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HOUSE OF REPRESENTATIVES

HEALTH COMMITTEE
PUBLIC HEARING

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HARRISBURG, PA

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ROOM 205

TUESDAY, MARCH 3, 2020
11:00 A.M.

PRESENTATION ON
CBD'S IMPACT ON THE MEDICAL MARIJUANA PROGRAM

BEFORE:
HONORABLE KATHY L. RAPP, MAJORITY CHAIRWOMAN
HONORABLE JIM COX
HONORABLE VALERIE S. GAYDOS
HONORABLE JOHNATHAN D. HERSHEY
HONORABLE DAWN W. KEEFER
HONORABLE JERRY KNOWLES
HONORABLE CLINT OWLETT
HONORABLE BRAD ROAE
HONORABLE PAUL SCHEMEL
HONORABLE DAVID H. ZIMMERMAN
HONORABLE MARY JO DALEY
HONORABLE PAMELA A. DELISSIO
HONORABLE MICHAEL H. SCHLOSSBERG

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Pennsylvania House of Representatives
Commonwealth of Pennsylvania
ALSO PRESENT:

REPRESENTATIVE RUSS DIAMOND

COMMITTEE STAFF PRESENT:

WHITNEY METZLER
MAJORITY EXECUTIVE DIRECTOR

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MAJORITY RESEARCH ANALYST

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TRACY KOCHEH
DEMOCRATIC LEGISLATIVE ASSISTANT
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**SUBMITTED WRITTEN TESTIMONY**

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(See submitted written testimony and handouts online.)
MAJORITY CHAIRWOMAN RAPP: Good morning, ladies and gentlemen. And, Members, thank you for attending today.

This is the Health Committee hearing. And the reason that we are here today is it is a public hearing on the CBD impact on the Medical Marijuana Program, but in fact there were -- I'm sure all of us, people across the State of Pennsylvania have seen the CBD oil on the shelf and other products, and many of us, including legislators, do not fully understand the effects of the CBD oil. We do know that through the Farm Bill of 2018, the U.S. Farm Bill, that we are seeing more and more products of the CBD.

So, we're really here today to gather information, the Committee, so I welcome all of you. Members, thank you for being here, and members of the public. The meeting is being recorded, and I believe it is also live-streaming, so if you would please at this time make sure that your cell phone is silenced.

And at this time we will introduce ourselves, the Members. I am State Representative Kathy Rapp, and I chair the Health Committee. And we will start to my right with Representative DeLissio.

REPRESENTATIVE DELISSIO: Good morning. Pam
DeLissio. I represent parts of Montgomery and Philadelphia Counties, the 194th, and I am sitting in today for Dan Frankel, who is the Minority Chair of the Committee.

REPRESENTATIVE SCHLOSSBERG: Good morning, everyone. Representative Mike Schlossberg, 132nd District, city of Allentown and South Whitehall Township, Lehigh County.

REPRESENTATIVE ZIMMERMAN: Dave Zimmerman. I represent the northeast part of Lancaster County.

REPRESENTATIVE KNOWLES: Good morning, everyone. Jerry Knowles. I represent the 124th District, which includes portions of Schuylkill, Berks, and Carbon Counties.

REPRESENTATIVE ROAE: Good morning. Brad Roae. I represent central Crawford County and parts of western Erie County.

REPRESENTATIVE OWLETT: Representative Owlett. I serve the 68th District, which is Tioga County, parts of Potter, and parts of Bradford County.

REPRESENTATIVE GAYDOS: I'm Valerie Gaydos, 44th District, representing Allegheny County.

REPRESENTATIVE KEEFER: Representative Dawn Keefer. I represent northern York County and a part of Cumberland County.

REPRESENTATIVE SCHEMEL: Paul Schemel. I
represented a portion of Franklin County.

MAJORITY CHAIRWOMAN RAPP: Thank you, Members. I also recognize Representative Russ Diamond, who is not a Member of the Health Committee, but I'm assuming you are here because this is of interest to you, so thank you for attending, sir. We appreciate it.

So, at this point in time we have two panels today. And thank you to our panels who are willing to provide us with information. And at this point in time the Committee is really not looking at any legislation, but it is a topic that we want to inform ourselves on. So, the information that you provide us is really informative to us and to the public and whoever is looking in on the informational hearing today.

So, first on the agenda is Dr. Rachel Levine, our Secretary of Health. We are honored to have you here today to provide us with information. I'll go ahead and introduce Natalie Krak, who is the Policy Director with the Department of Agriculture, and Fred Strathmeyer, who is the Deputy Secretary with the Department of Agriculture.

And at this point in time, Dr. Levine, if you'd like to begin.

SECRETARY LEVINE: Thank you. Well, good morning, Chairwoman Rapp and all of the Representatives and everyone here today. I'm very pleased to be with you this
morning on behalf of the Department of Health and to
discuss our Medical Marijuana Program but also, as you had
mentioned, the CBD products from hemp, which are widely
distributed in the Commonwealth and really throughout the
United States.

I'm just going to summarize my remarks. I'm not
going to read the whole thing.

But, as you know, since the passage of Act 16 of
2016 we have worked at the Department of Health to
operationalize the Medical Marijuana Program. Our Medical
Marijuana Program just had its second birthday and has been
very, very successful. And if I may say I think it is one
of the best Medical Marijuana Programs in the country. We
have a fantastic Director John Collins, who is here today,
and great staff.

We have been able to approve the operations of 22
out of the 25 approved grower/processors, 77 dispensaries.
We have registered over 268,000 patients. We have almost
170,000 active certifications of patients for the Medical
Marijuana Program. We have 1,830 physicians that have
registered to be medical practitioners in the program,
1,317 are approved with 23 new ones. The rest are in the
pipeline of taking the CMEs to be registered.

You know, we have gone through many different
phases in terms of the Medical Marijuana Program to approve
the grower/processors and the dispensaries, and we have 23 serious medical conditions for which medical marijuana can be recommended.

We have, I believe, six laboratories, which certify the quality and safety of the product, which is a key point which I'll come back and emphasize later. We have a seed-to-sale tracking mechanism, so we can keep track of every seed to make sure there's no diversion of product. And, you know, by any standard I think that we have really had a very, very successful Medical Marijuana Program and have threaded the needle to keep it very clinically and medically based.

In addition, we have the chapter 20 program for medical marijuana research with eight academic clinical research centers from throughout the State, our excellent medical schools, and seven of them now have approved clinical registrants that will serve as their grower/processors and their dispensaries. And then we have another round four for the eighth academic research center, so the goal is that we'll have all of them have a certified clinical registrant so that they can all start their program to do very needed medical marijuana research.

I held a research summit in August, and I have a new research summit coming up at the end of this month in March. And, as you know, my background is in academic
medicine, and so I am absolutely committed and the academic
clinical research programs are committed to doing more and
more research about medical marijuana to make it even
better in terms of targeting serious medical conditions.

So, while our Medical Marijuana Program is still
new and growing, the deregulation of hemp, which I'm sure
will be discussed more by my partners at the Department of
Agriculture, in the Federal agriculture or the Farm Bill of
2018 allowed for new hemp-derived CBD products to be
introduced into the market, which is completely outside of
the Medical Marijuana Program, and I don't think that
people realize that. But the CBD products that you may buy
it many different stores, some specific CBD stores but
other convenience stores and grocery stores and in many
different places is completely outside the regulation of
our program, and that is derived from hemp, and our program
is for medical marijuana.

There are specific differences, and I'm certainly
not a botanist -- took it in college, but not a botanist.
My colleagues from agriculture can go into more detail.
But hemp is not marijuana. They are both from the same
cannabis sativa plant, but they are different strains.
Through many years of cultivation, they are actually
genetically different. And one of the main differences
which is clinically relevant is in terms of the ratios of
two of the compounds in the plants of THC and CBD. And there are many other compounds, but medical marijuana will always have higher levels of THC and be varied through cultivation. And hemp almost by definition has a very, very low almost undetectable level of THC. It is predominantly CBD. But we do have CBD-rich marijuana strains as well, but that is the main difference. And it makes all the difference in the world in terms of the clinical impact.

And, again, the process by which our medical marijuana products reach the market and the hemp-derived CBD products reach the market are completely different because our supply chain is extremely tightly regulated. Again, we have specific licensed, regulated inspector grower/processors. We have specific license and inspected dispensaries. We have a two-point testing system for the product by laboratories to ensure the quality and the safety of the product that, one, it is what it says it is in terms of the ratio of CBD and THC, and that it has no contaminants, bacterial contaminants, fungal contaminants, et cetera. None of that is true with the hemp-derived CBD products. Now, I'm not saying that all of them are bad in any way, but there is no regulation of that.

Since it is unregulated, there are significant concerns about the quality, safety, and actually the
content of the hemp-based CBD products in Pennsylvania and in the country, and in fact we have no idea about the location of where CBD products that are in convenience stores are made. I would expect that most of them are not made in Pennsylvania. They're made anywhere else in the country.

According to a study by the University of Pennsylvania, nearly 70 percent of the CBD extracts that were bought online were mislabeled. Another study in the *Journal of the American Medical Association* noted that of the products they tested 26 percent contained much less CBD than labeled. Then again, there could be contaminants. There could be bacterial contaminants, fungal contaminants because none of it is regulated.

So, the question is how should it be regulated, and I think there's a lot of opportunity for discussion within the administration and our departments and the Governor's office and then of course with the legislature about how they should be regulated. In a perfect world they'd be regulated by the Federal Government, which did the Farm Bill. And the FDA has tried to create some parameters, but there is no specific enforcement of any of those parameters that the FDA has said.

New York passed legislation regulating the manufacture and sale of hemp-derived CBD products with
labeling requirements. We know that California and Illinois have contemplated similar legislation. Colorado regulates it as a food. And some States actually don't allow the sale at all, particularly Idaho, Iowa, and South Dakota.

So, the question is how that should happen, and so, you know, we'd love to be part of this discussion with the Medical Marijuana Program. But I think that the public does not understand that. We have tried to message that, but I would bet you if you asked the public, they think that that is part of our program, and it has nothing to do with our program either by the regulation of the growerprocessors, the dispensaries, the safeguards, the tracking, the laboratory testing, and then, again, our products are for 23 serious medical conditions, and you have to see a physician to get certified, and none of that is true with that program.

So, we very much appreciate your interest in the topic, and I'm pleased to answer any questions.

MAJORITY CHAIRWOMAN RAPP: Thank you, Secretary Levine. My plan was to have the two other --

SECRETARY LEVINE: Sounds great.

MAJORITY CHAIRWOMAN RAPP: -- members testify, and then are you --

SECRETARY LEVINE: Sure.
MAJORITY CHAIRWOMAN RAPP: -- timewise --

SECRETARY LEVINE: That would be fine.

MAJORITY CHAIRWOMAN RAPP: -- you're able to stay for questioning?

SECRETARY LEVINE: Thank you.

MAJORITY CHAIRWOMAN RAPP: Thank you so much.

So, at this time, Natalie, if you would want to go forward with your testimony.

MS. KRAK: Sure. I'll actually let Fred kick it off, Deputy Secretary Strathmeyer. He's going to give an overview of the hemp program, which is within his deputy, and then I'll follow up with the legality of the CBDs.

MR. STRATHMEYER: Thanks, Natalie. Thank you, Chairwoman Rapp. I appreciate being here. I appreciate your interest. There's a slideshow over here. I'm not sure who's able to run it. You have a copy of it in front of you to follow along. I am not going to sit here and read this entire thing, so you don't have to worry about that, but just highlight a few of the pieces that I believe are important that, you know, the 2014 Farm Bill allowed for research of the use of hemp across the country for cultivation and marketing under State-run pilot programs. You the legislature passed and the Governor signed in July of 2016 Act 92, which allowed us to have the Industrial Hemp Research Act.
In 2017 after we put out for applications, in 2017 hemp was officially growing here in the State of Pennsylvania, but, again, I will add just for research, which included cultivation and marketing. As Secretary Levine noted earlier, the early stages of the program here in this State were simply fiber and seed and not CBD. It wasn't until the 2018 Farm Bill that that happened.

So, as you follow the slides along, you'll see the progression. We opened it up in 2017, as I stated, five-acre limits. The Secretary felt that was good enough for research, 30 permits. The reality was that -- and then in 2018 we moved that, after listening to our growers, to 100 acres, and we were looking for 50 applicants. And you'll see that actually the numbers and how they laid out were much less than that. In 2017, although 30 permits were available, only 16 people participated. In '18, only 37. The acreage, again, first year, 36 acres, 585 acres in '18.

The reason I bring that up is just to let you know -- and I know that in the airwaves we continue to hear about other States and how far we're behind other States. I note this in '17 and '18 those numbers are very similar to a Kentucky, to a Colorado, to an Oregon when they first started. So, we felt very good about those numbers and the participation we had from our growers in this State.
As you know and has been noted, the 2018 Farm Bill reclassified hemp's status. It removed cannabis and cannabis derivatives that are low in THC, again relating to Dr. Levine's comment that hemp, the CBD must be .3 percent or less THC, and that has removed it from the Controlled Substances Act. Still -- and again noting that FDA has and continues to have authority over products containing CBD, but we'll get into a little bit further about that relationship between the Federal Government and State Governments and who's responsible, and so on.

So, in January of this past year, because of the '18 Farm Bill being passed, the Secretary decided to essentially open the gates up for anyone to participate here in the State. And I say that tongue-in-cheek because every grower does need to be permitted, and so there are certain parameters around permitting someone in the State. But there was no limit to the number of permits. There was no limit to the acreage. And we've reopened those applications and extended them into May of last year.

What this allowed for was interstate movement of seed, the movement of plant material. I will note again, being part of plant industry, all these plants still are required and fall under any plant laws that we have here in the State of Pennsylvania. And that's very important to remember. So, when plants are being transported from State
to State, if there's any disease issues, any problems with funguses, those types of things, we're looking for them regardless of whether it's a chrysanthemum or it's a hemp plant, so just remember that it still fell within that purview. So, it wasn't as if you could just send these plants anywhere, and nor do we accept them from anywhere.

The industrial uses, the fiber and the seed, as I mentioned, and again, now we are into the ability to extract and use CBDs. We'll talk a little bit later or some people in this panel will talk to you about CBDs because CBDs is just another part of this. There are CBGs, there are -- and just do the alphabet. These are all compounds. They're parts of this plant that are derivatives and continue to be studied. The nursery crop, again, seedlings clones, don't need to keep reading this to you.

So, in January of 2019 we submitted a plan to USDA. We followed the Controlled Plant and Noxious Weed Act as we put our plan forward. We also in March, the committee itself, voted to have hemp as a controlled plant. That gave us a little bit more of the rails around the plant. It just gave us more ability to make sure that it wasn't being planted freely in the State. It followed an act that the legislature gave us.

And I again will note that one of the reasons --
and maybe it'll come out later -- is that some of the States are falling back to the 2014 Farm Bill currently is because they would have to change so much legislation in those States. Because of the Controlled Plant and Noxious Weed Act, we've been able to stay -- and again, thanks for having it. We've been able to stay within the rails that allow us to continue to move forward in this State, one that I can tell you farmers are greatly appreciative of in our ability to keep moving the program forward.

I talked about that.

You can see that there are some parameters around the individuals that are applying for permits. Currently, with the new interim rule that was just put out in October of this past year, the people that have their felony background, their FBI background taken care of from this point forward have a three-year and before, it was every year. Now, after they get their tests done, the information back to us, the applicants can be good for three years. So, again, it's kind of streamlining the process going forward.

The 2019, going back there, as you can see, the numbers exponentially grew from the 36 I believe in '18 to over 324 permits, 828 growing locations, and somewhere close to about 4,000 acres, and that did include some of the greenhouse operations here in the State, as stated on
there, 55 counties.

The next couple of slides are simply to give you some insight as to what the plan is for us in the Department of Ag. The plant material and the CBD crops can be grown inside and outside for the crop being grown, hemp.

The next slide is simply a distribution, and again, that just goes back to, you know, that basically the crop is grown about everywhere in the State with a heavy concentration in the southeastern part of the State, which, again, you would anticipate that.

As I said earlier, the USDA interim final rule was published in October 31st of this year. USDA just last week approved our State plan, so we are good to go. There was a slight change in respect to DEA's involvement for this coming year that they've dropped back from, so we will adjust our plan accordingly to that piece.

Again, for this year, our hemp processors, they must be permitted. That is for the first time this year. In the past, we had permitted our farmers and producers. This year, we are taking a step in permitting the processors. Do understand that our jurisdiction basically runs from the field to the front door of a processor. I'm sure that, again, this is where some of the conversation today may go and the concerns of health and our partners in health is that, you know, what happens next, but just
understand that PDA's jurisdiction simply is from the farm
to the front door of a processor, that we've worked with
other States, as well as our experience.

The next note is about prohibited varieties and
varieties of concern. Last year, we ran about 12 percent
of what we call hot crops that had to be destroyed last
year. I can tell you that in the State of Kentucky they
were over 36 percent of a hot crop. And the concern there
is varieties, because there's not enough research on the
varieties out there, that some varieties that are actually
high in THC are ending up with our farmers, the seed or the
transplant, the seedling. That is a grave concern, and so
we've created a list of the prohibited varieties based on
our experience and on the experience of other States. We
also have a list of varieties of concern. Those lists,
you're allowed to plant the variety. However, we are just
letting you know that you may be running into problems.
Again, we're trying to create a situation where our farmers
succeed. It's all about success.

So, I'll leave it there and turn it over to

Natalie.

MS. KRAK: Thanks, Fred. Good morning. My name
is Natalie Krak. I'm the Policy Director at the Department
of Agriculture. We're really pleased to be here today. We
get tons of questions about CBDs, the legality of CBDs, as
I'm sure you all do as well. As Fred and Secretary Levine mentioned, the 2018 U.S. Farm Bill removed hemp from the Federal Controlled Substances Act, and it included CBDs in that definition of hemp. It's important to note that the U.S. Farm Bill preserved the FDA's jurisdiction over hemp as it relates to food products for both humans and animals.

Shortly after the 2018 Farm Bill was signed in December of 2018, the FDA did come out with a GRAS designation, which is generally recognized as safe. That GRAS designation applies to the seeds of hemp. You might see them in granola products. It also applied to hemp as a protein powder. Again, if you're in the GNC, you may see products of hemp protein powders, as well as the oil from the crushed seed. So, again, that's similar to olive oil or other cooking oils.

After that, we didn't hear a lot from FDA until much later in the year of 2019. And our USDA moved forward with their program as many States opened up their requirements allowing for unlimited growth, as we did in Pennsylvania.

As the Department of Agriculture, growing hemp for CBD production is legal in Pennsylvania as long as you are permitted by the Department of Agriculture. As Secretary Levine mentioned, these are separate growing systems from Medical Marijuana Program. There is no
overlap at all. So, we have a separate system through the Department of Agriculture and the Controlled Plant and Noxious Weed Act. There are no additional legal requirements or concerns if you are growing for fiber, whether you are a grower or a processor as long as you have your permit from us and your hemp plants are within .3 percent THC or lower. You are legal and there are no further barriers.

Currently, it's important to note there are no Federal approvals for hemp in animal feed or animal food products at this point. FDA does still have jurisdiction over that. We have some research as part of the Pennsylvania Farm Bill from our Center for Poultry and Livestock Excellence and that is actually looking at trying to get that GRAS designation for animal feed and poultry, so we're really excited about that. And there's certainly room for a lot more research across the various uses of hemp.

So, as I mentioned, growing hemp for CBD production in Pennsylvania is legal with our permit. It is also legal to produce, to process, and sell hemp-based CBD in its unadulterated form. That's if the CBD is grown from a legal State permitting process like we have in Pennsylvania. As I mentioned earlier, FDA preserves its oversight over the food supply, and FDA does not permit
CBDs to be added into food or beverages or sold as a dietary supplement.

I think it's important to note that there has not been a consistent application of this rule. Dr. Levine mentioned this. Certainly, CBD products were on the marketplace before the U.S. Farm Bill, and we've seen a proliferation of CBD products, as Secretary Levine mentioned, everywhere from gas stations to health food stores. There has not been consistent Federal enforcement. Basically, it is not legal to put CBDs into food or beverages or to make medical claims about what those CBD products could be used for. As Secretary Levine mentioned, there are diagnoses or under the care of a physician in the Medical Marijuana Program. For hemp-derived CBDs you cannot make health claims. And we have seen FDA take some limited action against companies that are putting products into the marketplace and making medical claims or putting products into the marketplace that are clearly being used in the same method as a drug.

We in Pennsylvania at the Department of Agriculture also oversee food safety, and we have adopted the Federal Food Code here in Pennsylvania, so, for example, if you call into the Department and ask for a restaurant permit for a CBD product, we're going to tell you that that is not allowable under current Federal law.
We have been advocating for Federal action on this issue. The FDA had a comment period open in 2019. We encouraged them to come up with a Federal standard, whether that is through some sort of interim regulation while they continue to conduct research, but we feel like it's really important for Federal consistency on this issue both for continuity of business for farmers and processors and also, of course, for consumer protection across the country.

We very much believe that there's a need for additional research, as Secretary Levine brought up, and in November of 2019 FDA did make an announcement that they will not be able to give that generally-recognized-as-safe designation for CBDs from hemp in the food supply for either humans or animals. So, more research is needed. We believe that that Federal action is really critical.

And I would like to mention that part of the Pennsylvania Farm Bill included the Specialty Crop Block Grant Program, which we have research announcements coming in the near future for some of the hemp research that we're supporting through that program.

So, in Pennsylvania we're really proud. Last week, we just found out that our State plan to regulate hemp was approved by USDA. Something that's really exciting about that is we've encouraged USDA to make their support programs available to hemp for States that have
approved plans, so we are one of nine States currently and
11 tribes that have approved State plans. We've worked
really hard to make our program work for farmers and to
encourage processors to come to Pennsylvania. We'll get to
hear from some of those later in the panel.

Last year in October we hosted the first-ever PA
Hemp Summit. We had over 600 participants from multiple
States, and we're looking to hold another one of those in,
I believe, December of 2020.

I think it's worth mentioning that there are
investment opportunities and opportunities for innovation
in hemp. Across uses, hemp has been described as -- I
think there are like 25,000 different uses of hemp spanning
industrial uses, technology, plastics, and of course CBDs,
which we're here to talk about today.

So, we'd be happy to take your questions, again,
really appreciate the focus on this important topic.

MAJORITY CHAIRWOMAN RAPP: Thank you very much.
This was very informative. And I'd like to note the
presence of Representative Mary Jo Daley and Representative
John Hershey. Thank you for joining us.

And we will open this to questions at this time.
Secretary Levine, there are 23 categories, illnesses,
diseases which we allow to be treated by medical marijuana.
And included in that would be, you know, children under 18.
Do you have any concerns with the cannabis oil being treated without -- as a treatment for our youth under 18? What are the safeguards --

SECRETARY LEVINE: Sure.

MAJORITY CHAIRWOMAN RAPP: -- and are there safeguards that you think that we need to look at that maybe aren't there right now for our minors?

SECRETARY LEVINE: So, we have taken a very close look at the conditions at the amount of young people under 18 for which medical marijuana is being recommended and the conditions for which they're being recommended. There is really limited use of medical marijuana for children under 18, but there are some specific indications. One of the indications that really served as the basis for much of the advocacy to the legislature for medical marijuana is use for children with intractable seizures and epilepsy. There are two specific conditions, Lennox-Gastaut syndrome and Dravet syndrome, but there are others -- actually children with absolutely intractable seizures that are not able to be treated with other conditions for which CBD-rich medical marijuana, which is different than the CBD in these hemp-derived products, can have significant utility. And so one of the conditions for which medical marijuana is being recommended are those children.

Another condition approved by the legislature for
which medical marijuana is being recommended for children is autism. There is less research about medical marijuana and autism, but there is research. There's actually some very promising research that was done, more observational research by the Children's Hospital of Philadelphia and some of their experts about medical marijuana with autism. But certainly more research is necessary. And we're advocating through our chapter 20 program and the academic clinical research centers that we are encouraging children's hospitals be doing that research associated with the academic centers.

Other conditions, there are a small number of children with cancer for which medical marijuana is recommended, primarily teenagers who might have either problems in terms of their appetite and eating, cachexia, or nausea and vomiting associated with chemotherapy with cancer. And there are some teenagers, not young children but teenagers for which medical marijuana is being recommended for particularly PTSD and then a small number for anxiety. And PTSD of course was approved by the legislature, cancer approved by the legislature, autism, and of course those children with seizures.

I did approve anxiety disorder as one of the conditions that was recommended to the board according to the system that we have set up, to the Medical Marijuana
Advisory Board, for new conditions and then examined by our medical subcommittee and then approved by the board, recommended to me.

And then last year after a lot of research I did approve anxiety. My caution was that I thought that and some provisos to anxiety was that the literature suggests that CBD-rich compounds, again, not the hemp compounds but in the Medical Marijuana Program have shown promise for anxiety and that I thought the indications for young people under 18 were very limited for anxiety. And I made the point that this should not be done as a first-line treatment, but it wouldn't really be recommended after other more traditional medications were considered, but then also not as a replacement for counseling and therapy. So, those were some of the guidelines. I mean, there's not in the guidelines that I can enforce. Those were my recommendations.

The other thing that the Medical Marijuana Advisory Committee recommended to me that I have put on hold is that medical marijuana should be recommended for young people under 18 by pediatricians or by other pediatric specialists. I haven't implemented that because we don't have enough pediatric specialists that are part of the program so that there wouldn't be a health equity issue in terms of geography. So, we don't have enough pediatric
specialists in either neurology, pediatrics, adolescent medicine, child psychiatry that have participated that it wouldn't serve as a significant limitation to the public. But I would like to do that if we can get more pediatricians to register for the program.

MAJORITY CHAIRWOMAN RAPP: Just one follow-up, since you mentioned pediatricians, so having said that, then I'm just assuming that there are pediatricians across the State who are prescribing medical marijuana and possibly CBD oil for their minor patients?

SECRETARY LEVINE: Yes, there are. Of course, we don't prescribe medical marijuana. You certify a patient as having the condition and then approve them in the program, but yes, there are pediatricians in the program or pediatric specialists that are part of the program but not enough for me to limit it for young people to pediatric specialists in my opinion because it's not throughout the State. It's only really particularly located in of course our big cities.

MAJORITY CHAIRWOMAN RAPP: Thank you. Representative Schemel, I think you had a question.

REPRESENTATIVE SCHEMEL: Yes, thank you. And, Secretary, this may be a question for you, but you've differentiated CBD as in the Medical Marijuana Program from the products that are available as derivatives of hemp.
For those of us who don't understand, what's the difference --

SECRETARY LEVINE: Sure.

REPRESENTATIVE SCHEMEL: -- and, as a follow-up to that, the research that's being done within the Medical Marijuana Program, does that pull over any of the CBD from hemp so we know how these work together?

SECRETARY LEVINE: So, I'll answer the second question first. No. The research in the Medical Marijuana Program is being done through our Medical Marijuana Program. The seven of the eight academic clinical research centers, ACRCs, as per the act, have clinical registrants that have been approved by the Department. One will have another round four. For the seven that have approved, those clinical registrants under the act will serve as their grower/processor of medical marijuana and then serve as their dispensary. And then they'll be working with that academic center. We're in this area, so we'll say Penn State, so they have a CR who will serve as their grower/processor and their dispensary for that research. None of it is being done with the CBD from hemp.

If you looked at a CBD molecule, you would not be able to tell, I don't believe, whether it's from hemp or from marijuana, but in terms of the way the products are being distributed, it's completely different. Again, our
products have the license, regulated, the
grower/processors, dispensaries, the labs, all that
testing. The hemp industry and the hemp CBD, as we've been
discussing, is completely unregulated. It should be being
regulated by the FDA, but they are not enforcing
essentially any recommendations.

So, if you go to any of our great convenience
stores and gasoline stations, you will find CBD. There is
a great concern of what is in that product and where it was
grown, probably outside of Pennsylvania, how it was grown,
how safe it is, the quality control, and what is actually
in it. And in studies that have been done what they say is
in it is not what's in it. So, that's the concern.

MAJORITY CHAIRWOMAN RAPP: Thank you, Secretary.
Representative Knowles.

REPRESENTATIVE KNOWLES: Thank you, Madam
Chairman. And thank you, Madam Secretary, for being here,
Doctor. We certainly appreciate it.

I'll be up front. I was a "no" on medical
marijuana not because I didn't want to see people benefit
from it but because of the way it was done. It was not
something that was supported by the American Medical
Association, the Pennsylvania Medical Society, and a good
number of the medical associations. But what's done is
done. It's something that we need to live with and that we
need to be certain that we do in the right way.

One of the concerns that I had was that some of
the States were handing out medical marijuana cards the way
Santa Claus hands out candy canes at Christmastime. You
know, I was deeply concerned about that. But I understand
from what I hear that we're doing a pretty good job. And I
commend you for that.

SECRETARY LEVINE: Thank you.

REPRESENTATIVE KNOWLES: I commend you for that.

The concern or the question that I have is having a
Governor and a Lieutenant Governor who seem hell-bent on
legalizing recreational marijuana, I have concerns about,
first of all, there are people that are investing a lot of
money into medical marijuana, and I have concerns about
people that would just, you know, grab some pot and smoke
pot instead of getting medical marijuana. Do you have
concerns about the recreational element of marijuana? Do
you have concerns about the effect that that would have on
the people who have invested, as well as the medical
marijuana itself?

SECRETARY LEVINE: Thank you for that question.

There are a number of different parts. One is my goal with
the Medical Marijuana Program has been to keep this
medically and clinically based. And I did not want
Pennsylvania to become Venice Beach. You walk down Venice
Beach, California, and you cannot help but be dragged in by somebody who said don't you want medical marijuana, here's your card, here's your product, et cetera. And so we have been able to thread the needle and to keep this a very medically based program for patients with serious medical conditions.

In terms of recreational marijuana, it really is a completely separate discussion, and so the Governor and Lieutenant Governor have supported recreational marijuana because of the social justice issues and the justice issues in terms of people who have had small amounts of marijuana have been arrested, have been put in jail over many, many years, and have had lives ruined. And so I think what they've been asking for immediately is decriminalization of marijuana so people don't go to jail and consideration of some of those extreme sentences that have been done. And the other is an economic issue in terms of the taxes that could be developed.

In States that have had medical marijuana programs and then have added recreational marijuana programs, they have been able to continue robust medical marijuana programs. A lot of it would have to do with the tax structure and how it's taxed and many others. I think the key would be the specifics about how the law was done and how it was implemented, but I feel confident that we
would be able to continue our robust Medical Marijuana Program even if recreational marijuana was legalized.

REPRESENTATIVE KNOWLES: Thank you very much.

SECRETARY LEVINE: Sure.

REPRESENTATIVE KNOWLES: I got the feeling that both the Governor and Lieutenant Governor were talking about legalization. They were talking about marijuana as not being a crime.

SECRETARY LEVINE: The -- yes.

REPRESENTATIVE KNOWLES: So, I'm not hearing about -- I'm hearing full legalizing marijuana, and that scares the hell out of me.

SECRETARY LEVINE: So, the first thing they talked about was decriminalization, and then they did talk about legalization of marijuana. But again, from a social justice point of view and from an economic point of view.

REPRESENTATIVE KNOWLES: Thank you, Madam Chair.

SECRETARY LEVINE: Sure.

REPRESENTATIVE KNOWLES: Thank you.

MAJORITY CHAIRWOMAN RAPP: Thank you, Representative. Thank you, Secretary Levine.

SECRETARY LEVINE: Thanks.

MAJORITY CHAIRWOMAN RAPP: Representative Brad Roae.

REPRESENTATIVE ROAE: Thank you, Madam
Chairwoman, and thank you, Secretary. My question is regarding, you know, Governor Wolf and Lieutenant Governor Fetterman have both, you know, advocated for making marijuana, you know, recreational, legal. My question is how would a State law be designed that was somehow supersede a Federal law that says marijuana is illegal? And if we did do that somehow, what impact would that have on hemp and CBD oil? By supersede I mean, you know, Federal law supersedes State law, so like we can't pass a State law that says you drive on the left-hand side of the road because the Federal law says you drive on the right side of the road. So, the Federal law says all marijuana is illegal. How do we pass a State law that basically does away with a Federal law?

SECRETARY LEVINE: So, I'm not an attorney, and so I'm not the expert in terms of the legal system of Federal laws and State laws. Of course, we did pass and have implemented a medical marijuana law in the face of it still being a DEA schedule I substance. And there have been, I believe, 13 States that have done that. But I'm not the right person to ask about the legal aspects of it. My job has been to implement the Medical Marijuana Program. Again, other States that have gone from a Medical Marijuana Program and then legalized nonmedical marijuana or legalized recreational marijuana have been able to
continue robust Medical Marijuana Programs. A lot of it would have to be due to the specifics of how it is implemented and how it would be taxed. And so we'd have to have a robust discussion with many policy experts about how to do that, but I feel confident that we could continue our Medical Marijuana Program. But in terms of the legal aspects, I'll defer to you all and the lawyers.

REPRESENTATIVE ROAE: Thank you.

MAJORITY CHAIRWOMAN RAPP: Thank you, Representative, Secretary. Representative Daley.

REPRESENTATIVE DALEY: Thanks, Madam Chair. I should also say that I served on the Medical Marijuana Working Group. I think that was in 2016 we were working on that. And I just have to say that it's really heartening to hear you speak about it, Dr. Levine, because I think you're talking about it exactly the way that those of us who worked on that wanted to see it happen.

But my question is actually about hemp and the research. So, on the Medical Marijuana Committee I was one of the legislators who was really interested in seeing research done because we could do research in Pennsylvania, but it hadn't been able to be done on medical marijuana for all of these years. You know, the Federal Government wouldn't support research, so we thought that we had an opportunity to actually add to the knowledge.
So, now in the hemp area where we seem to be a real leader -- and you mentioned in the PowerPoint I saw that there was a 2017 Pennsylvania pilot research program, the Pennsylvania Farm Bill had a specialty crop block grant. So, could you talk a little bit about what the research has focused on? Because one of the things that I kept hearing when we were talking about hemp originally was this excitement that it was a crop that was kind of an ancient crop and being able to be brought back in a legal kind of way and all of the different uses.

The CBD obviously is of great interest, and I'm very happy to hear that we're all in agreement that that needs to be looked at. But I am interested in generally what kind of research is being done, and are those dollars being accessed for hemp research?

MS. KRAK: Sure. I appreciate the question. Secretary Redding often talks about how this is a crop that we lost about 70 years of any experience, and imagine -- you know, we've seen so many advances in agronomy for crops such as, you know, corn or soybeans and we've lost that with hemp. Some of the research in the beginning was literally how do you grow this? If you get it to grow, how do you harvest it? The fiber varieties are incredibly strong and will -- you know, the first year we saw them taking combines apart. So, there's specialized equipment
that is needed. There are agronomic principles that we need to keep working on just to successfully grow hemp. And then you have a lot of research that is needed on how to utilize it in all of its forms. So, I think the beginning of the research program was pretty basic and just how do we get this crop to grow and what are the different impacts of various growing conditions.

One thing we found last year is that hemp that's grown in Canada or in Colorado, they have very different growing conditions, different soil, and that can have an impact on even the THC levels or the CBD levels of the final crop. So, that's part of why we're really happy to have both a prohibited variety of, you know, plants that just did not work in Pennsylvania and are not hemp, as well as those varieties of concern so that you can see this many growers last year had an issue of being over the .3 percent to help provide more information to our growers as they're making these business decisions.

For the Specialty Crop Block Grant Program, we had that available for especially on the agronomic side, research in that vein. I'm not as familiar with what the other allowable uses are, but we can certainly get back to you with that program. That is part of the Governor's request in the budget again this year, to fund that program again.
MR. STRATHMEYER: So, just to tag-team a little bit, you have to remember, as Natalie said, the public hasn't seen this crop in 80 years, so a couple three generations. One of the challenges that the hemp growers have is in fact the marketplace itself, identifying the market. And also a lot of the infrastructure that is required whether, you know, from -- once you have a processor, that's not the end of the product line, the supply chain. There typically are two or three steps beyond that.

I had the good fortune last week of being out in the Pittsburgh area. There's a plastics manufacturer out there that we are now talking to that is telling me that he just needs -- he's very interested. It's on their radar. But there are pieces of this research that you're referring to that need to happen for this industry.

If I can tell you one thing, what I'm hearing around the State is that although the CBD in the hemp area seems to be an area of we'll call the quick dollars, sustainability is going to be in the fiber, and I'm very strongly believing that the more I get around the State, the more I get around the product, I believe very strongly that our sustainability is going to be in the fiber and not necessarily in the CBD.

REPRESENTATIVE DALEY: So, I went to the
Pennsylvania Farm Show, as I'm sure many of us did, and the hemp display I thought was one of the more interesting because it's new, but the variety of products was just really fascinating, and the fabric was very nice. But it was more than fabrics. It was just all kinds of different items. So, I really appreciate the fact that we have this hearing today. It's really interesting. And it gives the farmers new things to be growing.

MAJORITY CHAIRWOMAN RAPP: Thank you, Representative. Thank you, Members.

I'd like to note the presence of Representative Jim Cox, who, by the way, was very instrumental in the medical marijuana bill. Jim, I hope you don't mind me saying that, but I know you were up front with that.

So, Representative Zimmerman.

REPRESENTATIVE ZIMMERMAN: Thank you, Madam Chair, and I appreciate the testimony this morning. I just want to give a shout out to both Deputy Secretary Strathmeyer and also Natalie as Policy Director for a really well done presentation, so it was well done, good information.

My question is really for Dr. Levine, and that revolves around -- so marijuana-derived CBD, does all of that contain some level of THC?

SECRETARY LEVINE: Yes.
REPRESENTATIVE ZIMMERMAN: All right. Thank you.

MAJORITY CHAIRWOMAN RAPP: That was quick, Representative.

Representative Schlossberg.

REPRESENTATIVE SCHLOSSBERG: Thank you, Madam Chair. And thank you, Madam Chair, for holding this hearing. Thanks to all of you. This is really interesting. It's an area that I've gotten involved with a little bit, and it's something that I hope people understand is really important to our constituents.

There's survey data out there that's six months old now that shows one in seven Americans have tried CBD, and we know that number is only going to keep going through the roof.

Two questions, and the first one, Dr. Levine, I'll address to you. There is research that shows that CBD can potentially help with a variety of physical and emotional ailments, but there are also concerns about its drug interaction and long-term impact on liver function. As medical practitioners, is this a concern of yours, and is there anything we can or should be doing about it right now as we have these conversations?

SECRETARY LEVINE: Sure. So, all medications have their benefits and they have their potential side effects, including many over-the-counter medications that
we commonly buy. And so that isn't new that medical marijuana as a medicine will have benefits and have some potential side effects. And so I think that we need more research about the benefits, about the side effects of CBD-rich medical marijuana, medications, or CBD medications from hemp, and we need more research about more THC-rich medications.

And so that is the beauty of the Chapter 20 program. I think that, you know, it's just getting started. Some of the CRs were approved about two weeks ago. But I'm hoping that as the clinical research program matures over the next number of years that Pennsylvania will actually be one of the national leaders in medical marijuana research, including the benefits and including the side effects.

REPRESENTATIVE SCHLOSSBERG: And we would actually need separate law for CBD-related research, right, because the research you've been discussing is explicitly related to medical marijuana?

SECRETARY LEVINE: No.

REPRESENTATIVE SCHLOSSBERG: No?

SECRETARY LEVINE: So, the CBD-rich medical marijuana in our program will be researched by the ACRCs, and so, you know, when you go to a dispensary, there are many different medical marijuana strains and many different
ratios of compounds, and so there are particularly CBD-rich compounds. They do contain some THC, but they are particularly rich in CBD. And those will be researched. If you want to do research on CBD from hemp, you can buy that in Pennsylvania. You'd probably want to have a distributor where you know -- not getting it from Turkey Hill but to get it from a known distributor -- nothing against Turkey Hill -- but that you would get it from a known, you know, distributor and know what you're -- I mean, with any research, you want to know exactly what's in it. And you could do that anytime.

REPRESENTATIVE SCHLOSSBERG: And that's actually my second related question as it comes to the commercial sale of CBD. I know, ideally, regulations should come from the Federal level when it comes to labeling requirements and regular testing, and we desperately need regular testing. It sounds like State action may be necessary because the FDA has said it could take up to five years for them to get more involved with labeling. Fortunately, if I'm understanding correctly, there are private companies that do some of this testing and they can certify what's in CBD.

We're having conversations about labeling and about testing. Has anybody had the conversation across the Nation about whether or not States should get more involved
in regulating the sale of CBD like selling it in a grocery store given that there are medical interactions?

SECRETARY LEVINE: I --

REPRESENTATIVE SCHLOSSBERG: And is that something that's appropriate? I don't know.

SECRETARY LEVINE: So, again, different States have done different things, but, I mean, no one has maybe done it best yet. But I think that that would be one of the issues. I think that the labeling, the quality control is critical with these compounds because whether the FDA says that they're not medicines, they're being used as medicines.

REPRESENTATIVE SCHLOSSBERG: And you could buy them off the internet right now.

SECRETARY LEVINE: Exactly. And, again, nothing is saying that those compounds that you buy at the convenience store are made in Pennsylvania. They could be made anywhere. And so that's another issue in terms of our industry is that those compounds are made throughout the country.

MS. KRAK: Yes, just to jump in on the discussion about research, Secretary Levine is absolutely correct. You can do research on hemp-derived CBD today. We would certainly encourage working with Pennsylvania growers, and to do that they would just need a permit, same with
Pennsylvania processors. We think there's a lot of opportunities there, but it's a fair point, you know, a lot of the CBD products that you see in grocery stores, there is no labeling or requirement of a State identification. Much of the product could be from Colorado or other places, but we would certainly encourage working with Pennsylvania growers and processors.

REPRESENTATIVE SCHLOSSBERG: Because there is nothing that could stop somebody from throwing something in a bottle, labeling it as CBD, putting it in a gas station, and saying this is CBD.

MS. KRAK: No. I would say the limitations are it is illegal to say that there are medical applications for it --

REPRESENTATIVE SCHLOSSBERG: Right.

MS. KRAK: -- and it is illegal to put it in food and beverages per the FDA.

REPRESENTATIVE SCHLOSSBERG: But other than those pretty broad restrictions, everything I -- that's pretty frightening.

SECRETARY LEVINE: The other point I want to make is that the laboratories that we use, the six, I believe, laboratories that are approved to test our product would be extremely pleased, I am sure, to get the business to test the product from hemp and could do that.
MS. KRAK: I do think one follow-up, we've had a lot of discussion about how there is no regulation on the hemp-derived CBD side, and I just want to make clear that is not because hemp growers or processors for the large majority are trying to do anything nefarious or avoid any sort of regulation. I think you'll hear later from other panelists that folks within the industry are taking this lack of regulation very seriously and in some instances are instituting their own testing and things like that. There is a need for ideally Federal action and the standard across the States, but lack of Federal action may lead to a patchwork of States.

REPRESENTATIVE SCHLOSSBERG: Thank you very much.

MAJORITY CHAIRWOMAN RAPP: Thank you.

Representative Gaydos.

REPRESENTATIVE GAYDOS: So, if I understand that the Department of Agriculture issues permits that allow hemp producers to produce CBD with THAT'S CORRECT in it?

MS. KRAK: Yes. So, we regulate the growth of hemp, including varieties that hemp is going to have THC in it up to .3 percent THC. That's the legal limit for hemp. So, whether you're growing for fiber or for CBD, you need a permit from us in order to grow. There are some restrictions, like you can't grow for personal use. You
have to be growing for a commercial-level production. And we this year started permitting processors so that we're aware of who is doing processing, whether that's for industrial uses or for CBD.

REPRESENTATIVE GAYDOS: So, who tests for the THC?

MS. KRAK: We do at the Department of Ag's laboratory, but then we also have contracts -- or folks can contract with private labs around the country.

REPRESENTATIVE GAYDOS: And then what else do you test for? You know, do you test pesticides, metals, bacteria?

MS. KRAK: At this time the only tests required at the Federal level is a THC test.

REPRESENTATIVE GAYDOS: Okay. And I have a second question. I understand that in the regulations it says it has to pass a certified sampler. What are the qualifications to become a certified sampler?

MR. STRATHMEYER: So, we're currently working on that. It's part of the interim rule.

REPRESENTATIVE GAYDOS: Okay.

MR. STRATHMEYER: Essentially, what we're going to say is that we're going to follow the guidelines that DEA has put out, but what we're looking for and have actually been approached by other people in agriculture
that are certified examiners or certified inspectors, milk inspectors, you know, people that inspect honey, other people that already have that mindset are a lot of the people that we're, you know, being approached by and saying can we be. So, we're setting those guidelines currently and hope to have those guidelines out here very shortly, but yes.

REPRESENTATIVE GAYDOS: So, currently, there's no definition of certified --

MR. STRATHMEYER: And there never was.

Understand, Representative, that is a whole new piece --

REPRESENTATIVE GAYDOS: Got you.

MR. STRATHMEYER: -- of the interim rule. That is nothing that we were required to do before. That is all part of the new requirements of the interim rule. So, it's not that we weren't. And then, quite frankly, even taking samples themselves, the farmers actually were the ones that took their own sample, took it to a laboratory, got it tested or sent it in to us. We did some auditing basically at the Department. We gathered samples ourselves. So, that whole area has kind of been built around a little better rails right now.

REPRESENTATIVE GAYDOS: And, no, I mean, I commend you all for addressing this, so thank you.

MR. STRATHMEYER: Yes.
MAJORITY CHAIRWOMAN RAPP: Thank you, Representative.

Representative DeLissio.

REPRESENTATIVE DELISSIO: Thank you, Chairwoman.

Deputy Secretary, is there currently a charge for permits now?

MR. STRATHMEYER: Yes. The new charge this year is $150. Last year, it was $600. The year before that it was $2,000, and the year before that or within that same year it was $3,000.

REPRESENTATIVE DELISSIO: So, it is currently $150?

MR. STRATHMEYER: Currently $150 --

REPRESENTATIVE DELISSIO: Is that --

MR. STRATHMEYER: -- and that is for farmers as well as processors. It's the same number.

REPRESENTATIVE DELISSIO: And is that an annual permit that somebody has to --

MR. STRATHMEYER: Correct.

REPRESENTATIVE DELISSIO: -- apply for and remit?

MR. STRATHMEYER: Correct.

REPRESENTATIVE DELISSIO: So, $150.

MR. STRATHMEYER: And, again, Representative, that is under the guidelines and the guise that we're playing by today. It's not to say that depending on the
Federal Government, if they come back with different rules as a final rule that we wouldn't adjust to that.

REPRESENTATIVE DELISSIO: So, then are those permits issued to individuals or can they also be issued to organizations or companies? Because I see there's, you know, about 300 permits, 800-some growing locations --

MR. STRATHMEYER: So --

REPRESENTATIVE DELISSIO: -- so obviously somebody has multiple growing locations.

MR. STRATHMEYER: So, this year what we're doing is it's going to be by the location quite frankly. So, if you have three locations on your farm, that's still one permit. If you have a location here and down in the next county you've got another location, in the next county you've got another, then that's three permits. The idea here is that we need to know where the product is.

One piece of this that we haven't really discussed much is law enforcement. They are also at the table in this workgroup that Secretary Levine has talked about. Law enforcement is there as well. And so we are making sure that because a lot of times the burden becomes part of their problem, whether, you know, they see the product -- remember, marijuana and hemp, they look the same, and so when law enforcement is dealing with it, they're dealing with a plant that looks the same. So,
we're trying to do our best to make sure that all parties are working together here.

REPRESENTATIVE DELISSIO: You mentioned that the processors must be permitted now, but you used the phrase "to their front door." Does that mean that you don't go inside to inspect a processing plant? I mean, was that literal?

MR. STRATHMEYER: So, again, the answer is sort of kind of yes. The answer is that our jurisdiction does not allow us to -- whatever is going on inside the processing plant is not in our purview. So, to Dr. Levine's point about where this gets a little bit gray is that the raw material is delivered to the processor. They get the proper documentation, i.e., they have to buy it from a permitted grower, and the permitted grower has to have documentation that the material has been tested. Once that happens, it's their product. They take it inside, and they process it. It is the part of this action that we don't have any control of the CBD material that comes out of the back side. Hence, you know, the Representatives relating to, you know, what's in it or what's not in it, that's part of the issue, and that's where we are continuing to hope for better guidance from FDA and our Federal partners.

But in the meantime I can tell you, as Natalie
said, our growers are really good growers. They're good people. There is no intention of showing up at the door with the wrong material. So, we're very proud of our growers here in the State of Pennsylvania. They've really stepped up and followed the rules.

MS. KRAK: Sorry. Just to add to that a little bit, with USDA's interim final rule, their jurisdiction ends at the farm gate. Their sole concern is whether that is compliant with a THC test. Part of why we have continued to work methodically at our program is because the Feds are making decisions and changes that, as Fred mentioned, have impacted some other States that have passed laws. So, we have taken it a step farther to actually track that plant material to the processor level so that we can make sure that plant material going in is not only compliant with THC tests but also that if folks are disposing of seeds, that they're not just getting dumped into a compost pile and then we have hemp sprouting in areas that aren't permitted.

So, that's part of our rationale for why we extended. At the State level we actually took it a step further to be aware of those processors. That helps out law enforcement, as well as making sure that the product is compliant with the rules that we have to date.

REPRESENTATIVE DELISSIO: And I'd be curious if
anybody has applied to the PA preferred program for any product to be approved under that --

MR. STRATHMEYER: We have.

REPRESENTATIVE DELISSIO: -- or stamped under that program for hemp --

MR. STRATHMEYER: We have, and the answer is no.

REPRESENTATIVE DELISSIO: -- or CBD. They have applied, but the answer has been no?

MR. STRATHMEYER: Because, typically, the products, as you know, the PA preferred program, it would be juice or something like that where it would end up being a product, a food product. And, as Natalie and myself have both said today is that is not allowed, and currently that's the stand that the State is taking is that we can't allow it -- of our own knowledge allow it to be in that food product.

REPRESENTATIVE DELISSIO: Thank you, Madam Chair.

MAJORITY CHAIRWOMAN RAPP: Thank you, Representative.

At this time my Executive Director has a few comments, questions, and that'll be the final for this panel. And so, Whitney, go ahead.

MS. METZLER: Well, actually, I have a number of questions, but this is being offered to the Members. As usual, if you have any questions that come up later for
this panel and they have left, email either Eric or I and
we will send it off to the departments and happily get you
an answer as usual.

So, the hot crop that you had referenced -- and
there's the destruction of it -- is there any interaction
or has there been any discussion at the administrative
level for interaction between the hemp product that is sold
and is now deemed hot, so therefore, I'm assuming the THC
level of above .3 percent, and any interaction with the
Medical Marijuana Program? Because it seems like these are
two programs that are operating side-by-side that really
could have a collaborative relationship.

SECRETARY LEVINE: So, under the law there can
only be a certain number of growerprocessors that are
participating in our Medical Marijuana Program, I believe
25 growerprocessors. And then we had round one and round
two to produce those. And so we would not be participating
with any other growerprocessors besides those that went
through the full RFA, two rounds of RFAs to be approved.
And then there are the clinical registrants through another
approval process. So, we would not be accepting any
product from any other farm. Under the law it has to be
under the growerprocessors in that system.

MAJORITY CHAIRWOMAN RAPP: Thank you, panel.
This was very informative. I think we probably have more
questions now than when we started, but this was very
informative. You are very knowledgeable, and we truly
appreciate your time in attending today.

MR. STRATHMEYER: Thank you. Thank you for
having us.

MAJORITY CHAIRWOMAN RAPP: And we may ask you
back.

MS. KRAK: That's fine.

MR. STRATHMEYER: Thank you for having us.

MS. KRAK: Thank you so much.

MAJORITY CHAIRWOMAN RAPP: Thank you. Our next
testifiers and panel is Billy Woolf, who is the Chief
Operating Officer for the Steep Hill Laboratory of
Pennsylvania. Gentlemen, please have a seat. And, Dr.
Steve Groff, who is the founder and Chairman of Groff North
America.

So, Mr. Woolf, are you going to be the first
presenter?

MR. WOOLF: If that's okay.

MAJORITY CHAIRWOMAN RAPP: That's fine.

Whatever. So, proceed whenever you're ready, sir.

MR. WOOLF: Thank you. Chairman Rapp and Members
of the House Health Committee, my name is Billy Woolf. I'm
the Chief Operating Officer of Steep Hill, Pennsylvania, a
licensed medical cannabis testing laboratory. I appear
here today on behalf of the Pennsylvania Cannabis Coalition.

In sharp contrast to our Pennsylvania medical marijuana law, which brought access to high-quality cannabis products to patients through a controlled and regulated supply chain, the de-scheduling of CBD in the 2018 Farm Bill unleashed a flood of hemp-derived CBD products to an unregulated retail market with unprepared consumers. The legal and social stigma of over 80 years of cannabis prohibition have left a huge knowledge gap in our understanding of the cannabis plant and its uses. Confusion abounds as our citizens lack the confidence to make important choices about new treatment options that may improve their own health. As stakeholders in the well-being of every Commonwealth citizen, now is the time to raise our own awareness of the plant's beneficial properties and uses if we are successfully to advance meaningful new law and policy.

A proud son of Harrisburg, I grew up just a few blocks up the street on this very same North 3rd Street, but I took the path less traveled to get here today for this special trip downtown. Along the way, I've earned degrees in analytical chemistry, biomedical engineering, and project management, attended law school, worked professionally in medical research and data consulting, and
owned and operated a steel construction business for over 25 years here in central Pennsylvania.

Without any good options for cannabis training a few years ago, I assembled a curriculum of my own from few resources. Industry certification as a patient-focused certification verified professional through the Americans For Safe Access validates my training in best practices. And the Oaksterdam Cultivation and Business Programs highlights the breadth of my industry preparation. Whether it be destiny or career renaissance, it is truly satisfying to work in a new field that requires me to use every one of my technical and business skills in the operations and compliance work I perform daily as a cannabis professional.

And now, as an educator, I pay this knowledge forward as an adjunct professor of medical cannabis education at HACC, central Pennsylvania's community college, where I prepare passionate students with the workforce skills needed to succeed in this exciting yet challenging new industry.

Thank you for the opportunity to provide my testimony before you today.

Generally speaking, there are two important types of plants in the world of cannabis: medicinal plants and hemp plants. Industrial hemp plants are grown for fiber and hempseed oil. Medicinal plants include both
psychoactive THC-rich plants and non-psychoactive CBD-rich plants. The main difference between hemp and medicinal plants is the amount of resin they produce. Hemp plants are low-resin plants, and medicinal plants are high-resin plants.

Industrial hemp varieties are typically a low-resin agricultural crop, grown from pedigree seed, with about 100 tall, skinny plants per square meter, machine-harvested and manufactured into a multitude of products. Medicinal plants are a high-resin horticultural crop, typically grown from asexually reproduced female clones, one to two plants per square meter, hand-harvested, dried, trimmed, and cured.

The modern era of medical marijuana began in the early 1960s with the isolation of CBD and THC molecule by Dr. Raphael Mechoulam, an Israeli scientist. Inspired by centuries of anecdotal evidence of cannabis healing, Mechoulam's research group continued to uncover the relationship between beneficial plant compounds and their physiological interactions within the endocannabinoid system within our bodies. Dubbed the father of medical marijuana, Mechoulam's work was peer-reviewed and accepted by the scientific and medical communities in 1992, which led the way for California to become the first State to legalize medical marijuana in 1996.
Pure THC and CBD are both odorless and colorless at room temperature, have the same molecular formula and molecular weight, but are found only in small amounts in the raw plant. They are just two compounds from a family of around 113 cannabinoid compound found naturally in cannabis. Only a slight difference in molecular structure is what gives the two compounds entirely different pharmacological properties. The final products of THC and CBD are actually converted via a chemical process called decarboxylation, from their acid form precursor THCA and CBDA, which are produced in much larger amounts by the plant.

The main difference between THC and CBD is that THC is psychoactive, and CBD is not. CBD has significant medical benefits and can actually counteract the psychoactivity of THC. This makes CBD an appealing treatment option for patients seeking antiinflammatory, antipain, antianxiety, antipsychotic, or antispasmodic effects without troubling lethargy or dysphoria. Though psychoactivity can be seen by some as an undesirable side effect, THC on its own is used effectively in many ways as an analgesic, antinauseant, antianxiety, appetite stimulant, sleep aid, and to reduce the chronic pain of muscle spasticity.

THC and CBD are the power couple of cannabinoid
compound because they work best together. Scientific studies have established that CBD and THC interact synergistically to enhance each other's therapeutic effects. CBD combined with THC require lower effective doses, have a wider therapeutic window, potentiate THC's antiinflammatory properties, has a more potent antitumoral effect in certain cancer treatments, and is more beneficial for neuropathic pain than either compound as a single molecule.

In addition to THC and CBD, cannabis contains several hundred compounds, including various flavonoids, aromatic terpenes, and many minor cannabinoids. Each of these compounds has a specific healing property, but, when combined, they create what scientists refer to as an entourage effect where the therapeutic impact of the whole plant is greater than the sum of the individual parts.

While it may be possible to extract CBD from some low-resin industrial hemp cultivars, fiber hemp is considered a poor source of CBD because it typically contains far less CBD and lacks critical medicinal terpenes and other plant compounds that interact with CBD and THC to enhance their therapeutic effect. Huge amounts of industrial hemp are required to extract even a small amount of CBD, thereby raising the risk of contaminants because hemp is a bioaccumulator that can draw harmful substances
from the surrounding soils.

Unfortunately, the lack of oversight in manufacturing hemp-derived CBD products has led to confusion, deception, and contamination. Blind testing of unregulated hemp-derived products has found that many are mislabeled as to CBD and THC content. Poorly processed CBD products may be contaminated with dangerous solvent and pesticide residues, heavy metals, microbiological threats, thinning agents, corn syrup, artificial flavors and colors, and other toxins.

Until confidence in retail CBD products can be assured through a program that includes laboratory testing, we encourage citizens with qualified conditions seeking CBD therapy to register in the safety of the Medical Marijuana Program. Doctors and pharmacists and other skilled professionals are already available to guide and train new patients toward micro-dosed therapies with low or no psychoactivity. However, well-intending citizens who may not qualify for the program ironically remain at risk of harm from unregulated retail products.

Thank you again for your invitation to appear today, and I welcome any questions you may have.

DR. GROFF: Good morning. I want to thank the Chair and Committee Members for this opportunity to speak with you today about hemp, cannabis, and our company's
efforts in this space and our vision of the tremendous opportunities for the Commonwealth and its citizens. I would like to think that we can shed some more light on some of the controversial discussion that's taken place here so far.

A quick background on myself, I was born in a farming family in Lancaster, Pennsylvania, a Pennsylvania native. I decided to go another direction from dairy farming. I forged a path into medicine, graduating from Albright College, University of Virginia, and I completed my orthopedic surgery training at Penn State University at the same time that Dr. Levine was there, so we crossed paths at Hershey for a number of years.

I built a clinical spine practice in York, Pennsylvania, starting in 1996. Along with clinical practice, I took an active role in leadership and development, ultimately resulting in the formation of OSS Health, now one of the premier musculoskeletal practices in the mid-Atlantic. Within a year of opening that hospital and developing it into a freestanding health system, I was struck by a motorist on my bicycle at 45 miles an hour sustaining a number of injuries. The most serious was an unstable cervical fracture with bleeding around the spinal cord. And me as a spine surgeon, that was pretty scary.

I was fortunate to recover but unable to continue
the surgical practice. So, in finding an act two in life, I joined with my family and developed an agritourism business and beverage business on Wyndridge Farm, an 80-acre farm in southern York County where my wife and I raised our kids. You can see a picture of it there on the screen. Since its 2014 opening, it's become an East Coast destination.

With my medical credentials intact -- I'm a board-certified orthopedic spine surgeon and licensed in Pennsylvania -- 2017 found me looking for some next steps in life, and I began to study cannabinoids, CBD, and hemp. And after seeing an opportunity with the 2018 Farm Bill, we decided to enter the space. Our family started a business called Groff North America, which is an integrated agritech company based on hemp. We have utilized the thesis of using the entire plant for seed nutritional value, medical use from cannabinoids, and industrial use of fiber from the stalk. We've built out a platform that has quickly pushed us into a leadership position in this space both in Pennsylvania and beyond.

Our team consists of experts from medicine, medical device manufacturing, industrial organic chemistry, and cannabinoids. We have invested heavily in creating a research park complex in York, Pennsylvania, specifically Red Lion, a town that was once a proud cigar-producing
actually capital of the country. And it's fallen on some
tough times, and we're proud to be there.

We have acquired advanced technologies that will
help us lead this industry both in the cannabinoid side, as
well as the fiber side. We've developed Farmacy Partners,
a retail and clinical arm with a flagship location in York
and six new locations set to open in 2020. I have
developed a clinical medical practice based on research,
education, and treatment of patients with multiple
conditions using hemp-based cannabinoids, which I need to
point are the exact same molecules in the high-THC cannabis
plant, as well as low-THC known as hemp. And that is
something I really want to emphasize as we try to educate
folks here making legislation.

Farmacy Medical Advisors is a physician group
that we formed consisting now of six clinicians from
Pennsylvania, among them sharing eight board
certifications. This group expects to receive a Federal
clinical research permit for a number of studies involving
these molecules.

Over the last 15 months we have counseled,
treated, and followed hundreds of patients, gaining
invaluable direct insight into patient results. This
community resource has been very well-received and will be
expanding into Hanover and Lancaster by May 2020.
Our commitment to whole-plant utilization has led us to work with Pennsylvania farmers and grow 2,000 acres of what we call dual-purpose hemp crop in 2019. That was 50 percent of the hemp grown in Pennsylvania this past year. This was the largest growth of this type of cultivar in 80 years in Pennsylvania. Our State was once home to the largest U.S. hemp growth in the 1940s and is known as Hempfield, Lancaster County, today.

We feel that Pennsylvania is poised to help guide this entire industry forward given the progressive policies implemented by the Department of Agriculture and Secretary Redding. Obviously, we heard from Secretary Strathmeyer earlier. They allowed unlimited acreage to permittees and also had prompt development of a USDA-approved hemp plan.

Our hemp research park, known as Hemplex, has a cannabinoid laboratory which will be opening in April, and this will feature leadership by myself and renowned scientist Dr. Dan Batzel, a Scranton native and organic chemist. Under his direction, our facility will feature the most advanced and environmentally friendly extraction, isolation, and formulation capabilities in the industry. We are building a pharma-grade facility that meets or exceeds any of the medical cannabis programs in the country.

It is important to note that our company is not
invested or involved with marijuana, medical or otherwise. We feel, however, that it's important to make some clarifications which are pivotal in making sound decisions in regulatory and legislative matters. Recognizing that marijuana or high-THC cannabis is still illegal at the Federal level and a stigma still exists, we think it's important to point out the similarities and differences between hemp, which is truthfully known as low-THC cannabis, and high-THC cannabis, which is known as marijuana. Those terms are more accurate and throughout the industry are being applied. Marijuana is a term that's really going away. Both are cannabis plants, and that was mentioned earlier. I think it's important for everyone here to understand they're both cannabis sativa plants. One simply has a high THC; one has THC below .3. The remaining molecules are exactly the same in both high and low-THC cannabis.

The psychoactive component that is often referred to is THC. CBD is also a very important molecule. Those are the two main molecules discussed, although, as my colleague here pointed out, there are well over 100 cannabinoids in these plants, again, the same molecules in both plants. Plants with THC below .3 are considered hemp, and if the THC is above that, it's considered marijuana or high-THC cannabis to be more accurate.
Medical marijuana is really just potent cannabis that's grown typically in stringent conditions and typically indoors, and hemp can be grown indoors or outdoors. So, there really is no such thing as medical marijuana. Cannabis either has high or low THC, and its use medically or not medically to be clear.

And I make this point because, as a clinician and a scientist, I know that the potential groundbreaking medical advances that can come from the use of these cannabinoid molecules, can be derived from either class of plant, either class of plant. Hemp is not just rope and fiber. Hemp is not just CBD, as the research from Penn State Hershey showed last year.

And I'd like to take a moment and refer you to an article that I added to the packet. This is a research paper from Penn State University, where I trained and Dr. Levine also trained. It's a research article that was funded by tax revenue from the cannabis program, the Medical Marijuana Program. It looks at colon cancer and use of what we call cannabinoids in treating colon cancer. For years anecdotally people talked about cannabis being able to have a number of medical effects, which we're talking about, number 23 here in Pennsylvania. Killing cancer cells is one of those. And this paper shows that cannabinoids were effective at reducing the growth of colon
cancer cells in a lab. But if you look at this carefully and very few people have -- this paper shows that THC and CBD had no effects on killing the cancer cells whatsoever. There were 10 other molecules known as cannabinoids, minor cannabinoids that were involved in killing these cancer cells. So, what this paper shows is that hemp can kill cancer.

And so one of the key things that I want to bring to this Committee's attention is that these molecules have powerful effects, and they are the exact same in hemp and cannabis. They can be grown differently. Hemp can be grown in a greenhouse under the exact same conditions as current medical marijuana growth here in the State. So, I think that's very important. So, here we have hemp killing colon cancer. No one brought that up, but that's the takeaway message. THC and CBD had no effect on those cancer cells.

I've been a licensed physician in the State since 1991 treating thousands of patients with surgical and nonsurgical care, mostly nonsurgical. I witnessed firsthand the national release of OxyContin, a powerful and addictive long-acting narcotic from Purdue Pharma, a company now disgraced and bankrupt. This, with a simultaneous decision by the Federal Medicare program that patients were not having their pain treated aggressively
enough. Programs were put in place that would punish physicians if patients didn't have their pain treated well enough. This became the foundation, this was the foundation of our country's disastrous opioid crisis.

Cannabis has been used by civilizations for many centuries, and by this I mean low- and high-THC cannabis, hemp and marijuana. Society has used the hardy plant for food, fiber, and medicine. It was well received and widely used. In the late 1930s the U.S. Government lumped both types of cannabis together in a Federal prohibition that we're all familiar with, and that still exists for high-THC cannabis today. Let's remember all those programs, 33 right now in the country that have established Medical Marijuana Programs, they're federally illegal. That's a fact. I'm just giving that as a fact.

Thirty-three States have established these programs following California's lead in 1996, defying Federal statute. The Federal Government has overlooked these programs now with 11 States actually approving adult recreational use that was mentioned earlier. U.S. cannabinoid research on cannabinoid medicine lags seriously behind countries like Israel. And this was mentioned earlier. Dr. Raphael Mechoulam is a pioneer in this space and really was one of the first people to study the endocannabinoid system, which is the set of receptors in
our body that are actually designed for these cannabinoid molecules.

I believe that our country will rapidly catch up and surpass the rest of the world in medical cannabis research. Most States like PA commit a portion of their tax revenue for clinical research programs, much like where this article came from talking about cannabinoids killing colon cancer cells.

The Pennsylvania Medical Marijuana Program is just a few years old. It's robust and growing with nearly 2,000 active patients, as Dr. Levine shared earlier. This well-run program has allowed these patients to utilize the plant after their condition is certified by a qualifying physician. There's no prescribing of medical marijuana. I have added that service to my practice over a year ago. I found it to be extremely gratifying and educational as few clinicians in this country, let alone in Pennsylvania, truly see these results at the frontline as our company and our team does.

Farmacy Advisors, the medical group that I formed, plan to obtain a Federal clinical research permit to complete further studies as an independent, privately owned organization. There is much needed data on low- and high-THC cannabis treatments, once again, remember, colon cancer being killed with no THC. I think it's an important
thing to understand as a possibility and opportunity. We're also exploring academic affiliation within Pennsylvania. As I mentioned, though, we are currently a private entity.

I have the unique vantage point of years of experience as a physician now involved in hemp and its resurgence made possible by the Farm Bill. I've been actively involved at the Department of Agriculture's Hemp Steering Committee working with the team advancing the cause for hemp. I also have a unique respect for our farming heritage in Pennsylvania and see the difficulties that American agriculture has encountered.

With farm incomes continuing to decrease, many see industrial hemp as a potential industry from an old crop. There is tremendous enthusiasm in this country and others about the positive attributes of this plant and its possibilities. 2019, however, saw some expected whipsaw effects in the market as some stakeholders took aggressive positions that were hit with market volatility. We remain a very stable company with diverse capabilities and are very bullish about the future of hemp in Pennsylvania and beyond.

Today, I would like to offer a few suggestions based on the observations that we have made. This first year, again, in Pennsylvania was somewhat rocky.
Processing was a challenge. There were many farmers that weren't able to find a place to process or purchase their hemp. The seed fiber markets will take many years to build out. There's tremendous reason to be enthused about use of the stalk from the hemp plant, the cannabis plant, but developing those markets and processing centers will take tremendous capital and commitment. And we have made a commitment to that as part of our plan.

Few people understand that hemp is actually low-THC cannabis, and I think there's a lot of comments made today that I would have to disagree with, and there's a lot of confusion. But I think you all need to understand that hemp is a cannabis plant and has the same powerful molecules with just less THC.

I would recommend not defining hemp in Pennsylvania as only seed fiber or straw, as this will destroy any hopes of significant economic impact to Pennsylvania agriculture. There is minimal margin in processing hemp or straw without the balance of using the seed and the cannabinoid from the hemp plant.

I also suggest allowing cannabinoids from hemp grown in an appropriate environment with appropriate testing to be integrated into the Department of Health medical cannabis program. This concept would allow raw ingredients and/or formulated products into the system. As
stated earlier, research into cannabinoids is producing
tremendous hope for many health issues, and we need to
expand into this area.

I would ask that you allow access to high CBD for
the general public for health wellness and consider
Pennsylvania's specific regulations for hemp cannabinoids
at appropriate levels. And I'd like to offer myself and
our team as a resource for your Committee, the Departments
of Health and Agriculture in farming, research, and
medicine to make Pennsylvania a shining example of
commonsense, progressive leadership and legislation to lead
the country.

I'm glad to answer any questions, and again, I
appreciate the opportunity to speak with you today.

MAJORITY CHAIRWOMAN RAPP: Thank you, Doctor,
very informative, gentlemen. We really appreciate your
presentations today and your written testimony.

Our first Representative with a question is
Representative Jerry Knowles.

REPRESENTATIVE KNOWLES: [inaudible].

MAJORITY CHAIRWOMAN RAPP: You are? Okay.

Representative DeLissio.

REPRESENTATIVE DELISSIO: Thank you, Madam Chair.

Dr. Groff, I think it was your last three sentences that
helped clarify for me the rest of what you were saying. I
was struggling a little bit as to where the cannabinoids fit in in this whole discussion, so they're from hemp only?

DR. GROFF: No, and I think that's an important distinction. These cannabinoids are plant molecules. THC and CBD are two of the most well-known of those. Think of salt and pepper and an entire spice rack. Salt and pepper are the two spices everyone knows about, but there's 100 other spices that are very important.

And as the gentleman next to me mentioned the entourage effect, right now, the medical conditions that we are treating in Pennsylvania with so-called medical cannabis -- and, again, I am a proponent of this --

REPRESENTATIVE DELISSIO: I got that part of your --

DR. GROFF: -- but it's a shotgun approach. We don't understand how these are working together yet. And so, just to be clear, the entourage effect is really saying they all work together and we're not quite sure how. So, I think it's just important to understand, the human body, whether those cannabinoids come from hemp or from high-THC cannabis, they're the same molecules and the same effects.

REPRESENTATIVE DELISSIO: So, do citizens have access currently to cannabinoids?

DR. GROFF: Yes, they do, and --

REPRESENTATIVE DELISSIO: Because they're the
same molecule as the THC that is in the high-THC plants?

DR. GROFF: And, to be factual, the hemp plant
and all the cannabinoids from the hemp plant are legal at
the Federal level. They are the only cannabinoids that are
federally legal because the Federal Government decided to
make it this way. THC from a hemp plant is legal both
federally. It needs to be .3 percent or less. Again, I'm
just relaying the facts. This is not my opinion; it's just
that that's true.

REPRESENTATIVE DELISSIO: So, you come out of the
traditional medical community. You're an M.D. or D.O.?

DR. GROFF: I'm a medical doctor --

REPRESENTATIVE DELISSIO: You're an M.D.

DR. GROFF: -- and I've been in practice here
since 1991 --

REPRESENTATIVE DELISSIO: Okay. So --

DR. GROFF: -- yes.

REPRESENTATIVE DELISSIO: -- do you know, what
you've presented today, is that being more looked at by
some of your colleagues in traditional medicine or they're
not sure what it is yet or --

DR. GROFF: We're talking about the same
molecules and the same processes. And I think there's a
lot of confusion between sectors trying -- again, those
molecules from hemp and marijuana are the same thing.
Hemp, if it’s going to be used in a medical situation, it needs to be very carefully grown and very carefully tested. And I think, again, hearing some of the comments earlier, our laboratory is going to be able to do full-on antifungal testing, testing of heavy metals. The testing we will be doing on our cannabinoid products from hemp will be as stringent or more stringent than the current Pennsylvania Medical Marijuana Program.

REPRESENTATIVE DELISSIO: So, do you anticipate applying for that --

DR. GROFF: No.

REPRESENTATIVE DELISSIO: -- remaining -- oh.

DR. GROFF: No, not at this point. Not at this point. And --

REPRESENTATIVE DELISSIO: I was just curious.

DR. GROFF: So, I want to just make it clear. We are invested in the hemp business, but I want to look at this from an academic standpoint and look at it for what it is across the board, that these molecules can come from both plants. And we have a tremendous opportunity here in Pennsylvania to set a leadership example by having these two work together at the highest level like some other States are doing and where farmers can benefit and patients can benefit and we can do collective research.

We are going into clinical research, and I think
that we would love to be working with the Department of Health and raising the bar for citizens of the State. Killing cancer cells, this is not the stoner play of years ago. This is about real science and real healing. And, again, myself and colleagues have treated hundreds of patients in the last year and specifically with cannabinoids and providing consultation and collecting data. Part of the reason we started doing that is because it's not being done otherwise in the State, and we saw that.

And so, again, I'm representing hemp, but I'm here representing myself as a physician, as a scientist, and someone who wants to see both these industries grow appropriately in the State.

REPRESENTATIVE DELISSIO: I appreciate that. One quick question for the other, Mr. Woolf. When you talked about the hemp-derived CBD as -- and I took from it that it's unregulated and therefore somewhat an inferior product or it seems to be, is that for a topical as well as an oral?

MR. WOOLF: It can be for all applications.

REPRESENTATIVE DELISSIO: All applications. Thank you, Madam Chair.

MR. WOOLF: These are traditionally the CBD products sold commercially in retail establishments.
DR. GROFF: Just one more point --

MAJORITY CHAIRWOMAN RAPP: Thank you.

DR. GROFF: -- I'm not here to defend the sale of a CBD product in a convenience store. And I think that there is a difference. And hopefully you'll understand what I'm trying to point out here. We're doing science. We're doing pharma-grade quality work, so that's a key thing. There's a difference, and we want to differentiate ourselves from that clearly. As hemp people, we're not advocating sale of CBD in a little plastic container over-the-counter at a C store. That's not the way it should be done, and we agree with that.

MAJORITY CHAIRWOMAN RAPP: Thank you. Thank you, Representative.

I do have a question just looking over briefly with the article from February of 2019, which is pretty recent, and the National Institute of Health supported that, and of course NIH is in the news, you know, quite a bit lately.

DR. GROFF: Sure.

MAJORITY CHAIRWOMAN RAPP: Yes. Yes, sir. And for the Members, that is at the very back of the testimony. So, is there ongoing research after this research project? Is Penn State continuing their research? And is the National Institute of Health, the CDC, anybody else, is
there other grant money going into more research in Pennsylvania in regards to the CBD?

    DR. GROFF: I can't comment officially. I'm sure there are. And then certainly the program that Dr. Levine was talking about, the C.R., the clinical registrant programs, they're being developed with some of the eight medical schools in Pennsylvania. But there are certainly other groups and other institutions around the world studying this. And this is not just a Pennsylvania or the United States. This is a global phenomenon both medical cannabis, again, high- and low-THC cannabis. That's really the way to talk about it. Using the word marijuana has really just kind of become passé. It's not accurate. High- and low-THC cannabis is really the accurate way to talk about these products.

    MAJORITY CHAIRWOMAN RAPP: And I did note that the medical marijuana, a lot of the research was done in Israel, and they seem to be a real leader in --

    DR. GROFF: Yes.

    MAJORITY CHAIRWOMAN RAPP: -- everything, in medicine and technology. So, thank you very much.

    And we have a question from Representative Daley.

    REPRESENTATIVE DALEY: Thank you, Madam Chair.

    Dr. Groff, my question I guess is directed to you. And I'm thinking that you provided information that's
really very different because I went back to Dr. Levine's testimony where she said since hemp-derived CBD products are unregulated in the production and processing to market, you're talking about a different kind of endeavor that you are making on your farm than the typical CBD or the typical hemp production? I mean, that's kind of what I'm hearing is that you don't want to be classified as one of these hemp producers with CBD products that are not regulated but that you are doing a lot of testing, you are holding ourselves to a very high standard.

So, I'm having trouble just like -- it was very interesting listening to it because having been on that Medical Marijuana Working Group, I mean -- and I heard people say that medical marijuana is not really actually an accurate term, but you're the first person that I've heard talk about it as low- and high-THC products. So --

DR. GROFF: I think I can make it very clear for you. If I --

REPRESENTATIVE DALEY: I just -- yes.

DR. GROFF: -- had a greenhouse, if I took a greenhouse and I grew hemp cannabis, low-THC cannabis in that greenhouse under stringent conditions exactly like the current medical marijuana, Pennsylvania medical marijuana rules, the cannabinoids could be isolated exactly the same, in a safe fashion, with the exact same quality. And I
think that's the confusion. Again, people are associating
the product at a C store and there's no question that the
Federal Government has not -- the USDA has not brought down
regulation. That's part of Fred Strathmeyer's challenge is
they're working within a framework. However, just remember
that the entire Medical Marijuana Program is illegal at the
Federal level. And it's just an important -- and, again, I
use it --

REPRESENTATIVE DALEY: I know.

DR. GROFF: -- and I'm part of it, supporting it,
so I'm here as a hemp investor, but clearly I'm looking at
it across the board from a scientist. And that's where I
want you and other --

REPRESENTATIVE DALEY: And that's what I heard --

DR. GROFF: -- legislators to understand.

REPRESENTATIVE DALEY: -- from you today, but I
think that what you were saying is so different at least to
me. And we spent a whole summer coming here every single
Wednesday. Jim Cox was -- we all sat in the room and
talked about this. And it was new information at that
point. But what you're bringing forward today seems even a
step further into something else to think about. And so I
really appreciate it from that point of view, but I know
that we constructed the law which became, you know, the
medical marijuana law very, very carefully. And hemp was
not really part of the discussion at that point. And we were using the term medical marijuana. You're saying that's not actually a good term. So, I feel like we have to continue to learn about this because I think you just --

DR. GROFF: I agree.

REPRESENTATIVE DALEY: -- presented information that is like -- it's new, it's different, it's a whole different way of thinking about even the way we are doing what we are doing now with our Medical Marijuana Program.

DR. GROFF: Understood.

REPRESENTATIVE DALEY: And we have to use those terms because those are the terms we have.

DR. GROFF: They're not going to go away. The academic terms in academic circles, it's more accurate -- again, the marijuana really relates to a sort of negative racial connotation. So, in academia that's really gone away. That's why I share that. It's not going to go away from the public quickly, but it's a more --

REPRESENTATIVE DALEY: So --

DR. GROFF: -- accurate term, and I just wanted you all to understand.

REPRESENTATIVE DALEY: So, I guess the other question is if NIH was supporting this work that was done with the colon cancer, was that done as hemp research?

DR. GROFF: No. And I think, to be clear, the
Pennsylvania marijuana program participated in this as well, so this was funded by in part -- there's another page from this, that this was funded as a medical marijuana project. And I just wanted to point out that in fact they were the minor cannabinoids that were killing the cancer with no THC effect. That's the only differentiator between hemp and marijuana. So, I just want you all to understand that. So --

REPRESENTATIVE DALEY: I appreciate it, but it's kind of like a complete reversal of in some ways some of the things we had talked about. And I just think it's important --

DR. GROFF: I think --

REPRESENTATIVE DALEY: -- to keep looking at it.

DR. GROFF: -- what I'm sharing is factual, and it is different, but it's factual. And keep in mind there are stakeholders that have some sway in how things are presented, and I think that's an important thing. And, again, I'm a stakeholder in hemp, but I'm sharing that the reality is what I've shared is factual, albeit maybe different than what you've heard or what was shared. I'd just like to elevate the game in Pennsylvania where we can work across the board to make this better for everybody in health --

REPRESENTATIVE DALEY: I agree. And one of the
things I learned during that, you know, back in 2016 was
that part of the reason that doctors, you know, didn't talk
about marijuana as a treatment was because it was illegal,
and they could not do that, so they weren't given --

DR. GROFF: It's still illegal.

REPRESENTATIVE DALEY: Well, exactly. It's

still --

DR. GROFF: And that's --

REPRESENTATIVE DALEY: -- illegal, but --

DR. GROFF: The point is we don't prescribe it

because we'd lose our DEA license.

REPRESENTATIVE DALEY: My point is that he said

they didn't even teach us anything about it in medical

school. We don't know anything about it.

DR. GROFF: That's correct.

REPRESENTATIVE DALEY: And I thought that was

like a really honest comment coming from a physician, an

M.D. who was down at University of Penn and was practicing

palliative medicine. And I will never forget him saying

that because you don't often hear doctors say they don't

know about something.

DR. GROFF: No, that's a great point. And I was

at University of Virginia from '87 to '91. In our

pharmacology class we had five minutes on cannabis, and the

only thing that was taught was there's no lethal dose.
That's it. And it's true. And that's an important fact. There's no lethal dose of marijuana. But now the endocannabinoid system really developed and understood by Dr. Mechoulam from Israel, that was just 15, 20 years ago. So, those of us who have trained and were in med school years ago, there's no question there's a lot of new knowledge and new research that needs to be --

REPRESENTATIVE DALEY: Well, I'm kind of hoping that somehow the Health Committee can continue to discuss this because I think there's just so many things that we don't know. And we can't really do good legislation when there are so many gaps in our knowledge.

DR. GROFF: Glad to help.

REPRESENTATIVE DALEY: Thank you.

DR. GROFF: Be glad to help.

MAJORITY CHAIRWOMAN RAPP: Thank you, Representative.

Representative Keefer.

REPRESENTATIVE KEEFER: Dr. Groff, I just have a quick question. I've read this a couple of different places, and it was one of the comments here is that hemp is a bioaccumulator, essentially it will suck whatever's out of the soil and its surroundings. Is that true also for the marijuana plant?

DR. GROFF: That's true for any cannabis plant.
REPRESENTATIVE KEEFER: Any other cannabis plant?

DR. GROFF: Correct. Correct.

REPRESENTATIVE KEEFER: So, it's not different?

DR. GROFF: Correct.

REPRESENTATIVE KEEFER: Okay. Just making sure --

DR. GROFF: And to --

REPRESENTATIVE KEEFER: -- that that is the case.

DR. GROFF: Yes.

REPRESENTATIVE KEEFER: Okay.

DR. GROFF: And that's one of the reasons we test for heavy metals in all our product and another reason why we made a commitment to an 80-acre organic -- certified USDA organic hemp farm in Gettysburg, so we will be utilizing certified USDA organic hemp, of which there's very little in the country, but we have exclusive access to that for our system. So, those are very important tests that need to be done for sure, and they're also done, pesticides. They're also done in the medical cannabis program as well.

REPRESENTATIVE KEEFER: Okay. Thank you.

MAJORITY CHAIRWOMAN RAPP: Thank you, Representative.

REPRESENTATIVE COX: Thank you, Madam Chair. My
first question is for the gentleman nearest me. Looking at
the page, it says six new sites opening in 2020. The
brick-and-mortar experience, do you have any brick-and-
mortar facilities right now?

DR. GROFF: Yes, we do. We have one in York, Pennsylvania.

REPRESENTATIVE COX: Okay. I thought you had
said that in your testimony.

DR. GROFF: That's correct.

REPRESENTATIVE COX: And so you've treated over 100? Is that the initial --

DR. GROFF: In my career I've treated tens of thousands of folks. In the last year --

REPRESENTATIVE COX: Right. And so you didn't --

DR. GROFF: Over the last year I've been counseling folks and providing certifications for the medical cannabis program, which does not involve a prescription.

REPRESENTATIVE COX: Right.

DR. GROFF: And so we've had ability to observe directly results from both high- and low-THC products. We do not participate in any high-THC product sales. It's illegal both in the State, for us in the State and federally. But we've seen tremendous results from a number of conditions, many of which are part of the Pennsylvania
program, the 23 that are noted for the high-THC program. So, yes.

REPRESENTATIVE COX: Okay. And so I guess what I'm digging at is what do you anticipate the ideal patient experience when your sites open? You know, they walk through the doors of Farmacy partners, what is that experience ideally? Or is it something where you're hoping that, you know, family doctors and so forth around the State will point people to your direction? What is your ideal model of patients coming to you, and what should their experience be if everything goes the way you hope?

DR. GROFF: Well, experience certainly would be a pleasant, comfortable experience that's approachable, accessible where they're not filled with fear or worried about stigma. So, I think we've achieved that in our first location. There was a slight picture of kind of the feel of our other facilities not unlike the medical dispensaries that exist, the medical high-THC facilities that exist in the State currently, comfortable feeling and educated and pleasant folks to interact and provide education. The folks that are working in the high-THC facilities are knowledgeable to the extent they can be, and our folks are educated to that level, at least similarly.

REPRESENTATIVE COX: Okay. And so would a patient walk in and speak with someone and say I'm having,
you know, joint pain in my elbow. Is there something that you would recommend? Is it at that level or is it more of a schedule-an-appointment kind of thing? What is that experience?

DR. GROFF: So, both opportunities exist. Currently, I see patients at the York location in a part-time basis, and we also have a retail component, maybe like a Starbucks where someone could walk in, talk to someone, and grab a high-quality product. Currently, these products, as you know, are legal by the Federal Government through the Farm Bill. And rather than folks buying stuff online where they have no idea where it's coming from, we assure supply chains that are controlled in a seed-to-shelf fashion. As I mentioned, we're using from a go-forward basis certified organic hemp, something that's very unique. So, we're very attuned to supply chain, very similar to the current system on the high-THC side --

REPRESENTATIVE COX: Okay.

DR. GROFF: -- controlling supply chain from seed to shelf --

REPRESENTATIVE COX: Thank you.

DR. GROFF: -- very important.

REPRESENTATIVE COX: My last question is for both of you. If you could nudge us in one direction or another -- and I very much would be comfortable with both of you
saying, you know, leave it as it is and let's see what happens -- but if there is legislation, if there's statutory authority that's needed or statutory restrictions that are needed, what would you advise us to take a look at first? Representative Daley pointed out, you know, this is an area we don't want to just charge right into, but if we're going to narrow our focus and say how do we best protect Pennsylvania's patients and consumers, and how do we make sure that the best product is getting to them, how on the State level would you advise us to take that next first step if you will?

MR. WOOLF: Great question. Again, while Dr. Groff's approach raises the bar on the use of hemp-based cannabinoids for health purposes, there exists in my opinion a public safety issue already with the existence of hemp-based and hemp-derived products that have flooded our market from the Farm Bill, right? There is a need for testing of those products as soon as possible. Our public is at risk from those.

DR. GROFF: I think there needs to be more dialogue. I hope I've provided some insight into some of the confusion that exists, some of the terminology that's somewhat inaccurate, and hopefully shared with the Committee that not all hemp operations are as dire as maybe what were represented here earlier. And I think that's one
of the biggest concerns I have in hearing how these -- hemp was described by some of the other witnesses, I think it's a concern. So, again, part of my goal here was to share the story of a company like ours that's doing cannabinoid research and growth at a pharma level, and there are others in the country but certainly there are others that are not doing it that way. So, clearly, we have to understand where these ingredients are coming from, and there needs to be some regulation.

As Dr. Levine said, I'm not the attorney. I don't want to weigh into all those things, but there needs to be more dialogue. And I think the opportunity here for Pennsylvania to do an amazing thing by recognizing these two can work together at the highest level, we could literally set the standard in the country.

And one quick comment. We're here talking about CBD. Hemp is an amazing plant on the non-cannabinoid side, and there are tremendous opportunities in our State to lead the industrial side of hemp. And I don't want to take a lot of time there, but there's an incredible opportunity to develop these industrial uses. And we've been involved in some of them, but they are going to take tremendous capital and probably a public-private partnership to really get them off the ground. But I know the Department of Agriculture is very interested. It would be a shame to let
this hemp industry really wither away because hemp farmers couldn't benefit from the higher value cannabinoid -- the value from straw, seed, and fiber is minimal -- not zero but minimal compared to the other side.

So, this industry will disappear, the hemp industry will disappear in Pennsylvania in a year or two if these cannabinoids aren't -- if we don't come up with a way where they can work together. And they should because it makes sense from science and academia. But there's certainly a lot of pull, and there's stakeholders, but I think it would behoove us all to find a way to work together at the highest level without compromising patient risk.

REPRESENTATIVE COX: Thank you.

MAJORITY CHAIRWOMAN RAPP: Representative Gaydos.

REPRESENTATIVE GAYDOS: Thank you, Chairwoman.

So, if I understand it, you're using hemp for your medicine, is that correct?

DR. GROFF: Yes, we're in a transition of using outsourced product, and literally as we speak our lab is finishing up, and we'll be using this USDA organic-certified product in our existing products within several weeks, so --

REPRESENTATIVE GAYDOS: But I thought I understood that according to the Department of Agriculture
that it cannot be used for, I guess, food product, which is
I would assume an ingestible. Are you doing ingestibles or
topical?

DR. GROFF: So, let's be clear. The Federal
Government has right now said that hemp products -- CBD is
not federally approved to be used in food and beverage.
And what the government is currently doing is going after
false claims. So, false claims are when you say that this
product could cure your cancer or your seizures.

Now, again, just for perspective, keep in mind
the 23 conditions that the State is currently advocating
for the use of marijuana is a false claim. There's not
enough science. So, I just want everyone to understand
that. Again, I'm seeing patients being treated, so I'm a
fan of both, but understand just the legality of those
things.

So, the incoming FDA Commissioner has said this
week that they know they need to find a way to allow CBD to
have safe access because the public wants that. And these
are comments literally from him this week. So, the FDA is
going after false claims more than anything on the CBD
side. And, of course, the Federal Government is completely
ignoring the 33 States that are making false claims to the
Medical Marijuana Program. So, again, just an important
perspective.
REPRESENTATIVE GAYDOS: But in Pennsylvania that's not permitted, is that correct?

DR. GROFF: The definition in the Pennsylvania Department of Ag is THC less than .3 --

REPRESENTATIVE GAYDOS: Okay. Okay.

DR. GROFF: So --

REPRESENTATIVE GAYDOS: Thank you. Thank you for that clarification.

DR. GROFF: From hemp products.

MAJORITY CHAIRWOMAN RAPP: Are there any other questions or comments?

Gentlemen, we truly appreciate your testimony, your knowledge of this subject. You have far more knowledge than we do on this matter. So, if we were to move forward on anything, we certainly hope that you would be there for us to consult with in the near future if we are looking at any type of legislation or regulation. At this point we have not really discussed that. And I said that at the very beginning. This was an informational hearing, and we did receive a lot of valuable information today, and for that I thank all of the panel members here today. And certainly, this is a subject that we need to be looking at, observing for the benefit of the people of Pennsylvania.

Thank you for being here today. Thank you,
Members. And we do have another hearing next week with the Subcommittee, and we will be sharing more information about that later. But thank you, gentlemen, for being here.

Thank you. Thank you, Secretary Strathmeyer. I think you're still here. Oh, you are.

(The hearing concluded at 1:03 p.m.)
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