help on.

Mr. Guthrie. Okay. Thank you.

And I will yield a minute and a half, my remaining time, to Mr. Griffith.

Mr. Griffith. Thank you very much.

Virginia actually has the oldest medicinal marijuana law on the books. It was passed in 1979 with Chip Woodrum, who is now deceased, as the House patron, and former member of this committee, Rick Boucher, who was then a State senator, as the Senate companion, to say that they would allow the use of medicinal marijuana in the Commonwealth of Virginia. However, the DEA had not allowed it, and so the doctors did not want to risk their license by prescribing it. It required a legitimate prescription. And that is where my bill came from, was that this is what Virginia has stood for, for decades.

In 1998, there was an attempt to repeal it because they thought it was like California's law that just said, you know, "if it makes you feel good, you can try it" kind of thing, which Virginia rejected, but, still, the DEA has not acted. So, when I hear people talking about, you know, "It will take us 3 to 5 years; we have to do the research," my question is, why hasn't the research been done?

And, Dr. Throckmorton, I would have to say that it causes me some great concern that apparently the FDA thinks it is okay for opioids and opiates and barbiturates, but somehow marijuana should stay schedule I. That is illogical to me. And so I just -- I lay that out.

Marinol, in the case of my two fathers, was available. The problem is they were so sick, they could not swallow it and hold it on their stomachs. That is why their friends were smuggling in -- with the doctors turning a blind eye -- smuggling in the marijuana so they could smoke it and then eat.

So we need to find a solution, and we should have started working on this back in 1979 or earlier, but we have not done it.

I yield back.

Mr. Guthrie. I yield back also.

Ms. Eshoo. The gentleman yields back. Excellent points.

Pleasure to recognize the gentlewoman from Florida, Ms. Castor, for her 5 minutes.

Ms. Castor. Well, thank you, Madam Chair, for calling this hearing. Thank you to our witnesses for being here today.

I think it is clear that cannabis research is caught up in conflicting regulations. You cannot remove cannabis from schedule I because it lacks proof for medical and controlled or controlled recreational use, but you can't research to determine if it is safe because it is included on the schedule I.

Dr. Volkow, you ended your testimony by saying that cannabis research is urgently needed, so let's focus on how we can streamline our research process for cannabis and possibly other schedule I substances.

First, what are the requirements and challenges for conducting research on schedule I substances?

Dr. Volkow. What I was commenting before, the main difference relates to the

fact that you have to get the DEA registration, so that makes the process much more complex than just doing research with any other substance, and that can take time.

Ms. Castor. And that clearly deters research --

Dr. Volkow. Yes.

Ms. Castor. -- on those substances?

Dr. Volkow. Correct.

Ms. Castor. In thinking about how we reduce those barriers for research with cannabis and possibly other schedule I substances, you did answer to Representative Guthrie -- you pointed out a few of the barriers.

What do you recommend should change in the process right now?

Dr. Volkow. Well, we have been working among the agencies to come to -- to try to come up with a process that will allow it to safeguard the public, but at the same time to facilitate and accelerate research. So those are the two issues that coming up with a category that enables researchers to be able to accelerate the pace at which they are doing research without in any way jeopardizing the public, and that is wherein, again, the DEA, the FDA, and the NIH have been working together.

Ms. Castor. There are a number of bills that have been highlighted for the committee's consideration today. Would you point to any of those pieces of legislation that would help streamline the process appropriately?

Dr. Volkow. You are putting me in a little difficult position because there are six of them, and we do not legislate; we basically bring science. And what I can tell is that the science tells us that marijuana is a substance that can produce addiction.

Now, we also know from studies that it is likely that there is potential for the

therapeutic use of the cannabinoids within marijuana, and, thus, to the extent that we, among the six ones that you are proposing, can accelerate research while protecting the public, then that is what you all have to weigh.

Ms. Castor. All right.

Dr. Throckmorton, has FDA seen an uptick or change in the number of applications from researchers to conduct research on hemp or other low-THC cannabis products since these are no longer considered schedule I substances?

Dr. Throckmorton. Thank you for that question, and short answer: yes.

Ms. Castor. Do you support removing marijuana from the Controlled Substances Act to remove barriers to research?

Dr. Throckmorton. At present, my focus is on cannabidiol, and focused on supporting those new INDs, those new investigational studies that we have seen inhouse.

So your first question is worth going back to for just a moment. We now have almost 40 investigators that have come in to us proposing to use CBD and other substances found in hemp. We believe that represents an important new opportunity for us in terms of investigating CBD and those compounds for drug development, and I want to make sure that we give them every opportunity, every support that we possibly can.

The question about marijuana is more complicated. It has to do with what you mean by "marijuana." Obviously, one street corner sells one kind of marijuana, and another street corner sells a different kind of marijuana. Making a conclusion that both of those marijuanas somehow have medical value is challenging scientifically, and I think Dr. Volkow would agree with me with that, and that is one of the findings that we would

be obliged to make were we to try to make a recommendation to the DEA to reschedule marijuana from schedule I. So, from a scientific perspective, there are real challenges to making that conclusion.

We have been asked to look at it three times in the past, and, each time, we have decided, as I had mentioned before, that it was not possible given where we were with the science.

Ms. Castor. You know, when it comes to CBD, it is like the cat is already out of the bag. It is amazing, the marketing for CBD. What would you advise the public about the efficacy of the products on the market today? Do they really help? And do we even have a handle on what is truly in all of those products?

Dr. Throckmorton. Both questions would be: We don't know. We don't know whether the various claims being made are accurate to the standard that I would expect for a drug product being developed, and we don't know well enough what is found in those products that are being sold under a variety of State initiatives. We need more data in both of those places.

With regards to efficacy, my job is to make sure that those manufacturers, those around 40 that want to study this are able to do that quickly, study what works and study what does not quickly.

With regards to safety, the agency understands that we desperately need to collect all of the available information about the safety of CBD in all of those various uses. That is challenging for us. We have been in the process of a yearlong effort to collect all of those available data. We have identified some gaps. I think I mentioned some in my testimony previously -- things we believe we absolutely need to know. We are in the

process of figuring out how to close those gaps.

Ms. Eshoo. The gentlewoman's time has expired.

Pleasure to recognize the gentleman from Virginia, Mr. Griffith.

Mr. Griffith. I thank the --

Ms. Eshoo. Looking for another good story here.

Mr. Griffith. Well, I may or may not have one at this point. I have got lots of stories, but we may not have time.

Mr. Strait, I know that you disagreed with the earlier assessment on the University of California, having attended the great university in Blacksburg, Virginia, Virginia Tech, which I am so proud to represent.

That being said, going back to Dr. Burgess' questions, if the FDA recommends that the DEA reschedule a compound, is the DEA required to comply with that rescheduling recommendation?

Mr. Strait. If they recommended rescheduling, we are bound to their -- the statute actually says that the Attorney General shall be bound by the recommendations of the Secretary as it pertains to scientific and medical matters.

Mr. Griffith. As the Secretary determines?

Mr. Strait. Correct.

Mr. Griffith. All right. So you can confirm that the DEA has never refused to reschedule a compound after being given a recommendation to do so by the FDA or the Secretary?

Mr. Strait. I am certainly not aware of any instance where that would be the case.

Mr. Griffith. All right. Now, continuing, Mr. Strait, as you know, the U.S. is a party to the United States Single Convention on Narcotic Drugs, which imposes manufacturing and distributing restrictions on marijuana. Some have cited our involvement in that agreement as a potential reason why the Federal Government should not lift restrictions on marijuana.

Regarding American domestic manufacturing of research- grade cannabis, why is it that other countries who have signed the same treaty, such as Canada, Israel, Ireland, New Zealand, Australia, and the Netherlands have several legal manufacturers of research-grade cannabis, and their products are legally imported to the U.S., but the U.S. has only one, the University of Mississippi, as we have heard earlier?

Mr. Strait. So you are precisely right; there is a growing number of countries that have implemented laws in their countries that fully effectuate their requirement, their obligations under the Single Convention on Narcotic Drugs. We have, too, and that is the reason why we have the University of Mississippi, or this NIDA drug supply program. What we are trying to do is, as we expand the number of growers, we are trying to take a look at whether or not there are things that need to be changed -- altered, I would say; not newly created, but just altered slightly -- in order to make sure that we are in compliance with our treaty obligations.

Mr. Griffith. Well, then I hope that you all would work on that quickly. You said earlier applications for research are being approved, but you said regulations and paperwork -- and I am paraphrasing -- are perceived to be so onerous that people will not do it. Well, connect the dots. The paperwork and the regulations, the perception becomes reality, and, as we have heard from Dr. Volkow, sometimes that becomes a

problem, and I think that is why you have not received more applications.

Do you want to say something on that point? And I just have a couple minutes.

Mr. Strait. If I may?

Mr. Griffith. Quickly.

Mr. Strait. And I am going to be very quick. But I did want to go back to your comment and that of Congresswoman Castor's, which is to say that there is a solution that this interagency group and others worked on all throughout the summer as it relates to some important legislation dealing with the permanent control of fentanyl-related substances in schedule I. We as an administration came out with kind of some commonsense practical solutions to address all of the concerns raised by the research community. We are happy to share that if --

Mr. Griffith. And whatever -- and if you could share that, and whatever you can -- whatever help you need from us, I think this committee would be willing to help in any way it can.

The DEA's 2016 policy statement said it would be consistent with the 1961 Single Convention on Narcotic Drug Treaty if the DEA were to register research-grade marijuana growers outside of the NIDA contract system so long as the growers agreed to only distribute marijuana with prior written approval from the DEA. However, in your testimony, you said DEA has changed course, saying that, quote, since publication of the 2016 policy statement, the Department of Justice determined that adjustments to the DEA's policies and procedures may be necessary to be consistent with certain treaty functions.

What changes need to be made in order to be consistent with those treaty

functions?

Mr. Strait. Well, I cannot really get into too many details because, again, it is a deliberative process that we are engaged in right now as we speak with the Office of Management and Budget.

Mr. Griffith. Can you get that to me as quickly as you can?

Mr. Strait. I absolutely will.

Mr. Griffith. And I appreciate that. If you would give it to the committee and to me as well, that would be appreciated.

Can you provide any additional rationale that would mandate the DEA to re-evaluate the 2016 policy statement beyond the volume of the applicant pool?

Mr. Strait. I am sorry. Can you repeat that? I am not sure I understand.

Mr. Griffith. Yes, sir. Can you provide any additional rationale that would mandate DEA to re-evaluate its 2016 policy statement beyond the volume of the applicant pool?

Mr. Strait. I would say the size of the applicant pool is probably one of the single greatest issues that we are trying to contend with, is how to meet the statutory text of the basis by which we are supposed to be evaluating all applications for both manufacturers of schedule I controlled substances.

Mr. Griffith. We will be happy to change that statutory text if need be.

I yield back. Thank you, Madam Chair.

Ms. Eshoo. Gentleman yields back.

Pleasure to recognize the gentleman from Maryland, Mr. Sarbanes, for his 5 minutes of questions.

Mr. Sarbanes. Thank you, Madam Chair. I thank the panel for being here today.

Dr. Volkow, first of all, thank you for your work, which I know well, and you have brought a lot of important testimony to this committee in the past.

I have heard from schools in my State, such as University of Maryland-Baltimore, that have communicated to me the difficulty in conducting research due to the current regulations and are nervous that any unintended violation of these strict and arduous restrictions can result in loss of their Federal research grants. Obviously, we have had a lot of discussion about that here today.

Despite these barriers, schools and researchers are eager to advance the understanding of the topic, and, just last year, the University of Maryland School of Pharmacy began offering a master of science in medical cannabis science and therapeutics. They now have this degree and focus opportunity.

I have a letter here, Madam Chair -- I would like to submit this for the record -- from the University of Maryland-Baltimore on the topic of cannabis research and cannabis training programs for the record. I would ask that this be accepted into the record.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Sarbanes. Dr. Volkow, would you agree that, as more patients are accessing cannabis products in States where they have been legalized for medical or recreational use in Maryland -- of course we have taken that step with medical use -- that our provider workforce should be educated on these topics and ready to respond to patients' questions?

Dr. Volkow. I agree that we need to have much more education with respect to actually how and that the use of marijuana products can negatively impact or help someone. The problem is that we do not have sufficient evidence that could help us mount those programs in a way that it is actually required. So, at this point, I don't feel that the evidence, like the National Academy of Science concluded, is sufficient to say we are going to recommend that this product be used by this patient.

There are many concerns, and it is not trivial. One of the problems that was noted is many patients -- for example, the elderly may be given some of these products; they are on other medications, and they are not told what effects of the combination of THC with these medications, and the clinicians do not even know about it, nor do the patients.

So I do believe in the importance of expanding our knowledge so that we can then develop educational training programs that are based on knowledge, not on anecdote. And that is why I highlight the urgency of doing research on its therapeutic, as well as on its potentially adverse, effects.

Mr. Sarbanes. Well, I think you are highlighting the impediment to creating workforce categories that can be a resource of expertise and perspective when it comes

to cannabis that is presented by the kind of research issue that we are talking about today because, if you cannot -- it is sort of a chicken-and-egg situation. If you cannot open the doors to more effective research, then, obviously, creating specific workforce categories that can take advantage of that and help push it forward and sustain it is made more complicated.

I would note that a survey of health providers from 2015 concluded that the health providers themselves perceive a knowledge gap in areas relating to medical cannabis dosing, development of therapeutic treatment plans, differences between various cannabis products and other areas. So the providers themselves have certainly perceived that there is the need for more research and expertise to be developed in this area, and I assume you would agree that incentivizing research on medical cannabis, for starters, would help address these knowledge gaps and support a more informed and robust provider workforce?

Dr. Volkow. Yeah. I think we have an obligation to do the research to determine, what are the consequences of the products that people are taking with the expectation that they are going to be beneficial? We owe it to them to give them that knowledge, whether it is true or not. That is why we do research. So I completely agree of the urgency of expanding our understanding of the so-called medical properties of marijuana in diverse patient populations.

Mr. Sarbanes. Thank you. I yield back.

Ms. Eshoo. The gentleman yields back.

Pleasure to recognize the gentleman from Oregon, Mr. Walden, for his 5 minutes of questions.

Mr. Walden. I walked back in from the other hearing, Madam Chair, so thank you because I know how important this issue is to all of us and especially to Oregonians.

Mr. Strait, I want to shift gears to hemp, as there is a lot of interest in my district from farmers who are growing hemp for CBD, and Oregon State University is working with the USDA's Ag Research Service to launch Federal hemp research. Given that the 2018 farm bill removed hemp from the CSA, is a DEA registration required to conduct research on hemp-derived CBD?

Mr. Strait. No.

Mr. Walden. No. Relatedly, USDA's interim final rule for hemp production, DEA is supposed to participate in oversight. Is the DEA prepared to handle registration of the private and public labs to handle hemp-compliance sampling?

Mr. Strait. The issue of hemp testing, which is actually baked into the U.S. Department of Agriculture --

Mr. Walden. So to speak, yes.

Mr. Strait. -- interim final rule -- no pun intended. Sorry about that.

Mr. Walden. There you go.

Mr. Strait. -- was predicated on the concept that those who performed testing probably made reasonable sense for them to hold a schedule I license in the event that they ended up procuring a sample that was not hemp; it actually ended up being hot and contained more than 0.3 percent THC. So that is an interim final rule. I know they are soliciting comments on that, and I know that that is an issue of concern that has been raised by some in the public.

Mr. Walden. Yeah. There are quite a few of these issues. I know somebody

that had a commercial driver's license who was using CBD oil to deal with something, or taking it, and then did a drug test, and it triggered the drug test as if he had used marijuana, which of course affected his CDL. So these are issues we are running into in real lives. He was not a marijuana user. You can have your own opinion on that, but he tried CBD.

And I want to go to Dr. Throckmorton. When it comes to CBD, are you able to tell us if FDA is any closer to determining if there are appropriate regulatory frameworks for nondrug uses, including for products marked as food and dietary supplements, and has the lack of research on the substance been an impediment to that process?

Dr. Throckmorton. I can tell you that process is a high priority for us. We understand the interest. As I said before, we are committed to working with you to find a path forward on that.

I would also say that the lack of information we have about the safety regarding cannabidiol is a challenge for us that we are looking to fill. We need to understand the use of CBD, the safety of CBD, in order for us to decide how best to place it in nondrug products.

Mr. Walden. And so I guess I want to push a little just in terms of the impediments to getting answers because this is playing out in real life. I have friends that swear by CBD. I have friends whose doctors have said, "Do not worry. Go ahead and take it. It does not impact anything else you may be taking." They know that? Have you done the research?

Dr. Throckmorton. Well, in fact, we know that is likely not accurate. Based on what we know from the Epidiolex, the approval of the product that contains cannabidiol,

cannabidiol does interact with other drugs, and we can get you that list if you are interested, but, in fact, there are interactions that could occur that could be clinically significant, and I think blood thinners are one, for instance.

Mr. Walden. Yes.

Dr. Throckmorton. And so we would want to make sure that information is available to people.

Mr. Walden. Let me suggest they don't know that is available. They are actually being told by medical providers, at least this one case I know, that "don't worry, there is no interaction," and this is a legitimate doctor telling a patient.

This is happening in real -- I mean, I have got colleagues that have been on television proclaiming the importance of CBD in food products and drinks and consuming it. That is fine. That is up to them, but I do not think -- and if people want to use it, that is their business. I got it. But I just want people to have the facts and the data.

So I think what we are trying to do here is figure out what are the impediments to getting that data, and what does it take to get the agencies to a point where you are leading, not way trailing? Because the States are way ahead of where we are federally. We have got legacy rules we are trying to figure out here. Doctor?

Dr. Throckmorton. And we have been fortunate to work with the States. So you are right; the States are further ahead in some ways because they have had to be. You have had to face the use of these products in your own jurisdictions. The States have been very interested in understanding these same things. The State public health officials get that we need to understand the safe uses of cannabidiol and then make it -- educate the prescribers, educate the choices that they are making very quickly.

Unfortunately, historically, marijuana was used for its THC content.

Mr. Walden. Sure.

Dr. Throckmorton. And it has only been recently that the cultivars containing large amounts of CBD have sort of come to the floor.

The State data collection has been, historically, largely focused in that other direction.

Mr. Walden. Yeah.

Dr. Throckmorton. And so they are changing course. It is just a matter of time.

Mr. Walden. Oh, yeah. No, I understand all that. If you could get me that list, if it is readily available.

Dr. Throckmorton. Absolutely.

Mr. Walden. Is it on the FDA website? Is it -- I mean --

Dr. Throckmorton. Absolutely.

Mr. Walden. Please do. Thank you.

And thanks for your indulgence, Madam Chair, and I yield back.

Ms. Eshoo. The gentleman yields back, and I think it is terrific that we have our next member, another gentleman from Oregon, so we have got a set of bookends here, Mr. Schrader, for his 5 minutes of questions.

Mr. Schrader. Thank you very much, Madam Chair.

I think it is great that, if we have -- all three witnesses agree we need medical research into the effects of the hemp or CBD or marijuana products. The sad part is we are not testing the right stuff.

I fail to understand, with all due respect, Mr. Strait, why we have one bloody

facility in an artificial environment, Mississippi, that is the really the sole nexus for research and analysis of CBD products.

Could you explain why that is?

Mr. Strait. So that location is actually more -- probably better asked of Dr. Volkow because it is pursuant to a contract administered by the National Institutes of Health. DEA is mainly interested in --

Mr. Schrader. Well, I guess if I may interrupt briefly here. It is limited time. You know, it seems to me we ought to be testing the products that are on the marketplace. That is where FDA, NIDA, you are most concerned. What is the consumer -- what is the American citizen actually being exposed to or hopefully benefiting from?

Mr. Strait. Yeah.

Mr. Schrader. The idea that we are using a specific facility that does not mirror what people are actually ingesting, smoking, whatever, is ludicrous. I am worried -- you are talking about more regulations coming out. We should be making less regulations and just say there is a legally approved facility in the State of Oregon, Colorado, District of Columbia. Those are things that people are actually going to be exposed to. We approve that research for that facility. Why are you not doing that?

Mr. Strait. And, Dr. Schrader, I cannot agree more in what you are saying, and that is certainly a conversation we have been having internally. The challenge, of course, is that the underlying principles of the CSA, the Controlled Substances Act, require that people who are going to lawfully possess, distribute, conduct research with schedule I controlled substances have to procure those substances from a valid source,

and that valid source is -- you know, at this point, it is another DEA-registered facility.

Mr. Schrader. Well, valid source in the eyes of the Federal Government --

Mr. Strait. Correct.

Mr. Schrader. -- not just you, perhaps, is this -- you know, is whatever. I am arguing respectfully that the committee should be looking at legislation, if need be. I do not think we need legislation. It just should be something FDA, NIDA, and DEA can say, "Hey, you know, there is all these approved facilities out there in these States. We are not adjudicating whether or not it is a controlled substance or not. They are here. They are being used for certain products that consumers are being exposed to. We need to investigate them and make sure that they are not affecting adolescents adversely, fetal development, male fertility, whatever the deal is," and get it out there. There is so many benefits.

My colleague from Oregon talked about benefits. I have got a farmer in the State of Oregon, a farm that is very conservative by nature. They had a father that was ailing, facing terminal illness. Pain relief was not getting done. They turned to CBDs. Their father was able to communicate for the first time in weeks with them, and he had a productive quality of life to the very end.

These are the products we need to be starting to get engaged in, or I just do not see that happening.

Talk to me a little bit, Mr. Strait, about approvals by both Tilray and Biopharmaceutical Research. Talk to me a little -- these are not from Mississippi. How come they get through and not other products?

Mr. Strait. I am not familiar with those two companies in particular, but there

are instances where pharmaceutical companies can be manufacturing through synthetic means some of these substances and then making those substances available for research purposes.

Mr. Schrader. Okay. It concerns me that you are not aware of those being approved by DEA. I guess I would like to get more information after the hearing on that.

And there is an apparent tendency to approve more foreign applications than domestic applications that get held in limbo for years. We have got, what, 12 or 15 different applications that are pending and going through this long, exhaustive regulatory process. That seems incongruent with the fact that these products are out there now. We need the research now. Everyone on the panel has agreed to the research. Let's just get it done. What is the holdup?

Mr. Strait. Congressman Schrader, we have the same frustration you do.

Mr. Schrader. Very good. Well, Madam Chair, I will yield back. I just appreciate everyone's interest, and we just need to move forward and test the products that people are being exposed to.

Ms. Eshoo. I agree 100 percent. I do not understand -- I still do not understand why the agencies, the three that are before us, can't get this done, but we will keep questioning, and the next one to question is the gentleman from Indiana, Dr. Bucshon.

Mr. Bucshon. Thank you very much, Madam Chairwoman.

This hearing is really very important. I was a physician before I was in Congress. I am still a physician; I just do not practice. And, as a doctor, data is critical. You practice medicine based on facts and data. So I really appreciate this hearing.

And I do support the legitimate medicinal use for THC, but our knowledge on this

subject actually is very limited and needs more research.

Dr. Volkow, I am going to go along the lines of the developing brain. Up to what age would you say the brain continues to develop?

Dr. Volkow. The fastest growth is during the first two decades and then until probably age 24 and then it slows down, but it never really goes away.

Mr. Bucshon. Right. So I think people, a lot of times, have a misunderstanding. When we are talking about the developing brain, people think it is little children, but, actually, it really goes up substantially until your mid-20s approximately?

Dr. Volkow. Right.

Mr. Bucshon. Great. Thanks. And you presented this, but we all know THC can have damaging effects on the developing brain, as you mentioned. In fact, the studies you conducted, the National Institute of Drug Abuse, show a direct correlation between persistent cannabis use and cognitive decline from one's childhood to midlife.

Epidemiologic studies have further found that youth who regularly use cannabis have lower academic achievements and a higher risk of dropping out of school. Frequent cannabis use during adolescence is associated with changes in the area of the brain involved in attention, memory, emotions, and motivation. And, Madam Chairwoman, I have a slide deck that Dr. Volkow presented to the Doctors Caucus a number of years ago, and I would like to introduce that into the record.

Ms. Eshoo. So ordered.

Mr. Bucshon. It outlines some of the things that you have been talking about today.

Additionally -- and this is where I am going to focus my question on. NIDA

recently put out research describing record levels of teens vaping marijuana, vaping THC products. Can you elaborate on that data?

Dr. Volkow. Yes. We have seen overall vaping has increased among teenagers, and, in the United States, 40 percent of the teenagers have vaped in their lives, and despite the fact that this is a new technology. Three years ago, most of the vaping was related to flavors. Two years ago, most of the vaping was related to nicotine. And what we saw this last December was there was a significant -- a doubling of the number of teenagers vaping for THC.

Now, considering that vaping THC delivers very high content of THC, this is worrisome. It is also worrisome because, as you know, the injuries from -- the acute injuries from vaping are predominantly associated with vaping of THC.

Mr. Bucshon. Right.

Dr. Volkow. So this is concerning, and we are seeing also significant increases from in the past 2 years up on the regular use of cannabis, which we think are driven in part by the vaping.

So it is affecting the pattern of use of marijuana among teenagers.

Mr. Bucshon. Okay. So, then, along those lines, are researchers able to conduct Federal research on the THC and e-liquids and THC vape liquids sold at vape shops in States that have legalized marijuana for recreational use, and, if they can't, why not?

Dr. Volkow. The researchers are afraid that, if they use Federal funds to purchase products that are illicit by buying them in dispensaries, they will lose their funding. So, as a result of that, overall, research is not done by investigators that are

being funded through the NIH, which is a Federal agency.

Mr. Bucshon. And, based on what you just talked about, about the rapid increase in vaping amongst teenagers, would you say that we need to do something about that?

Dr. Volkow. I would completely agree. We need to be able to move rapidly into the field and understand the products that patients or citizens are being exposed to.

Mr. Bucshon. I think that just confirms what all of us have been saying throughout this hearing.

And I am also concerned that law enforcement is not equipped to address cannabis-impaired driving. I did have also a case in my district where a young lady was sledding and was hit by a car, and the person that hit her was not impaired by alcohol or opioids, failed a field sobriety test, and subsequently we find out it is marijuana, but there is no legal standard. Unlike alcohol, obviously, there is no reliable test.

For that reason, I introduced H.R. 3890, the Combating Impaired Driving Act, in 2019, to direct the Department of Transportation to provide funding for grants and pilot programs to address impaired driving.

Dr. Volkow, according to your organization, marijuana is the illicit drug most frequently found in the blood of drivers who have been involved in vehicle crashes, including fatal ones, and in your testimony, you describe that the risk of being involved in a crash significantly increases after cannabis uses.

Can you describe the difficulties law enforcement may have in testing for marijuana? Do you agree we need more funding to provide advanced measuring testing for cannabis- impaired driving?

Dr. Volkow. Yeah, and, as I mentioned before, the problem that we have is the content in alcohol, you know a certain level is associated with motor impairment, but, in marijuana, it has a very long half-life, and it accumulates in the fatty tissues in our body. So, if you are a regular marijuana user, you may get high, and, 3 hours later, you still have very high levels even though you are not intoxicated.

On the other hand, if you are a naive user and you consume marijuana, have very low levels, you may be intoxicated. So there is not a one-to-one correspondence.

Mr. Bucshon. Right.

Dr. Volkow. So we are trying to actually incentivize researchers to come up with innovative ways of determining whether someone is intoxicated or not, and we are funding researchers in that way.

Mr. Bucshon. My time has expired, but, Madam Chairwoman, I think that again outlines why we need more research. I yield back.

Ms. Eshoo. I think, if there is anything to come out of this hearing is that the research is absolutely essential -- absolutely essential. So much of this is two and two equals five. Well, it does not.

So the gentleman from Massachusetts, Mr. Kennedy, is recognized for 5 minutes.

And I want to say how much I appreciate his -- the input that he gave the chair, and we will, as he said earlier, have a followup hearing with other stakeholders. Important to start out with our three government agencies, but I think that our subcommittee will benefit from the additional testimony of others. So he is recognized for his 5 minutes of questions.

Mr. Kennedy. Thank you, Madam Chair. Thanks for holding this hearing, and

thanks for adding the weight of the committee behind this conversation. Thank you to our witnesses for being here, for your service, for your work, and for your diligence.

As some of you know, I was initially hesitant to support legalization. My concerns stemmed from my work with the mental health community where many advocates have told me that they are worried about the impact of increased access to another controlled substance on the patients that they serve. But as States have moved forward with legalization, including my own, I tried to understand how we could protect for the public health concerns. I talked to experts. I talked to doctors. I talked to families. I talked to advocates. I talked to regulators. I have talked to some of you.

And that is where I started to get frustrated; frustrated that, as a Federal legislator, my hands were tied because our Federal policies still rested on Richard Nixon's decision to put marijuana in the same category as heroin; frustrated, as constituents told me that marijuana was the only thing that eased their pain. We have heard some of those stories today.

But when I asked regulators and subject agencies how we could ensure that this drug, like all drugs, was subject to the highest patient safety standards, I was told that we could not until we had more research. So I asked, how do we get more research?

Remove marijuana from schedule I, I was told.

How do we do that?

Well, we need more research.

The Federal Government has hid behind that catch-22 for a long, long time, and, meanwhile, millions of Americans, mostly Black and Brown, have been locked up for nonviolent drug offenses.

Meanwhile, desperate parents are forced to turn to a black market with no concern for patient safety to get their children the relief that they need. Meanwhile, our cities and States are trying, at times stumbling, to put in place a thoughtful and thorough regulatory framework with zero support from Federal partners. And, meanwhile, a brandnew corporate industry is rising up, rife with predictable economic injustices that spring up whenever government fails to regulate.

Prohibition has clearly failed, and America is not waiting for its government anymore. That is why I decided to co-sponsor Congressman Nadler's MORE Act, which would finally deschedule, not reschedule, cannabis. It would expand critical research, and the reason I think this bill is superior to the policy on the table today, it makes an intentional and aggressive commitment to restorative justice in communities of color.

But, to the witnesses today, I understand and appreciate the deliberative detailed approached that you have outlined. I commend and I share your commitment to public health and safety. Clearly, that is why you are here. But I think it is clear that we are also out of time. States just are not waiting anymore. Incremental adjustments and the long path and a little more research are not enough. If the Federal Government wants to be active and honest and a smart stakeholder in marijuana policy, we have to break free from that catch-22.

So, in your testimony, you each pointed to the restrictions imposed by research because marijuana is a schedule I drug.

Dr. Throckmorton and Dr. Volkow, you have already indicated, and I just wanted to make sure I am clear, in your opinion, would those barriers be eased if marijuana was descheduled. Dr. Volkow?

Dr. Volkow. What was the question specifically?

Mr. Kennedy. Would those restrictions on research be eased if marijuana was descheduled?

Dr. Volkow. The scheduling of marijuana -- and that is why I want to comment on it because that is not specifically what we do. We have to recognize that marijuana has harmful effects. We know that, and the harmful effects can actually be very consequential, and, at the same time, it is a drug that is addictive.

So my perspective is -- that is why I keep on saying it -- what is the policy that will protect the public of the adverse effects of marijuana while at the same time accelerate our ability to take advantage of the potentially beneficial effects that the plant has? That is my perspective.

Whether it is descheduled or not, that is not what our agency does.

Mr. Kennedy. Understood. And so let me just be clear about the question. Would the barriers to research be eased if marijuana was descheduled?

Dr. Volkow. If it were descheduled, it would be easier to do research; we know that.

Mr. Kennedy. Yes. Dr. Throckmorton as well?

Dr. Throckmorton. I agree.

Mr. Kennedy. And, additionally, in your opinion, would your office or agency be unable to continue its regulatory role regarding marijuana if it were to be descheduled, Dr. Volkow?

Dr. Volkow. Well, we do not regulate marijuana. We do research. So our agency is not involved. That would be transparent to us.

Mr. Kennedy. So it would -- your agency would not be harmed in any way by continuing to conduct its regulatory authority?

Dr. Volkow. It will -- I mean, it is -- by descheduling a drug, it is not -- it is going to accelerate the ability to do research, but at the same time, it may have unintended negative consequences in that more people may be afflicted. So that is, again, why we bring the science, and the policy decisions of what is the optimal way of moving forward takes other factors into consideration, like the ones that the FDA has described.

Mr. Kennedy. And, Doctor, again, just to clarify, I understand the balance, and I appreciate that balance. I think that is what we are all trying to strike today.

My question was, does the role of your agency change if marijuana is descheduled?

Dr. Volkow. No.

Mr. Kennedy. Yes. Dr. Throckmorton?

Dr. Throckmorton. Well, it would matter how it happened obviously. It is, in essence, another system on a subset of drugs under development. So drugs containing compounds for marijuana potentially are used -- go through the Controlled Substances Act, as well as the Food, Drug, and Cosmetic Act. To the extent that that step was removed and the authorities of the Food, Drug, and Cosmetic Act were maintained, it would not have an impact.

Mr. Kennedy. Mr. Strait, I assume that the answer for you would be, yes, it would change from DEA?

Mr. Strait. Yes.

Mr. Kennedy. Yes.

Mr. Strait. Since our obligation is to enforce the Controlled Substances Act, yes.

Mr. Kennedy. Understood.

I yield back. Thank you.

Ms. Eshoo. Gentleman yields back.

Pleasure to recognize the gentleman from Florida, Mr. Bilirakis, for his 5 minutes of questions.

Mr. Bilirakis. Thank you, Madam Chair.

And I really thank the witnesses for testifying today. It has been very informative. Unfortunately, I was at Telecommunications for a while, but I am back now.

Dr. Volkow, do you think that the process for conducting research on schedule I substances coupled with the limitation on the supply of research-grade cannabis have discouraged some researchers from investigating the compound?

Dr. Volkow. The answer is yes, and it has slowed it down, yes.

Mr. Bilirakis. Okay. Let's see. I have a couple of questions here that I want to go over.

RPTR DEAN

EDTR ZAMORA

[12:00 p.m.]

Mr. Bilirakis. Mr. Strait, would you agree that scientists studying cannabis and its effects, either bad or good, is it a fundamentally different question than legalizing, decriminalizing, or even discussing medical or recreational cannabis?

Mr. Strait. Absolutely. We want DEA just like our colleagues at HHS want to be tethered to science as it pertains to research with marijuana

Mr. Bilirakis. Very good.

Next question is for Mr. Throckmorton -- Dr. Throckmorton, excuse me. Are products available in State-regulated markets like edibles, concentrates, oils, wax, tropicals, for example, et cetera? I mean, those particular products, are they commonly available to clinical investigators through Federal sources? And if not, how might that pose a risk to the public health?

Dr. Throckmorton. So I wouldn't be able to comment on their availability to the nondrug centers because that isn't part of what I regulate. I focus on the drug side.

On the drug side, with the passage of the farm bill, hemp-derived compounds are now available for research. And we are eager to support that any way that we possibly can. We think that is an exciting new avenue to get some of the questions we really desperately need answered.

Mr. Bilirakis. Doctor, one more question. With the recent spate of lung illnesses related to illicit THC vaping products, what were some of the key takeaway lessons learned regarding the Federal state of oversight and research into current

products and consumption methods?

Dr. Volkow. Sorry. I thought you were asking --

Mr. Bilirakis. Yeah. No, this is for --

Dr. Volkow. You are bringing up an example about why --

Mr. Bilirakis. And I would like --

Dr. Volkow. We need so much more knowledge. We did not know about hyperemesis until 2006. And as a result of that, we didn't know how to diagnose it. Now we are seeing it in the medical emergency rooms, and it is associated with high content THC and chronic use. But we are just assuming based on what the patients are telling us, since we are unable to actually sample from the sources that they are consuming. And that is just one example about why we need to understand the consequences of consumption of different products of marijuana, because we are seeing adverse effects.

And so if we want to proclaim, well, there are medical qualities to it and we need to have evidence to show that it is the case, we also need to understand how to optimally dose it and what product characteristics are safe, and we don't have that data.

Mr. Bilirakis. Thank you.

Dr. Throckmorton?

Dr. Throckmorton. I just want to say Dr. Volkow is raising an incredibly important point. Patterns of use, how these substances are being used are changing year to year. The new use of cannabidiol vaping, things like that. Just the ways these are being consumed, the doses they are being consumed, the populations, the perceived benefits are all changing. We as a Federal architecture need to find some way to track

that, to understand it, to identify new risks as they emerge quickly, ideally find new ways to assess efficacy and things like it that are identified. But it is a central challenge, I think, for all of us working in this area.

Mr. Bilirakis. Thank you very much. And I agree.

I am going to yield the rest of my time to Mr. Griffith, please.

Mr. Griffith. Thank you very much.

Mr. Strait, several studies found that research-grade marijuana from the University of Mississippi is genetically distinct from the marijuana coming from State dispensaries, such as we heard of earlier in the testimony from Oregon. Four years ago, DEA announced that it would accept applications for the manufacture of research-grade marijuana in order to increase the diversity of products for scientists to study. Thus far, the agency has not acted. And as we heard earlier today, DEA intends to propose new regulations that will govern the marijuana growers program for scientific and medical research.

Can we have your assurance publicly and on the record that the DEA will work expeditiously to review legitimate applications to produce marijuana for federally approved scientific research? And will current applicants be permitted to amend their applications to conform to the new rules so they are not caught in a catch-22 or a vortex of time?

Mr. Strait. On your first comment, yes, we definitely will move expeditiously. We are moving expeditiously, although I know it is not acceptable for anyone here in public office. So we appreciate your patience on that.

And your second question?

Mr. Griffith. The second question was, if you already have an application pending and the rules change, instead of having to start back at go, you know, proceed directly to go and do not collect your $200, can they just amend so they can move forward? And a yes or no, because my time is up.

Mr. Strait. On that point, when we announced the notices of application in August of 2019, some of those applicants had been -- had applied 2 years ago. We gave them the opportunity then to get a full refund. And, of course, we would do that.

Ms. Eshoo. The gentleman's time has expired.

The chair now recognizes the gentlewoman from Michigan, Ms. Dingell, for her 5 minutes of questions.

Mrs. Dingell. Thank you, Madam Chair.

I want to associate my comments today with everybody at this podium. And I think there is bipartisan frustration on this issue. I think my colleague, Mr. Kennedy, probably summarized where I am very deeply. I -- Michigan is one of the States that is now one of the legal States that this is being traded in. I was -- I will be very blunt, I did not support it when it was on the ballot. I come from a family that has seen what drug addiction does to people. But like my colleague, Mr. Griffith, Mr. Schrader, my husband, who many know in this room, suffered from great pain, and many people said that marijuana would be the only thing. Though would he try it, and he would not try it -- can you see John Dingell smoking marijuana -- because it was not legal, you didn't know the side effects, and it might have given him relief in the end.

But I was the keynote speaker at Hash Bash this past year. Yes, you should laugh. My staff told me -- I don't even know how it got scheduled, if you want to know

the truth. I am still trying to figure that out.

Ms. Eshoo. It wasn't schedule I.

Mrs. Dingell. But I got up and said, I have never smoked marijuana, and don't think I ever will smoke marijuana, but I was getting a lot of indirect smoke that day. But I made the point -- I talked to a lot of the scientists, and there were very clearly three things that need to happen. And I am as committed as anybody at this -- we need to get more research on this issue. And we all keep asking you the same questions because we are not -- we don't understand what the answers are or why if we all agree we need more research and we need it for medicinal purposes, we need it for automobile. I am working on impaired driving legislation right now too. Every one of us has got a story from our districts somehow, some way that there is a problem. And we are in the biggest catch-22 that you can ever see or imagine. So you have got to help us figure out how we are going it to get out of this catch-22.

It is one of the reasons I introduced, with my colleague, Representative Blumenauer, the Medical Marijuana Research Act, because just in case you can't tell, I am pretty passionate about it now. Even though it is legal for recreational use in 11 States, Michigan being one, we have just started it, it has gone recreational marijuana the last couple of weeks. The National Academy of Sciences has done a study, which I have right here, that found that the research of the health effects of cannabis and cannabidiol has been limited in the United States. And this lack of knowledge poses a public health risk.

I would like to make sure it is submitted for the record, Madam Chair.

Ms. Eshoo. So ordered.

[The information follows:]

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

******** COMMITTEE INSERT ********

Mrs. Dingell. So having agreed with all of my colleagues here, having the three of you already establish we have got problems, can we go back and look at some of these questions that everybody keeps asking?

Dr. Volkow, you talked about the administrative burden that current Federal rules mandate. We keep asking you why it takes months to navigate, but we are looking for those details. How would simplifying Federal guidance surrounding schedule I registration improve NIDA's ability to conduct this research? What do we need to do? And why is it only one kind of marijuana that is okay at the University of Mississippi? Can you give us more detail and highlight, you know, why Federal research is done only a single source of cannabis? How does this reliance on a single source limit our understanding of the health impacts?

Dr. Volkow. We agree, and we are also, of course, frustrated by the challenges of advancing the science and at the same time recognizing that we have a problem. I wish marijuana had no untoward effect; it would be quite remarkable. But unfortunately, high content THC can have, as I mentioned, pretty adverse effects.

Now, there is, as the national academy mentioned, there is evidence, though it is not solid enough for FDA approval, that there are some benefits clinically for some effects of the active ingredients of marijuana. So how could it -- what is one of the things that we have been proposing? And again, we are not legislators. And it is the FDA and the DEA that regulate. But what we wanted to achieve is can there be a subcategory for schedule I that allows researchers to do research with the proper regulations but expedited. That is one of the things that we have been working with our colleagues on.

Mrs. Dingell. How do we keep you from working and getting it done?

Dr. Volkow. We need to actually solve the problem, and I -- and I agree. And I also think that we need to figure out a way to be able to also take advantage of some of the new producers of different cannabis plants in order to evaluate the diversity of problems that are out there, as opposed to limiting us with a Mississippi farm. These are regulations. This is not us wanting to say territorially we are the only place that can provide it. It is impeding research and knowledge.

Mrs. Dingell. I am unfortunately out of time, but I could have asked a lot more questions.

Thank you, Madam Chair.

Ms. Eshoo. The gentlewoman yields back.

A pleasure to recognize the gentlewoman from Indiana, Ms. Brooks, for her 5 minutes of questions.

Mrs. Brooks. Thank you, Madam Chairwoman.

And I apologize to the panel, there is another hearing going on, so I have been going back and forth a bit, but your testimony is critically important to us. And I think from my colleague across the aisle there has been frustration, because I think we are trying, as Members of Congress, to figure out what specifically we need to be doing to help to accelerate medical research. I think that is the top priority of this committee, I believe, and the purpose in having this hearing.

And so -- and with that, you know, hearing testimony and knowing friends who have suffered from tremendous pain, particularly from cancer, I want to focus a little bit on pain therapy. We have talked a little bit about it and, Dr. Volkow, thank -- and thank

all of you for your work. I have very mixed feelings about the issues around marijuana, having long ago been a criminal defense attorney and seeing so many of my clients have substance abuse problems and many of them starting at a young age with marijuana, and then later as a former United States attorney working with the DEA and involved in, you know, disrupting trafficking organizations, drug trafficking organizations that ruined neighborhoods and communities and caused a lot of significant problems. I -- but yet I also have a number of friends and people I know who have suffered tremendously, whether it is with cancer or other things, where marijuana has helped them with their pain, or those at end of life, as we have heard those stories. So we are really conflicted here.

We as a Congress, I think, have a lot of issues around we are trying to figure out how to break through and move the ball forward because it is taking years, and we just don't have the answers and we are so behind.

So what barriers, Dr. Volkow, remain at NIH to study the new therapies around pain and where cannabis can particularly help with pain? And even addiction therapies we are hearing. Can you share with us what are the barriers around the research specifically relative to pain?

Dr. Volkow. We are prioritizing as it relates to cannabis research, its potential value for the treatment of pain, for addiction, and also for HIV, and as an anti-inflammatory drug. So researchers are being funded both for THC as well as for CBD. We would like to have more investigators involved, and that is where the whole discussion has been going back and forth. Many investigators that don't have the infrastructure support that is necessary shy away because they feel it is too much of an

obstacle to try to go through a schedule I. But we are funding research.

Mrs. Brooks. Dr. Volkow, would these be private sector investigators or these university investigators or hos- -- what type of investigators do we -- what kind of investigators do we need?

Dr. Volkow. We want both of them. And one of the areas that we are very interested is actually pairing academic investigators with industry so that the products that are being developed then can go into the market. So we fund different mechanisms to try to facilitate those interactions. So you don't want to limit it just to the academicians. You want to also facilitate research by the private sectors.

Mrs. Brooks. Are there any significant pieces of research that have been completed? I know you talked about 11 year -- or studies over long periods of time of adolescents and of children that you are following, and I appreciate. What are the numbers of years that you are typically looking for relative to research?

Dr. Volkow. Well, it depends on what you are aiming for. For example, to try to understand how marijuana affects the developing brain, you need to follow it up doing brain development. So that will take 10, 15 years. If you are trying to determine, for example, to what extent THC can have analgesic effects for, say, in a patient suffering from low back pain, I am just -- that may be a study that you can complete in 3 or 4 years. So it depends very much what the aim is, what the study is going to be doing.

Mrs. Brooks. And approximately how many studies are we funding now, you know, focused specifically on pain management?

Dr. Volkow. On pain management we are funding $39 million for therapeutics of cannabis. And of them, I would sort of say probably 35 to 40 percent may be pain, but I

have to check the figures, but I just guesstimate.

Mrs. Brooks. Off the top of your head, are there any significant negative results that have shown in your current research?

Dr. Volkow. Too early to say, from the ones that are ongoing.

Mrs. Brooks. Thank you so much. Thank you all for your work.

I yield back.

Ms. Eshoo. The gentlewoman yields back.

Pleasure to recognize the gentlewoman from Illinois, Ms. Kelly, for her 5 minutes of questions.

Ms. Kelly. Thank you, Madam Chair. And thank you to the witnesses for being here today.

My State of Illinois was the 11th State to approve adult use cannabis. But with that said, I am interested in hearing about the research that exists about cannabis, particularly for vulnerable populations. I am the chair of the Congressional Black Caucus Health Brain Trust and have worked with my colleagues to create legislative and policy solutions to reduce health disparity and promote good health in all communities.

So, Dr. Volkow, your testimony discusses the adverse health effects of cannabis when it comes to prenatal and adolescent development. What is the state of the science in this area? And are there studies that focus on minority populations?

Dr. Volkow. Yes. And based on the science, we do know that the use of THC during pregnancy is associated with significantly negative outcomes for the newborn and the mother. There are cannabinoid receptors in the placenta, and the cannabinoid receptors emerge very early on in fetal development and they guide, tell the brain

actually how neurons in the brain are moving and connecting. So it is something that needs to be taken with caution.

We know that in adolescents, as has been mentioned, in all, every single story has shown overall independently that it leads to worse educational outcomes. And what we are now using is more sophisticated technology, larger samples, to understand how factors differs between one individual and the other. For example, through the ABCD study, we have shown that adverse social environments have a very negative effect in amplifying the consequences of insults into the brain. So if you come from a deprived environment, your brain is actually going to have a much slower development than if you are in an environment that enriches your experience. And in those circumstances, drugs have a greater negative effect.

So we -- I mean, these are stories that are ongoing, but it is clear drug and marijuana is not a good thing for the developing brain.

Ms. Kelly. Well, I am glad to hear that you have a more diverse sample than it sounds like you did from the beginning. You said you are bringing more diversity.

Dr. Volkow. Absolutely. We need to understand diversity. Diversity in terms of ethnic background, diversity in terms of economic opportunities, because those are influencing multiple factors on the development of a child.

Ms. Kelly. And, Dr. Throckmorton, in your testimony, you mention that the FDA is actively working to learn more about the safety of CBD and CBD products. Among the list is work to understand the effects of CBD of special populations, such as the elderly, children, adolescents, and pregnant and lactating women. Can you elaborate more on this?

Dr. Throckmorton. The best data we have available comes from the control trials that were used to approve Epidiolex, which is the product for procedure disorders. It was conducted largely in young children. And so we simply don't have any extensive randomized controlled trials in those populations. We all sort of acknowledge they are terribly important.

When we approved Epidiolex, we also posted on the web what we do know about the demographics of response to the drug. So you can go on to what we call our drug trial snapshot page, and it will show you the safety and effectiveness of Epidiolex broken down by sex, gender, age, ethnicity. And you can look and see for yourself what we know about Epidiolex, but we need to have a lot more information to expand that to understand the impact on the elderly, for instance, and on pregnant and lactating women, because they just simply weren't in the trials and so we haven't had that opportunity yet. But it is something we recognize, and we are working to try to fill as quickly as we can.

Ms. Kelly. Assuming you are working to get more diversity in the trials.

Dr. Throckmorton. Absolutely, yes.

Ms. Kelly. I, like my colleague, I go back and forth about how I feel about recreational marijuana. I don't know if that is because I went to college in the 1970s, if that is the reason why. But I just read in the paper, you know, Chicago allowed it starting January 1. And the paper talked about how the emergency room visits have gone up because of this. And even places that treat dogs, because people are, I guess, careless with the edibles. I don't know. And they found more dogs are getting sick too. So it just seems like we need to educate the public more too about the effects.

And I don't know if it is just an early overexuberance because it just became legal or will we continue to see increased emergency room visits.

Dr. Volkow. And I am just going to comment on that because, actually, one of the aspects that have been coming back and back, marijuana is not a safe drug. It has negative effects. And among the ones that we are more concerned is that is what affects young people. And one of the ones of greatest concern has been the association of the use of marijuana with psychosis. And stories across the world, for example, as a psychiatrist, I was trained that the prevalence of schizophrenia is the same across the world, it is 1 percent. Well, it so happens that that is not the case. And in some places, it is six to eightfold higher. And in those places, it is associated with the consumption of very high content THC.

So in the Netherlands, for example, which has the highest rate of schizophrenia linked with the consumption of THC, you can have plants that have 38 percent THC. And this is not just explained by having the genetic risks. There is something about high-content THC that is triggering psychosis, and we need to recognize it.

Ms. Kelly. I know my name time is up. Thank you, Madam Chair.

Ms. Eshoo. The gentlewoman's time has expired.

Pleasure to recognize the gentleman from Montana, Mr. Gianforte.

Mr. Gianforte. Thank you, Madam Chair. And thank you for the panel being here today.

Understanding the full consequences of readily available marijuana on public health and individuals is imperative. We have heard that today. We should be concerned about the lack of Federal research on marijuana because, when we consider

such a drastic change, we must ensure that that policy is based on sound science. So the focus today on research is very appropriate.

In November, I joined with 16 other Members of Congress in asking Attorney General Barr to study the societal impacts of legalizing marijuana for recreational purposes. As we start to see preliminary data from States like Colorado and Oregon, it is important to fully evaluate their experiments before making Federal policy. I appreciate that Mr. Walden and Mr. Burgess have asked for a hearing on this research, and we should continue to investigate.

We should know how best to help people who need medical marijuana and how greater access to recreational marijuana will impact our communities, families, and users. However, expanding access to marijuana without the benefit and guidance of the facts and sound science is of grave concern. This is incredibly concerning because we have an addiction crisis in my home State of Montana. Methamphetamines and now opioids devastate our communities and tear up too many families.

Meth accounted for 86 percent of drugs trafficked in Montana in the past 5 years. Montana has worked hard to support people fighting addiction through drug treatment courts. These courts help people get clean and get back on their feet while staying engaged in their communities, all at a fraction of the cost of incarceration.

To consider making any schedule I drug legal and more readily available without adequate research is a misplaced priority when addiction continues to ravage our country. Instead, we should support focusing on combating addiction, building on this committee's bipartisan work and the success of the SUPPORT Act from last Congress. We need to continue to support those who face addiction and need the help the most,

rather than making marijuana easier to access when we don't know the full effects on our communities.

Dr. Volkow, ensuring access to mental health services is a top priority of mine. Unfortunately, Montana has the highest suicide rate in the country. I have introduced the National Suicide Hotline Designation Act, which makes 988 the national suicide hotline number. This important bill will protect emergency access to care for those facing a mental health crisis, especially those in rural areas who lack access to mental health professionals.

In your testimony, you state that serious mental illness and suicides are on the rise in our country. And while multiple factors very likely contribute to this rise, it is imperative to understand if exposure to cannabis in adolescents is one of them. Does current research draw a connection between marijuana use and increased risk for suicide or mental health problems?

Dr. Volkow. There have been some large epidemiological studies that have noted an increased risk for suicide among regular users of THC, but the evidence is not as extensive as associated with psychosis. And so we cannot ignore it, but we need to determine if it is reproducible and understand the extent to which it is contributing indeed to suicidality. So it is something that has been noted by large epidemiological studies.

Mr. Gianforte. Okay. And from your experience as a researcher in this area, do we fully understand the connection between marijuana and mental health and suicide?

Dr. Volkow. Marijuana, if you take high-content THC, in almost any one of us, if the content of THC is high enough, it is going to make us paranoid, extremely anxious, and

very, very afraid, if not fully psychotic. And that can explain and one could conceive why in those circumstances someone, if they feel threatened, may actually attack someone else or attack themselves.

So in some people, that results in a chronic syndrome, and that is where we don't have sufficient knowledge of understanding why is it that in most cases it is just a very short limited psychotic episode and why is it that use of marijuana in some results in long-lasting effects; that we do not know yet.

Mr. Gianforte. Okay. So just to summarize -- I appreciate your expert opinion -- it is possible that cannabis could increase suicide rates. Is that correct?

Dr. Volkow. The epidemiological data has given some evidence that it may. But I want to be cautious again. I think that one of the issues that we have been criticizing the whole field of marijuana is that people say you are exaggerating. How do you know that a person to start with was depressed and was suicidal thinking that put them at risk to take marijuana to auto-medicate? So how do you now it is really a causal as opposed to an auto-medication? That is what I want to --

Mr. Gianforte. But it brings us back to the fact we just have to do the research.

And with that, Madam Chair, I yield back.

Ms. Eshoo. The gentleman yields back.

A pleasure to recognize the gentlewoman from Delaware, Ms. Blunt Rochester, for her 5 minutes of questions.

Ms. Blunt Rochester. Thank you, Madam Chairwoman, for this important hearing. And thank you to the witnesses.

As you can tell, many of my colleagues, we are going over time on the time we

have because there are so many questions that we have. And as I thought about this, it really is a multitude of issues that we are dealing with in this one hearing, both protecting and enhancing public health, providing economic opportunities but in a just way, restorative and criminal justice as well as public safety.

I am encouraged at the inclusion of comprehensive legislation that addresses some of the social justice aspects of cannabis reform. Even a minor criminal record can lead to barriers in employment, housing, and education. It is also a significant drain on our national economy. That is why I have introduced bipartisan legislation, the Clean Slate Act, which would seal an individual's Federal record, criminal record for nonviolent or simple possession offenses involving cannabis.

As Congress continues to evaluate our Nation's approach to cannabis, let us continue to include criminal justice reform as a critical part of the conversation.

Dr. Throckmorton, as you mentioned in your testimony, the FDA has approved one cannabis derived product for medical treatment, Epidiolex, which is used to treat rare pediatric seizures. Can you walk us briefly, very briefly through how the FDA came to approve it?

Dr. Throckmorton. Happy to very shortly. So we have a process that we have laid out in a variety of different ways, including small business assistance and things that basically gives a roadmap to drug developers, beginning with conversations with us, coming in and just basically saying I want to develop a drug to do the following and this is where I think I might get my drug, my active pharmaceutical ingredient so called. We walk them through a series of meetings leading to, if successful, a drug approval of the kind that we were able to do for Epidiolex.

Ms. Blunt Rochester. So you have a roadmap that we can actually get a copy of?

Dr. Throckmorton. Absolutely.

Ms. Blunt Rochester. Okay. So we will we request a copy of that roadmap. And also, what I would like to follow up on is what you have learned through the clinical trials from that as well.

Since the 2018 farm bill, we have seen a massive expansion in commercially available CBD products, everything from CBD active wear to CBD toothpaste. Many of these products assert that they contain various wellness benefits like reduced levels of anxiety or better sleep. I want to continue on. The FDA has stated that many of these products are marketed with unsubstantiated therapeutic claims.

Doctor, could you talk about what the FDA does to -- what actions do you take for these bad actors? What are you currently doing?

Dr. Throckmorton. Sure, thank you. And we would be happy to follow up with details too there. So, fundamentally, if someone makes a claim that their product treats, diagnoses, mitigates, or prevents a disease, they are a drug. And if they are doing that without approval from the Food and Drug Administration, they are an unapproved drug, the subject to our enforcement actions. You know, they are making claims that they don't have any substantiated evidence for, we take an enforcement strategy that focuses on the high-risk things, the really egregious claims.

Ms. Blunt Rochester. So can you just give us some examples of what you did, who you targeted, what you did?

Dr. Throckmorton. So the egregious claims that we have -- recently we took an action, we sent 15 warning letters out, identifying specific products that made those kinds

of claims or in some other way violated the Food, Drug, and Cosmetics Act. We called on them to stop whatever the violation was that they were committing. Most of them had to do with labeling, and gave them steps that they needed to take in order to come back into compliance.

Ms. Blunt Rochester. Just so I am clear, the warning letter went to the person who is the bad actor.

Dr. Throckmorton. Manufacturer.

Ms. Blunt Rochester. The manufacturer. How is the public informed of that to be aware?

Dr. Throckmorton. So those letters are public. You can go on to our website and see the series of warning letters. This is actually I think the third time we have done this that we put out. And then we obviously have a follow-up plan for each of those companies to make sure that they come into compliance.

Ms. Blunt Rochester. One of the areas I didn't, when I ran through all of those intersections, I didn't run through consumer protection, and I think that is another big area. I know if I go into a store, I am not likely to then go on your website to figure out, is this dangerous for me or not. And so I think this is something else that we need to follow up, as we look at research and other issues, how to best protect the consumer.

Thank you so much, Madam Chairwoman, for this very important hearing, and I look forward to the next one. And I yield back the balance of my time.

Ms. Eshoo. And thank you for your important work as well. The gentlewoman yields back.

A pleasure to recognize the only pharmacist in the Congress, Mr. Carter of

Georgia, you are recognized.

Mr. Carter. Thank you, Madam Chair.

Mr. Strait, I am going to start with you. Dr. Burgess asked you earlier in this hearing about changing a drug from one schedule to another. And I wanted to expound upon that and ask you, you mentioned that it can be initiated a number of different ways. When was -- what initiated the change from hydrocodone from a C-III to a C-II? Do you know?

Mr. Strait. Yeah, that was a petition from a doctor.

Mr. Carter. From a doctor. Why did it take so long? The opioid epidemic started in the early 1990s, lasted -- and arguably the epitome of it was in 2006 to 2010, and yet it took you until 2014 to initiate that -- or to complete it. Excuse me.

Mr. Strait. Yeah, to complete it. So I believe that petition came in --

Mr. Carter. Why did you have to wait on a petition?

Mr. Strait. I am sorry?

Mr. Carter. Why did you have to wait on the petition?

Mr. Strait. We don't have to wait on a petition.

Mr. Carter. Then why, with the opioid epidemic being as bad as it is, did it take the DEA until 2014 to reschedule hydrocodone from a C-III to a C-II?

Mr. Strait. Well, actually, back when that petition came in, I would argue that a lot of folks in the medical community were actually concerned about access to opioids. And so a petition to reschedule marijuana, despite its potential for abuse and its actual abuse, kind of ran contrary to some of those other broader concerns by the medical community.

Mr. Carter. I -- okay. Dr. Volkow, you and I have worked together for many years now, and I have great admiration for your work and great respect. You were asked earlier, I believe it was from Representative Castro, if marijuana is a gateway drug. And I have to be quite honest with you, you gave a very scientific response, something about sensitivity.

Is marijuana a gateway drug, in your opinion? And I ask you that as a psychiatrist. You understand we have had, in this subcommittee here, we have had panels of parents, of loved ones who have lost loved ones to opioid addiction, who have all said that it started with experimenting with marijuana.

Dr. Volkow. Indeed, they all -- most of the epidemiological studies show that the first drug of initiation is marijuana. And because of that, that is another big argument for saying why it is a gateway drug. The counter argument and why it is not so simple is that it states that if you have the vulnerability for drug taking, it is much more likely as you are a teenager that you will encounter marijuana, then heroin. And, ergo, you start with marijuana and then you go into other drugs.

That is why it is not such a simple and that is why I basically say, overall, I would state, based on stories, not just in epidemiology or in laboratory animals, that if you expose them early on, they are more sensitive to other drugs that it --

Mr. Carter. Wouldn't you agree that the psychological effects of experimenting with marijuana lead to experimenting with other drugs, which leads to more addiction? No question about it. That has been proven time and time again.

Dr. Volkow. But the same thing pertains to nicotine. So nicotine is another one --

Mr. Carter. And what have we done with nicotine? We put limitations on it.

And I want to cut to the chase. If you want to see time fly, wait until you get up here for 5 minutes, but I want to cut to the chase. Everyone up here has expressed the same concern: We need more research. Tell us what we need to do.

Mr. Strait, what do you need? Do you need a schedule I-A that is not going to have anything in it except for marijuana? That is fine with me. I will create it. I will legislate that. But tell me what it is going to take. I don't -- please.

Mr. Strait. Two things. We have seen a 150 percent increase in the number of schedule I marijuana -- manufacture -- researchers in the United States in the last 5 years. We are making progress. We want to do more, for sure.

What do we need in terms of improving access to research? I feel as if this interagency group of folks here have worked collaboratively on a proposal that would actually do just that.

Mr. Carter. And is that the proposal you mentioned earlier about Fentanyls?

Mr. Strait. Correct. Absolutely. Yes. It is within the context of fentanyl --

Mr. Carter. Can you make sure we get a copy of that? Because I want to see it, because we invite your input. We want to do the right thing.

You know, I saw an article just here recently that said that there is actually the -- the use of new research found opioids were prescribed less often in States where marijuana had been legalized for medicinal or recreational use. You know, as a practicing pharmacist for many years, I have always said that the only thing worse for me than filling a prescription for someone who doesn't need it is not filling a prescription for someone who does need it.

If marijuana truly does have medicinal benefit, I want to use it. I am adamantly opposed to the recreational use of it. I think it is a gateway drug, and it should not be used recreationally. But if there are benefits to it, I want it to be used. All we want here, everyone has expressed the same thing throughout this whole hearing. Tell us how we can get this research done. Tell us how we can find out.

It is the epitome of ineptitude that the Federal Government has this scheduled as a schedule I drug and 11 States have approved it recreationally. Embarrassing.

Thank you, and I yield back.

Ms. Eshoo. So there.

Okay. The gentleman from California is recognized, Mr. Cardenas, for his 5 minutes of questioning.

Mr. Cardenas. Thank you very much, Chairwoman Eshoo and also Ranking Member Burgess, for having this important hearing in this committee, in this committee where it belongs, the Health Subcommittee of the Energy and Commerce Committee.

Too often we either talk about cannabis as either a criminal justice issue or a medical issue. The reality is that we cannot pull them apart. Research has shown that for youth, in particular, incarceration is tied to poor physical and mental health outcomes later on in life. Compared to those not incarcerated, children and adolescents in the system for more than a year were three times more likely to have functional limitations, over four times more likely to have symptoms of depression, and over two times more likely to have suicidal effects into adulthood.

Now, I am not talking about the use of cannabis. I am talking about incarceration. Let me make that clear.

Nearly 75 percent of all of the people arrested for cannabis-related offenses are under the age of 30, and one in four -- one-fourth are under the age of 18. That is almost a quarter of a million teenagers arrested for these types of offenses each year in the United States of America.

Given that we know being arrested for possession, growing or selling cannabis, can lead to incarceration, and we know that incarceration has adverse health consequences, we can establish that, at a minimum, cannabis criminalization causes some negative public health consequences. So the question then turns to balancing these public health concerns. We also know that a conviction for a controlled substance can lead to difficulty with job prospects, which could lead to both unemployment and underemployment, which has potentially adverse public health consequences. Similarly, a drug conviction means a currently enrolled college student receiving Federal student loan money would have their financial assistance terminated. This can harm the future employment, earnings, and ultimately, health prospects of that youth.

Examining the public health harms created by criminalization of cannabis is the type of research that could be conducted without having to expand the research supply.

I think it is really important for us to understand that calling cannabis a gateway drug in an anecdotal fashion is unfair to the American people and it is really not the proper dialogue that policymakers and/or researchers and/or medical experts should be having. And the reason why I say that is because, if we are going to have that discussion, we should have the discussion and the question, is alcohol a gateway product or substance? Is nicotine a gateway product or substance?

So to think that cannabis is in and of itself a category I, an evildoer to all that

touch it, is something that should not be the subject of dialogue when it comes to true policymaking and also when it comes to real honest research, not anecdotal answers and questions.

What I have -- I think one of the main things that we need to understand as policymakers is that the inception of the United States Congress calling cannabis a class I drug, I would encourage everybody in this room and everybody in this country to look at the footage on the floor of the United States Congress and the nonresearched derogatory statements that were being made specifically about a certain community and how using cannabis would lead to rape and murder of women and citizens of this country. I am cleaning it up a little bit because I think it is unfortunate that we have that stain on the United States Congress. And so far, we haven't had the will to actually correct it.

The United States Congress made a mistake, and every Congress since has not had honest hearings and honest dialogue and has not allowed, truly allowed, the researchers in this great country to do the true research that needs to be done for us to properly categorize cannabis in this country. And as a result of that, we have millions of individuals in this country, as I outlined earlier, who have been subjected to incarceration and a criminal record that otherwise they would have a much more productive and better life, and that society would be much better off, including the taxpayers, if we were to actually get this right.

So hopefully we will have the opportunity to do that in future hearings of the United States Congress so we can get it right and we can get the research done and we can end this anecdotal discussion and have a real, real discussion about the facts.

With that, I yield back.

Ms. Eshoo. The gentleman yields back.

The gentleman from Illinois, Mr. Shimkus.

Mr. Shimkus. Thank you, Madam Chairman.

Ms. Eshoo. My partner in all things 911.

Mr. Shimkus. Oh, yeah, that is right.

Thank you all for being here. It is been a long day for you all. And I didn't have to sit through all of it, at least in the hearing room. So I appreciate that you have had to do that. And so I am going to try to be fairly brief.

And this one is to Dr. Volkow first. Are you familiar with the most recent article that came out of The Lancet Psychiatry about the risk of drug-induced psychosis converting to full schizophrenia?

Dr. Volkow. That is correct.

Mr. Shimkus. Can you comment on -- I mean, I have got the stats and stuff. Can you tell me -- I mean, summarize that report and maybe comment on your observations of that.

Dr. Volkow. This report is consistent with a concern that the use of marijuana, particularly high THC, can produce chronic psychosis. Overall, the statement, as I have made, is that most cases are of the use of marijuana trigger an acute psychosis that by itself will go away. What this study does is it shows that those individuals that went into an emergency department for an acute psychotic episode associated with the use of cannabis were much more likely to subsequently go into a chronic psychosis.

So this study links the use of marijuana, not just with acute psychosis, but provides evidence that it increases your risk of transitioning into a chronic psychotic episode, as is

the case of schizophrenia.

Mr. Shimkus. Okay, thank you. Let me -- because I have been -- mental illness, mental health, early use, what we call when they -- a lot of people self-medicate through drugs based upon psychosis. And I think a lot of us may have had personal experiences with family members or friends and neighbors that have kind of fallen into this trap. And I think part of it is early drug use at an early age.

Let me go to this other subject that we have been dealing with. And this will be back to you, Dr. Volkow, and to I think Mr. Strait, and it really deals with this vaping and the THC and also the vitamin E acetate issue. So the question is, first of all, is it possible for scientists with a schedule I license to conduct federally funded research on THC oil in these vaping products?

Mr. Strait. Are we talking about the stuff that is actually being consumed illegally, I presume, as opposed to --

Mr. Shimkus. Right.

Mr. Strait. -- creating a THC extract that could then somehow be tested?

Mr. Shimkus. Yeah. I think part of -- that is the direction, yes, sir.

Mr. Strait. Yeah. So as we had said earlier, the challenge, of course, with that is we certainly understand that researchers want access to that material. Under the Controlled Substances Act, researchers generally or have to obtain a controlled substance from another DEA registrant. This is something that Dr. Volkow has mentioned it. A failure to do so might impact their ability to keep their Federal funding for their program. So some of them have expressed some concerns about that.

Mr. Shimkus. And then let me just follow up. Would you agree that, with the

CDC, that the scheduling status for cannabis makes it challenging for the epidemiological testing of these vaping products?

Dr. Volkow, you are shaking your head yes. Do you want to elaborate?

Dr. Volkow. Yes. Yes, it is, because you want to, when you start to see, for example, these emergency room admissions occurring in different States or communities, you would like to be able for researchers to go in and try to understand what is it in those products that is accounting for the rise in these cases, and that is not -- currently not possible, if you want to use funding from Federal agencies like ours.

Mr. Shimkus. Great. Thank you. And I want to yield my last minute to Morgan.

Mr. Griffith. I appreciate the gentleman very much.

Earlier, Mr. Strait, we were talking about the applicants that are already in place. So 33 applicants who grow marijuana for research are out there. Y'all are changing the rules. I asked if they would be able to amend their petition. You said, well, yeah, we did this before. We refunded their money. I don't think they want their money refunded. They want to be able to not have to go back and start all over again with their application.

So can they just amend their application? Wouldn't that make sense?

Mr. Strait. Thanks for giving me the opportunity to clarify. What I meant and what I said and meant was for -- because the applications had come in prior to passage of the farm bill and that some of these applicants may have actually applied to produce things that now are no longer controlled under the CSA, we gave them the opportunity to withdraw their application for purposes of no longer needing it. Those that have

applied, they are in the queue and they will not have to reapply. We will be adjudicating every single application.

Mr. Griffith. I appreciate that. Thank you. That makes more sense than what I thought I heard. I appreciate the clarification.

Mr. Strait. You bet.

Mr. Griffith. I yield back.

Ms. Eshoo. The gentleman yields back.

The chair recognizes the gentleman from Illinois, Mr. Rush, for his 5 minutes of questions.

And we have -- we don't have very many members left, and it is my understanding that votes are going to be called shortly, so I think that we will be on time.

Mr. Rush, you are recognized.

Mr. Rush. I want to thank you, Madam Chair, for holding this hearing.

And this hearing is particularly timely and more and more States are loosening their restrictions around marijuana, including my home State of Illinois, which just legalized recreational marijuana beginning the first of January of this year. As such, I believe more than ever that it is important that we prioritize the research upon, not only the benefits, but also on the risk of marijuana.

I worry, Madam Chairman, that too little is known about when and how marijuana can be harmful, particularly after frequent and long-term use. And that said, it seems to me that many States, including mine, are stampeding to legalize both medicinal and recreational use of cannabis, particularly because there is a budgetary crisis that these States are confronting. And the revenues from increased marijuana sales and legalized

marijuana, particularly at the recreational level, is meant to help correct the budgetary issues that they are facing.

And I want to ask Dr. Volkow a question. Would you please expand on the possible health risk and implication for citizens, both on adults and adolescents of these States, which are exhibiting what I call a mob marijuana mentality and who are engaged in what I would refer to as a marijuana mania, that really exists in my State and in some of the situated States across the Nation?

Dr. Volkow. Yes. And I like you way you call it the marijuana mania, because it is actually a change in belief without the fact that there hasn't been any evidence to make us think that it is safe. And I don't want to negate the possibility that, in some instances, cannabis can have therapeutic benefits, but we cannot deny the fact it has some very untoward effects. That does not negate the possibility that we can come up with indications that can -- where marijuana can be used safely for therapeutic purposes. These things are not exclusive.

But it is clear, the evidence is clear that use of marijuana is associated with negative effects. And we are already seeing it by the significant increase in emergency department admissions that are being observed in the States that are legalizing marijuana, as well as hospital admissions. This is happening.

By changing the culture, by legalizing it, by creating a sense that it is a safe drug, more people are being exposed to it. And as a result of that, that otherwise they wouldn't have because they wouldn't want to do something illicit. The more people get exposed to it, the greater the likelihood that we are going to see adverse effects, which is what we are observing.

So the data is clear that it can have adverse effects and why -- I mean, and at the same time where we are leading as a country, which is quite amazing, is how rapidly the perception of risks disappear among the public. And we need to actually create the balance that brings evidence of really what marijuana can do, so that the individuals that want to take it know the positives and the negatives and they don't do it blindly, which is what we are observing happening.

Mr. Rush. Another area that I am really concerned about, along with this mania that exists is this empty excuse of -- or this expungement of records. It is okay, all right, but the cause of those records is being ignored.

Is there a nexus between marijuana -- the offense of marijuana, smoking marijuana or ingesting marijuana, and abhorrent social behavior which creates a law enforcement issue which, in my theory, is that led to mass incarceration? I don't know whether or not you can make the connection, but can you make that connection?

Dr. Volkow. Well, I think at the point of incarceration and incarceration of individuals with a substance use disorder, when you do the studies, it has clearly showed that not only it does not in any way benefit or protect anyone; it actually makes them much more vulnerable to relapsing and drug taking and other adverse mental consequences. So incarceration has an adverse effect on those that are suffering.

Mr. Rush. I want to thank you, Madam Chair. I yield back.

Ms. Eshoo. The gentleman's time has expired.

It is a pleasure to recognize the gentlewoman from -- so we are going to go to Ms. Barragan for her 5 minutes of questioning. And we have two members that are waiving on to the committee. And I sure hope we will be able to take your 5 minutes of

questions as well.

Ms. Barragan, you are at bat.

Ms. Barragan. Thank you.

Ms. Eshoo. Five minutes.

Ms. Barragan. Great. Thank you.

And thank you all for being here today and providing informative information. I thought it was pretty powerful, and the most powerful was to hear from Congressman Griffith and his story. It is the personal stories that are the most impactful.

When I was very young, my father had Parkinson's disease, and he had it pretty much all of my life. And I remember when I would see him in pain, I would just ask is there anything that could be done for him. I don't care if it is legal or not. And it was more of the sense of, you know, you are a child and seeing your parent suffer and you want to give them something to make that pain go away. And so I am firmly in the same boat of supporting efforts to make sure that we are providing things like marijuana for medical purposes to make sure patients are having access to what they need to help give them some comfort, especially when they are near the end of their life. There is no reason that people need to be suffering. And so his story was pretty compelling for me.

I am wondering if anybody on the panel today supports any of the bills, any of the legislation that is before us today. Does anybody want to comment on any support on any of the bills?

Dr. Volkow. We have been asked that question, and I actually was asked more specifically which one I favor, and I said I favor actually the advancing of science and the ability to do things in a way that can help us accelerate research. But specifically which

is the best bill, I think that that is more on the side of you who are actually the ones that are creating them. But my colleagues may -- I may put them on the spot.

Ms. Barragan. And I am not asking for the best bill. I am asking for, you know, these are the three bills I would support that I think would be helpful or that I think would be beneficial.

Dr. Volkow. And the one that I had -- have gone on the record for these that are basically -- and we have been working with my colleagues at the FDA and the DEA that are favored is the creation of a subcategory for schedule I substances that would allow us to do research expeditiously. And it is not just for marijuana, it is in general schedule I substances, so that researchers don't -- don't have to go through all of the obstacles and the delay process. That is what we have been -- actually one of the things that we are very specifically tried to achieve.

Ms. Barragan. Gentlemen, any --

Dr. Throckmorton. I would be happy to provide comment on any particular bill that you wanted us to help you with, obviously. I think Dr. Volkow said it very well before. The goal needs to be kept in mind. So whatever the vehicle, decontrol or other approaches that are suggested and that are included in some of those legislations, we need to think about the goals in mind. And in particular, from the FDA's perspective, the outcome needs to keep in mind the need for continued drug development and appropriate scientific study.

Mr. Strait. And from the Department of Justice side, none of these bills have actually been reviewed by the administration, so there is actually no official position in terms of any of the proposals. But as we are all talking about today and as I think we all

have kind of mutually agreed upon, the key is science and having the access to the data to support sound decisionmaking, whether that be legislative or within the executive branch absent legislation.

Ms. Barragan. Right. So I want to shift for a moment on the issue of sickle cell and the impact it has had on African Americans. I think in some States they have a list of medical marijuana uses, and I have talked to patients -- I have seen what sickle cell has done to patients and the pain that they have suffered, and many sickle cell patients use marijuana to address acute pain that is a symptom of the disease. And some of the States currently have medical marijuana laws but have chosen not to include sickle cell disease on the list of conditions that would qualify a patient to receive the medication.

Dr. Throckmorton, is there a way we can assure that States that allow for medical marijuana have a comprehensive list of conditions that would qualify for the medication so that those who would potentially benefit from its effects are not excluded?

RPTR GIORDANO

EDTR SECKMAN

[12:59 p.m.]

Dr. Throckmorton. So which medications are you talking about? So --

Ms. Barragan. We are talking about the use of marijuana for sickle cell.

Dr. Throckmorton. Okay. Yeah. So the medications for sickle cell disease that I would advocate for are the ones that we have had the good fortune to be able to approve in recent years.

Ms. Barragan. Well, no. I am asking --

Dr. Throckmorton. They are not for pains. And those medications, we can and do work with providers to make certain that they understand they are available. We hope to include them -- make them available --

Ms. Barragan. Right. That was not the question. The question was that the States that provide the lists where people can use medical marijuana, like how do we ensure that some of these diseases are included. So --

Dr. Throckmorton. I am happy to talk with you offline.

Ms. Barragan. Okay.

Dr. Throckmorton. Those States are making those choices without Federal input, so --

Ms. Barragan. Okay. Thank you. I yield back.

Ms. Eshoo. The gentlewoman yields back.

Pleasure to recognize the gentleman from California, Dr. Ruiz, for his 5 minutes of questions.

Mr. Ruiz. Thank you, and thank you all for being here. Dr. Volkow, you say in your written testimony that, quote, CBD is ubiquitous, and it is possible to purchase CBD extracts as well as food, drinks, cosmetics, and other CBD- containing products which are sometimes marketed with health and wellness claims that are not backed by science, unquote.

It is also worth noting that, while more than 30 States allow for comprehensive medical use of cannabis and the FDA has approved some derived and cannabis-related drug products, cannabis does not have the FDA approval for any indication.

We have seen that cannabis can be used to treat certain ailments, such as for children with particular seizure disorders that are refractory to other treatments; as an appetite stimulant for patients suffering from AIDS or receiving chemotherapy; as an adjunct to other therapies in the treatment of chronic pain syndromes, which is of particular interest during the current opioid epidemic. Pain and spasticity in multiple sclerosis is another use. However, there is evidence show that chronic use is not without its consequence: for example, cannabinoid hyperemesis syndrome, a syndrome of cyclic intractable vomiting and chronic abdominal pain; disadvantaged attention, learning, and processing speed among teens who use marijuana regularly.

These neurobehavioral changes can even be seen on brain MRIs of these patients. These changes can be permanent. Earlier onset, as you had mentioned earlier, of schizophrenia and bipolar disorders in young users of marijuana.

So it is clear that more research need to be done to better understand the risks and benefits.

Dr. Throckmorton, it seems the FDA has found therapeutic value in

marijuana-related compounds, but for limited and specific uses. Can you discuss what factors went into approving these drugs for medical use for these specific populations?

Dr. Throckmorton. Sure. It began with the basic science work that groups like NIDA does, so it began with supporting the kinds of research that NIDA supports to identify compounds and targets -- therapeutic targets of interest; so suggesting from animal models or other places that the drugs had use in those areas.

And then something called translational science needs to happen, which is a drug manufacturer or a drug developer picks up that idea and comes and talks to us and says: We believe this is a product that we can turn into a drug. What are the pathways -- what do we need to do? What are the next steps?

Typically that includes additional clinical studies, sometimes additional non-clinical studies, and the result is something called the new drug application, chosen -- the therapeutic area then is chosen by the individual company. They are choosing to invest in pain, or they are choosing to invest in -- you know -- I do not know -- infectious diseases, or whatever else it is, with a particular product. Our job is to make sure that that assessment occurs, occurs quickly and efficiently, and is scientifically driven, and results -- you know, if the data are what they need to be, and then approval of a drug for a specific condition with an understanding of its safety and effectiveness.

Mr. Ruiz. And, based on this approval process, can FDA extrapolate the safety of CBD for other products?

Dr. Throckmorton. Extrapolation for effectiveness is very hard to do, and we have done it in very limited spaces. It is probably something we could talk about in more detail offline.

Safety is something that we are sometimes able to do more readily. A drug in a class that has an adverse effect, we will worry about does that same adverse effect occur in other drugs in the class? We have discovered over the years that very small differences in molecules have very large impacts in terms of effectiveness.

THC and CBD are very close to one another at a molecular level and yet have extraordinarily different patterns of use.

Mr. Ruiz. So your comments earlier said that CBD does not come without its risks. That is what we have all been talking about here. Your testimony outlines some of these risks. Can you elaborate more about what you know about CBD so far and what questions the agency may still have related to other uses?

Dr. Throckmorton. And now you are talking about safety, or are you talking about effectiveness?

Mr. Ruiz. Safety in other uses.

Dr. Throckmorton. So safety, I think, as you said, my testimony outlines, I would say, several buckets: one, adverse effects that we have observed in the clinical trials leading to the approval of Epidiolex; two, unknowns, things that we believe we need to have additional information about. I would put in that category particularly things like --

Mr. Ruiz. Right.

Dr. Throckmorton. -- the liver injury and testicular injury.

Mr. Ruiz. I only have seven minutes, and I just want to make a very important statement here, that, as you conduct your data collections, you have got to ensure that you have a diverse sample of populations. Too many research is done on men and non-Hispanics and non-African-Americans in the medical world, and I believe that, in all

categories of research, you need more women, and you need more people of color. Okay?

Dr. Throckmorton. Agreed.

Mr. Ruiz. All right. Thank you.

I yield back.

Ms. Eshoo. The gentleman yields back.

The chair now recognizes Ms. Schakowsky of Illinois, waiving onto the subcommittee, for her 5 minutes.

Ms. Schakowsky. Thank you, Madam Chair, and I appreciate being able to waive onto the committee.

I am a proud original cosponsor of Representative Jeffries' Marijuana Freedom and Opportunity Act and a cosponsor of Representative Nadler's MORE Act, which would both remove cannabis from regulatory Controlled Substances Act and add the criminal justice and mass incarceration address-it issue that we have been perpetually backing, and so that would get rid of that.

Here is what -- I want to focus on research, too. Everybody has, it seems, or most people. On January 1st, Illinois legalized recreational cannabis across our State, and dispensaries sold more than $19.7 million in cannabis over the first 12 days.

However, research at Northwestern University, which is in my district and is a leading research institution, have no way of accessing the cannabis that is sold in these dispensaries. And instead Northwestern scientists often face extreme difficulty in securing and maintaining cannabis and Federal funding for the research.

So I am glad that there is strong bipartisan support, at least for most of H.R. 3797,

Representative Blumenauer's Medical Marijuana Research Act of 2019. The bill would streamline the cannabis research process to ensure that our academic institutions remain at the cutting edge, et cetera.

Dr. Volkow and Dr. Throckmorton, how can we establish a process by which researchers in a State like Illinois, where recreational marijuana has been legalized and several different strains of cannabis are now widely available -- how could Illinois acquire the research supply through local dispensaries?

Ms. Volkow. And this is a question that we have been discussing it, and DEA is the one that is actually on the process of identifying additional sources of marijuana so that researchers can investigate marijuana from different dispensaries. So that is ongoing, and so -- but that is regulated by the DEA.

Ms. Schakowsky. And can we look forward to some change there?

Mr. Strait. As we have previously discussed, I think one of the challenges is unfortunately the fact that, for your purposes, a researcher who is procuring a controlled substance for research purposes is obligated under the Controlled Substances Act to procure that substance from another Federal DEA register --

Ms. Schakowsky. Right.

Mr. Strait. -- to research it.

Ms. Schakowsky. Right.

Mr. Strait. So none of these dispensaries are applying for a registration. None of them are registered with the DEA, and, therefore, they are unable to distribute to researchers.

Ms. Schakowsky. So we would have to get marijuana off the Controlled

Substances Act -- out of it in order to do the research that we absolutely need to do on what is being sold right now, and millions and millions of dollars being spent on it, and many, many users?

Mr. Strait. Well, certainly that is your discretion and Congress' discretion as one way to solve that issue. I do not know at the end of the day where this administration would come down on that approach.

Ms. Schakowsky. Is that the only way?

Mr. Strait. No. I think there are other legislative means by which Congress could propose to change that specific requirement, but I do believe that it would require some legislative changes to the Controlled Substances Act.

Ms. Schakowsky. I did want to say about that piece of legislation, H.R. 3797, that I do have a concern that DOJ would have the ability to deny medical marijuana licenses based on even minor past drug convictions, and I hope that we can also remedy that. Though I know that we do not all agree on deregulation and descheduling, we, I think, at the very least, should be able to work together to ensure adequate research is able to be conducted so that we know the consequences of what people are using right this very minute in the State of Illinois and many other States.

And I yield back.

Ms. Eshoo. The gentlewoman yields back. Votes have been called, and I recognize the gentlewoman from the State of Washington, Ms. McMorris-Rodgers, for 5 minutes.

Mrs. Rodgers. Thank you.

Thank you, Madam Chair, and I also want to recognize the ranking member and all

the committee members. I appreciate this committee being engaged on this public health and consumer safety topic around cannabis. I get asked about this a lot in Washington State. We legalized both recreational and medicinal marijuana the same year as Colorado. I believe we were the first two States.

I am a cosponsor of Blumenauer's Research Act because I do think that we need more research. I also represent Washington State University, and it is in the same situation as Ms. Schakowsky's university around wanting to do more research around the issue.

Since we have legalized marijuana, the number of cannabis products available on the marketplace has exploded over the years, and so have the marketing tactics that promise cannabis is a miracle for your health. A quick search promises you cannabis products will help you sleep, relieve your pain, calm your anxiety, shrink tumors, cure diseases, and a whole lot more.

The concern is that these claims are not yet backed by scientific research or clinical trials. I am concerned about manufacturers who are ignoring all the unknowns of cannabis and spending health promises to fuel an industry that is projected to be nearly $2 billion by 2022.

I do believe that this industry, like with the FDA- approved CBD oral solution for epilepsy -- and others have mentioned this -- is on the verge of major breakthroughs that can improve people's lives, and we should be encouraging these developments. Like other cures and treatments, cannabis products should be held to a standard that people can trust so that the bad actors cannot spin to make a quick buck.

Bottom line: this is a public health and a consumer safety issue. Those priorities

should be at the forefront as we unlock the mysteries of cannabis.

Dr. Throckmorton, I wanted to ask -- and others have been on this topic also, but, as I mentioned earlier, the FDA has approved only one CBD product, a prescription drug product to treat epilepsy.

That being said, all sorts of CBD products are being marketed and sold throughout the country. We have no idea what the health implications may be.

So what is the solution to this? How should it be handled?

Dr. Throckmorton. So not one solution; that shouldn't be a surprise, right? I personally believed one really important element is to encourage the development of a mature industry using these products -- an industry used to manufacturing standards; industry used to packaging standards, labeling standards; an industry of the kind that you see when you go into Walmart and Costco and places like that. Those products are being manufactured to a standard, as you said, which I think is very valuable.

I hope that, by the recent increase in interest in doing research using these products, behind that will be a growth of an industry that wants to do the right thing, that wants to be science-driven, appropriately labeled, manufacturing to a high-quality standard. I think that is one important element, among other things.

I also think it is terribly important that we lay out a pathway for nondrug products containing compounds from hemp so that there is a clear path that developers can follow to find a way forward as far as developing those products and making them appropriately available.

Mrs. Rodgers. Do you see that happening at the State level in any of the States where marijuana has been legalized?

Dr. Throckmorton. Yeah, I do.

Mrs. Rodgers. Either for the industry or the nondrug products?

Dr. Throckmorton. We have really benefited from talking with the states. I would say your State has been particularly helpful to us as we talked to them about their experiences because you have had to deal with all of these things.

The States are all taking different approaches, but many of them -- and I would say including your state -- I know are grappling with these issues around labeling and dosing and manufacturing quality and things like that, and we are trying to learn from those experiences as we try to formulate a policy at the Federal level.

Mrs. Rodgers. Another big concern is the increase in traffic accidents and traffic fatalities around the use of these products, and we have seen some pretty dramatic increase in numbers around accidents, at the very time that we are working here diligently to make our roads safer, and now also the number of fatality accidents that involve one of these products.

What needs to happen in that regard to make sure that we are safe on the roads?

Dr. Throckmorton. So it is one of the unknowns we have identified for cannabidiol. We have studied it in children. We never did those kinds of studies because children don't drive, but we understand we need to understand the effects of CBD on driving impairment. We need to have that -- those data as soon as we can.

Mrs. Rodgers. Okay. Well, there is a lot more to explore here. Thank you all for being here.

Thank you, Madam Chair.

Ms. Eshoo. The gentlewoman yields back, and we thank her for participating in

our hearing.

So let me, on behalf of all of the members of the subcommittee, thank our witnesses. This is a long hearing. I might add it is the very first hearing on cannabis in the history of the Energy and Commerce Committee, which is the oldest committee in the Congress.

So it has been a long hearing, but I think a highly -- excuse the expression -- instructive one because of the participation of all of the members, and we will have another hearing from other stakeholders that are not agency stakeholders. So thank you again to each one of the witnesses.

Where you weren't instructive, it was instructive to us, and so much of your testimony was. We learned from you. And we have, I believe, the vehicles to develop a roadmap to address this lack of really substantive research that is absolutely needed. That is foundational to what -- you know, so many of our undertakings.

So I want to submit the following statements for the record, and I also want to remind members -- of course they are not here -- that, pursuant to committee rules, they have 10 business days to submit additional questions for the record to be answered by the witnesses or to whomever questions are submitted. We count on our witnesses to respond promptly to any of the questions that you may receive, and I trust that you will do that.

So I request anonymous consent to enter into the record the following documents: the statement from the Greenwich -- from Greenwich Biosciences; a statement from the American College of Occupational and Environmental Medicine; a statement from the National Safety Council; a letter from the National Consumers

League; a statement from Doctors for Cannabis Regulation; testimony of Aaron Smith, executive director of the National Cannabis Industry Association; a letter from over 100 organizations in support of H.R. 3884; a letter from five organizations representing State legal cannabis businesses; a statement from the California Cannabis Industry Association; the testimony of Congressman Hakeem Jeffries in support of H.R. 2843; a statement from Kris Krane, president of 4 -- the number 4 and the word "Front" -- Ventures; a statement from Americans for Safe Access; a report from the National Cannabis Industry Association entitled "Adapting a Regulatory Framework for the Emerging Cannabis Industry"; a statement from the American Property Casualty Insurance Association; the testimony of Paul Armentano, deputy director of the National Organization for the Reform of Marijuana Laws; a response letter from FDA/NIH to Senator Schatz; a letter from the minority requesting a hearing on cannabis, and here we are, and I said yes; a letter from the American Academy of Neurology in support of H.R. 171; a letter from the American Academy of Neurology in support of H.R. 601; a Bloomberg News article entitled "Pot Imports Grow as U.S. Stalls on Medical Research" -- quite timely; a collection of six letters from organizational supporters of H.R. 3797; a statement from the Biopharmaceutical Research Company; a letter from Smart Approaches to Marijuana; a letter from the Michael J. Fox Foundation in support of H.R. 601; a statement from the Consumer Brands Association; a letter from the DEA in reply to an application to grow marijuana for research purposes; and slides created by NIH entitled "Effects of Cannabis on the Human Brain."

Without objection, so ordered.

[The information follows:]

**This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.**

******** COMMITTEE INSERT ********

Ms. Eshoo. Does the ranking member have anything he wishes to submit?

Mr. Burgess. I would not do anything to prolong the hearing.

Ms. Eshoo. All right. So, on that happy note, thank you to each one of our witnesses again.

To everyone that remained in the hearing room, thank you for your attentiveness.

And, to the reporters, the press, thank you for your interest.

At this time, the subcommittee is adjourned.

[Whereupon, at 1:22 p.m., the subcommittee was adjourned.]