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HEMP PRODUCTION AND THE 2018 FARM BILL

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

JULY 25, 2019

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C O N T E N T S

Thursday, July 25, 2019

Page

HEARING:

Hemp Production and The 2018 Farm Bill 1

STATEMENTS PRESENTED BY SENATORS

Roberts, Hon. Pat, U.S. Senator from the State of Kansas, Chairman, Committee on Agriculture, Nutrition, and Forestry 1
Stabenow, Hon. Debbie, U.S. Senator from the State of Michigan 3
McConnell, Hon. Mitch, U.S. Senator from the State of Kentucky 4

Panel I

Ibach, Hon. Greg, Under Secretary for Marketing and Regulatory Programs, U.S. Department of Agriculture, Washington, DC 7
Vaden, Hon. Stephen Alexander, General Counsel, U.S. Department of Agriculture, Washington, DC 7
Dunn, Hon. Alexandra Dapolito, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, Washington, DC 9
Abernethy, Amy P., M.D., Ph.D., Principal Deputy Commissioner of Food and Drugs, Office of the Commissioner, U.S. Food And Drug Administration, Silver Spring, MD 10

Panel II

Furnish, Brian, Farmer, Cynthiana, KY 20
Stark, Erica, Executive Director, National Hemp Association, Reading, PA 22
Seki, Hon. Darrell G. Sr., Tribal Chairman, Red Lake Band of Chippewa Indians, Red Lake, MN 24

APPENDIX

PREPARED STATEMENTS:

Ibach, Hon. Greg 36
Dunn, Hon. Alexandra Dapolito 40
Abernethy, Amy P., M.D., Ph.D. 46
Furnish, Brian 58
Stark, Erica 61
Seki, Hon. Darrell G. Sr. 66

DOCUMENT(S) SUBMITTED FOR THE RECORD:

Roberts, Hon. Pat:

The Association of American Pesticide Control Officials, Inc., prepared statement for the Record 76
Drug Policy Alliance, prepared statement for the Record 78

QUESTION AND ANSWER:

Ibach, Hon. Greg:

Written response to questions from Hon. Pat Roberts 82
Written response to questions from Hon. Debbie Stabenow 83
Written response to questions from Hon. Joni Ernst 83

Page

Ibach, Hon. Greg—Continued
Written response to questions from Hon. David Perdue 85
Written response to questions from Hon. Patrick J. Leahy 86
Written response to questions from Hon. Amy Klobuchar 87
Written response to questions from Hon. Michael Bennet 88
Vaden, Hon. Stephen Alexander:
Written response to questions from Hon. Pat Roberts 91
Written response to questions from Hon. Debbie Stabenow 92
Written response to questions from Hon. Deb Fischer 100
Dunn, Hon. Alexandra Dapolito:
Written response to questions from Hon. Debbie Stabenow 101
Written response to questions from Hon. David Perdue 101
Written response to questions from Hon. Deb Fischer 102
Written response to questions from Hon. Michael Bennet 103
Abernethy, Amy P., M.D., Ph.D.:
Written response to questions from Hon. Debbie Stabenow 105
Written response to questions from Hon. John Hoeven 105
Written response to questions from Hon. Joni Ernst 106
Written response to questions from Hon. David Perdue 106
Written response to questions from Hon. Charles Grassley 108
Written response to questions from Hon. Deb Fischer 109
Written response to questions from Hon. Patrick J. Leahy 110
Written response to questions from Hon. Michael Bennet 111
Furnish, Brian:
Written response to questions from Hon. Debbie Stabenow 113
Stark, Erica:
Written response to questions from Hon. Debbie Stabenow 114
Seki, Hon. Darrell G. Sr.:
Written response to questions from Hon. Amy Klobuchar 118

HEMP PRODUCTION AND THE 2018 FARM BILL

THURSDAY, JULY 25, 2019

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The committee met, pursuant to notice, at 9:33 a.m., in room 328A, Russell Senate Office Building, Hon. Pat Roberts, Chairman of the Committee, presiding.

Present or submitting a statement: Senators Roberts, McConnell, Boozman, Hoeven, Ernst, Hyde-Smith, Braun, Stabenow, Brown, Casey, and Smith.

Chairman ROBERTS. Good morning. I call this meeting of the Senate Committee on Agriculture, Nutrition, and Forestry to order.

Before beginning my remarks, both the Ranking Member and I received a letter regarding hemp production from the Association of American Pesticide Control Officials, Inc. and there is a separate letter from the Drug Policy Alliance regarding the hemp felon ban that I submit for the record today. Without objection.

[The letters can be found on pages 76-79 in the appendix.]

STATEMENT OF HON. PAT ROBERTS, U.S. SENATOR FROM THE STATE OF KANSAS, CHAIRMAN, U.S. COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Chairman ROBERTS. Today's hearing on hemp production first convenes the three Federal agencies that directly regulate or affect hemp cultivation. USDA is preparing a rule on hemp as directed by the Farm Bill. FDA is faced with issues that are relevant to processor demand for this crop. EPA will play an integral role in how producers raise this crop through the choices available to them. This hearing is designed to provide a forum for the agencies to discuss the decisions they are facing as well as stakeholder perspectives regarding the USDA rule in development.

On today's second panel, the Committee will hear from those on the ground as they provide insight from the producer, industry, and tribal regulatory perspectives.

I have talked repeatedly about two themes here in the Committee, providing certainty and predictability for farmers. However, this developing industry has a great opportunity, but, to be truthful, also has much uncertainty and risk for farmers.

Hemp was only recently removed from the Federal Controlled Substances Act. Because of its historical legal problems, hemp agronomics suffer from a relatively short history of data, research,

and good farming practices compared to other new crops that we have seen ramp up toward more significant acreage in the past.

Farmers bear significant risk regarding hemp production regardless of their operation's business model. A producer may share risk through a contract to grow hemp for a processor, with the processor providing an input, such as seed, though there have been instances where some growers may not have always received timely payment by a processor. A different farmer may grow hemp to sell either the fiber, grain, seed hemp, or flower on the open market.

At present, there is not Federal multi-peril crop insurance available to generally cover lost production costs, and there is a need for production data to develop any revenue insurance policy.

These are cautions regarding this new crop, but let me be clear, I am extremely supportive of new opportunities for farmers. Everybody here on this Committee, and especially the Leader, who has provided a lot of leadership in this regard, it is not often that an almost entirely new crop with this level of interest and market potential comes along. I am proud to say we even have new facilities now being built in Russell, Kansas.

As we all know, times are tough. Our producers across the country have been experiencing increased costs and low commodity prices over the past several years. On top of that, many farmers dealt with Mother Nature's wrath this spring as flooding prevented many from getting a crop, or a quality crop, in the ground.

These economic conditions drive further margin erosion and financial stress for many operations. However, producers and agricultural stakeholders continue to look for ways to adapt to the downturn in agricultural prices. Many are positioning themselves for longer-term opportunities that might warrant further investment or provide an additional profit opportunity.

Today we are here to ask questions, learn from stakeholders, and better understand the multitude of issues surrounding hemp cultivation and this industry.

I support the implementation of the 2018 Farm Bill in a farmer-friendly manner, and hemp is no exception. Needless to say, based upon my history with the Federal Fungicide, Insecticide, and Rodenticide Act, or FIFRA, I strongly support the development of the data and information needed to provide this crop with conventional crop protection tools.

There are complex questions in this space. Is hemp the crop of a generation? What will this industry look like in 10 years? I do not know the answers to these questions, and I am not sure if anyone actually can answer them.

However, witnesses testifying on both panels today have valuable insight to share. Facilitating the flow of accurate information regarding this new endeavor, especially as it relates to the pending decisions by the Federal agencies, will hopefully be of use to the agencies, the industry, and in the end, the farmers upon whom much of this success will be built.

I now recognize my distinguished Ranking Member, Senator Stabenow.

STATEMENT OF HON. DEBBIE STABENOW, U.S. SENATOR FROM THE STATE OF MICHIGAN

Senator STABENOW. Thank you, Mr. Chairman, welcome to all of our witnesses today. The 2018 Farm Bill includes many new opportunities to strengthen and diversify American agriculture. We know something about that in Michigan where we grow a wider variety of crops than any other State but one in the country.

One of the most anticipated opportunities we included in the Farm Bill is the newly legalized production of hemp. This exciting new opportunity is actually part of a great American tradition. George Washington, John Adams, and Thomas Jefferson all grew hemp. Maybe Lin Manuel Miranda will make his next musical about that!

Majority Leader MCCONNELL. Henry Clay as well.

Senator STABENOW. Henry Clay as well. Thank you, Mr. Leader. [Laughter.]

During World War II, the USDA encouraged farmers to grow hemp in order to produce rope for the U.S. Navy. Michigan's own Henry Ford saw great potential in hemp and experimented with using it in biobased manufacturing. In fact, hemp used to be so prevalent in my State, they say you could see it growing on the side of the road while driving down I–94 in Southeast Michigan.

This new old crop is creating exciting opportunities for farmers and the greater supply chain. Hemp products are already popular in the U.S. marketplace. Nationally it is estimated that U.S. hemp retail sales are at more than $700 million annually, and this market is expected to grow at a 10 to 20 percent rate.

According to the Michigan Department of Agriculture, more than 30,000 acres have been registered for hemp production. Over 700 growers and processors have received a license to produce hemp and derive products. Michigan farmers can cultivate hemp seeds to make new food products, with whole hemp seeds, seed protein, and hemp seed oil.

Innovators are looking at ways to use industrial hemp in biobased manufacturing. There is exciting potential to create products like biodegradable water bottles, construction materials, clothing, and even cement to improve our roads.

Because hemp is a new crop, more research is still needed to provide information to producers on the right soils and seeds, pest management techniques, and other best practices. In order to support growers and processors we need to conduct aggressive research.

Just last week, this Committee discussed the concerning loss of researchers at the Department of Agriculture, driven by the relocation of two USDA research agencies. I mentioned that the USDA is losing irreplaceable expertise, including one of the top researcher's on hemp. Instead of throwing away knowledge, the Department should be doing everything it can to continue important work that will help our farmers succeed.

In addition to research, farmers need access to adequate financing to cover the high cost of seeds and new equipment. It is also critical that entrepreneurs have capital to build the infrastructure needed to process hemp, which will create exciting new business opportunities in rural communities. We also need to ensure that

these opportunities in hemp production are fair and equitable for all farmers. It is also critical there is fair testing and enforcement of regulations regarding harvesting hemp across the board.

With any change there are always questions that need to be addressed. There are still many outstanding federal and local issues related to CBD oil, risk management tools, and testing methods for harvesting hemp crops.

I look forward to hearing from the panel of experts that we have today who will speak to all of these issues and give us an opportunity to learn more about the implementation of these provisions.

Mr. Chairman, I also have to apologize in advance. As you know, we have a markup going on in the Finance Committee. I have amendments I am offering. As I indicated to the witnesses, I apologize for moving back and forth. That is the reality of trying to be two places at once, which we are frequently challenged to do.

So welcome again.

Chairman ROBERTS. I recognize the dilemma we face with the hearings in the Finance Committee. I will be there on final passage. I was going to say I wish you luck on your amendments. I am not too sure that I want to say that.

[Laughter.]

Senator STABENOW. Can I count you as a yes, Mr. Chairman?

Majority Leader MCCONNELL. No, I do not think you do, do you?

[Laughter.]

Chairman ROBERTS. I have three but I have withdrawn them, so we can get this one on the road.

I am very pleased and privileged to represent Leader McConnell, Senator Mitch McConnell. If it had not been for him I am not sure we would put the emphasis we did in the Farm Bill. It was through his suggestion and gentle nudging—not so gentle nudging—that we are on the road we are on. It has been a long time coming and the time is now. Leader McConnell, please.

STATEMENT OF HON. MITCH McCONNELL, U.S. SENATOR FROM THE STATE OF KENTUCKY

Majority Leader MCCONNELL. Thank you, Mr. Chairman. I want to thank you and Senator Stabenow for your willingness to be leaned on, not that you needed it. This was an extraordinary development that we are all excited about in last year's Farm Bill.

Kentucky, I gather, like Michigan, has a long history with hemp. I am glad it is making a comeback and it has created incredible excitement all across my State.

When we began the pilot programs as a result of language that I put in, thanks to you, Mr. Chairman, and others, back in 2014—I believe you were Chairman then—we put in pilot projects in the 2014 Farm Bill. As we all know, and as the Chairman and Senator Stabenow pointed out, this product is incredible, from food to clothing to wellness products. What a diversified product.

I am especially grateful to the two of you. It was fun being there with the President. A little awkward for the Senator from Michigan but she was there for the signing of the bill, I recall, wondering what she was doing. It was almost an out-of-body experience, I am sure. We were all there together, which underscored, I think, the

bipartisan nature of the effort that went into putting together last year's Farm Bill, and it was exciting to see the President sign it.

I had Secretary Perdue down, just a week or two ago, on a hemp-focused visit, and I think USDA is trying to be helpful in every way they can. The biggest thing they have to come up with, as I think all of us know, is crop insurance, which is not going to be there for the 2019 crop, but the Secretary has assured us all, and I have helped him do that, by writing it into one of the bills we recently passed, that at least the whole crop, crop insurance will be ready for next year. Getting crop insurance for a specific, hemp, is going to take more time, but whole-farm crop insurance will be available for hemp next year.

All of the agencies are playing a vital role, and you are going to hear from them. EPA and FDA obviously have a role to play in all of this.

I have got a constituent here today that I am awfully proud of, Brian Furnish. Brian is an eighth-generation farmer who is going to be on the second panel, from Cynthiana. When he purchased his first farm back in the late 1990's he turned to what had been our big cash crop, tobacco. Tobacco's history in Kentucky and across our country goes way back to the founding of our country. There are tobacco leaves at various places, painted in the Capitol. It was an integral part of the beginning of this country.

To show you how pervasive tobacco was in our State, when I first came here, to the Senate, we grew at least some of it in 119 of 120 counties. It was everywhere. Under the old quota system set up during the New Deal, they actually measured your historical production, assigned that quota to your farm, and it added value to your farm. I mean, you paid property taxes on it. The government had created the asset. It distributed the income into a lot of different hands and provided an awful lot of income for an awful lot of people for a very long time.

What happened next to Brian is the same story that has been shared by thousands of farm families in Kentucky. Demand for tobacco started falling. Foreign competition grew. In collaboration with leading Kentuckians like Brian Furnish, who is here today, I introduced the tobacco buyout legislation in 2004, to help free tobacco growers from the Depression-era quota system. Signed it into law in 2004, levied a fee on the producers, and we basically bought back the asset that the government had created back in the 1930's, compensated them for the asset that had been created by the government back in the 1930's.

That 10-year buyout ended in 2014, so that coincided with the 2014 Farm Bill, where we all worked together to put in pilot projects, in the hopes that maybe, just maybe, hemp could be a really big deal at some time in the future. Brian and dozens of other Kentucky farmers hit the ground running with the pilot program, just as the quota buyout over the 10-year period ended.

The hemp legislation that I offered, and you all were happy to accept and participate in, could not have come at a better time. Brian has grown different strains of hemp, for fiber, for seed, for CBD. In addition to farming hemp he has also had experience processing the crop.

He is not the only one benefiting from hemp's resurgence in my State. Right now, farmers in 101 of 120 counties, in just one year of legalization—or six months of legalization, actually—we are now growing it in 101 out of 120 counties. That is how fast it has gone in our State. We have more than 200 processors operating in our State, and this has only been legal for six months.

It was recently announced that around $100 million worth of Kentucky-grown and processed hemp products are expected to be sold this year alone. Look, I do not think any of us know if hemp will ever be as big in Kentucky as Burley tobacco, but with farmers like Brian leading the effort I am confident we have a bright future with this crop in our State.

As the Committee reviews the implementation of the hemp initiative I can think of no better voice to hear from than Brian Furnish. I am pleased to welcome him. I want him to stand up. I think he has got his daughter with him. There you are, Brian. His daughter, Gracie. She is one of the National FAA officers last year and is currently attending University of Kentucky. She is following in her dad's footsteps and is a strong voice for Kentucky agriculture.

I am thrilled that Brian and Gracie could be here today. I want to thank you, Mr. Chairman, and Senator Stabenow again for your consistent interest in this. I think this is a necessary hearing as we sort of deal with the last three things. If you look at this as a football, we are in the red zone. We are not quite in the end zone yet. We are in the red zone.

There are three issues out there—the crop insurance issue, which we discussed; the people who are growing it this year are pioneers. They are out there without the insurance, taking a chance. FDA, you are going to hear from them, what kind of representation is going to be made that reassures the public and do not overState. We have some banking issues. I am not clear whether you are going to hear from them or not, but there have been some credit card issues. There are some EPA issues. You have got them on the schedule here today.

I want to conclude by thanking you all for doing this. I think we are close to the end zone on this, and we are all hopeful it is going to be a really big deal in a whole lot of States, maybe even in Kansas, and we will see what the future holds.

Thank you so much for the opportunity to be here, and good luck, Brian. These are really tough questioners. I am sure you are as nervous as you can possibly be.

[Laughter.]

Chairman ROBERTS. If we are in the red zone I am going to let you call some of the plays. You could just go up the middle but I do not think you are gaining that many yards. I think the end-around situation might work out pretty good. We will work on that.

Our first witness is the Honorable Greg Ibach, Under Secretary for Marketing and Regulatory Programs, U.S. Department of Agriculture. Greg is USDA's Under Secretary for Marketing and Regulatory Programs. This includes the Animal and Plant Health Inspection Service and the Agriculture Marketing Service, the USDA agency responsible for administering the implementation of the

hemp production provisions within the 2018 Farm Bill. Greg, we welcome you back.

Our next witness is the Honorable Stephen Vaden, General Counsel at the U.S. Department of Agriculture. Stephen is General Counsel to the U.S. Department of Agriculture where he provides legal advice and services across the Department and its agencies, including implementation of the hemp production provisions of the 2018 Farm Bill. Stephen, welcome back to you too.

The Honorable Alexandra Dunn is here to represent the U.S. Environmental Protection Agency. Ms. Dunn currently serves as the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention at the U.S. Environmental Protection Agency. In this capacity, she oversees the Office of Pesticide Programs, the Office of Pollution Prevention and Toxics, and the Office of Science Coordination and Policy. Our welcome to you, ma'am.

Our last witness, at least on the first panel, is Dr. Amy Abernethy. She is the Principal Deputy Commissioner of Food and Drugs, U.S. Food and Drug Administration. Dr. Abernethy oversees the agency's day-to-day functioning and directs special and high-priority initiatives that cut across the offices overseeing the FDA's regulation of drugs, medical devices, tobacco, and food. To that point, she is Co-Chair of the FDA's internal CBD Policy Working Group. We welcome you, ma'am, as well.

Greg, why don't you start this off?

STATEMENT OF THE HONORABLE GREG IBACH, UNDER SECRETARY FOR MARKETING AND REGULATORY PROGRAMS, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.;

ACCOMPANIED BY THE HONORABLE STEPHEN ALEXANDER VADEN, GENERAL COUNSEL, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Mr. IBACH. Thank you, Chairman Roberts, Ranking Member Stabenow. I appreciate this opportunity to appear before you today to discuss USDA's implementation of the hemp provisions contained in the 2018 Farm Bill. I am Greg Ibach, Under Secretary for USDA's Marketing and Regulatory Programs mission area, which includes the Ag Marketing Service, the agency that is charged with implementing the core hemp provisions of the bill. With me today is USDA General Counsel, Stephen Vaden. The Office of the General Counsel has been a valuable partner as we work toward implementation of the 1918 Farm Bill's hemp provisions.

We know there is a lot of interest around the country in the economic potential for hemp production. I am sure you have heard from farmers in your districts about the importance of USDA issuing clear regulations and moving quickly to do so. With that in mind, I would like to provide you with a synopsis of USDA's hemp-related activities since enactment of the Farm Bill last December. I will also provide the Committee with the Department's plans, moving forward.

As you know, the 2018 Farm Bill authorized the production of hemp and removed hemp and hemp seeds from the Drug Enforcement Administration's schedule of Controlled Substances. USDA is required to issue regulations and guidelines to implement a pro-

gram for the commercial production of industrial hemp in the United States.

The rulemaking will outline provisions for USDA to approve plans submitted by States and Indian tribes for the domestic production of hemp as set forth by the Farm Bill. It will also establish a Federal plan for producers in States or territories of Indian tribes that do not have their own USDA-approved plan.

As outlined by the Farm Bill, the program includes provisions for maintaining information on the land where hemp is produced; testing THC levels; disposing of plants that are not in compliance with program requirements; licensing requirements; and ensuring compliance.

For the 2019 planting season, the 2018 Farm Bill provides that States, tribes, and institutions of higher education can continue operating under the authorities of the 2014 Farm Bill, which permitted these entities to produce hemp under pilot programs for research purposes. These authorities will expire 12 months after the effective date of the AMS rule.

In addition to AMS, the Farm Service Agency, the Natural Resources Conservation Service, and the Risk Management Agency are also impacted by the 2018 Farm Bill's hemp provisions. I would refer you to my written statement for more details on their respective responsibilities.

Following passage of the 2018 Farm Bill, AMS participated in hundreds of meetings and consultations with interested entities in Washington, DC. and across the country. These entities included States, Congress, tribes, other Federal agencies, private businesses, industry organization, and producers. In addition to these meetings, USDA has provided a number of information documents and engaged the public through information-gathering sessions.

The following are a few highlights of these activities. On March 13th, USDA held a Farm Bill Hemp Listening Session to allow interested parties to share their perspectives and ideas on hemp production. This was a 3-hour webinar with approximately 2,100 participants. The webinar was recorded and is available on our website, along with comments that were submitted to AMS.

On April 18th, a Notice to Trade was issued, which provided guidance to U.S. hemp producers and seed exporters seeking an avenue for hemp seed exports to the United States.

In late May, the USDA's Office of General Counsel issued a legal analysis regarding the interState transportation of hemp and who may obtain a license to produce hemp.

Last but certainly not least, an interim final rule to establish the domestic hemp production program is currently undergoing interagency review. We hope to finalize the rule this fall to accommodate the 2020 crop year. Once the rule is published and becomes effective, USDA will move quickly to fully establish the program. We are unable to comment on the specifics of the rule at this time as it is under interagency review, but we will be happy to provide more detailed information once it is published.

As you can see, USDA is committed to a timely establishment of this program, and we look forward to your questions.

[The prepared statement of Mr. Ibach can be found on page 36 in the appendix.]

Chairman ROBERTS. Our next witness to have a prepared statement is the Honorable Alexandra Dunn of the U.S. Environmental Protection Agency. Ms. Dunn, please proceed.

STATEMENT OF THE HONORABLE ALEXANDRA DAPOLITO DUNN, ASSISTANT ADMINISTRATOR, OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION, U.S. ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, DC

Ms. DUNN. Good morning Chairman Roberts.

Chairman ROBERTS. Good morning.

Ms. DUNN. Thank you for having me here today. I am Alexandra Dunn, Assistant Administrator of the Office of Chemical Safety and Pollution Prevention at the U.S. Environmental Protection Agency, and it is a privilege to discuss EPA's role in and our plans for regulating hemp, and being here with my colleagues, Dr. Abernathy, Under Secretary Ibach, and General Counsel Vaden.

As hemp comes into its own as our Nation's newest cash crop, growers will need pesticides approved for use on hemp to ensure healthy and stable crops. EPA will play a role in helping hemp reach its full potential in three ways. First, EPA can authorize pesticides for use on hemp plants under FIFRA, the Federal Insecticide, Fungicide, and Rodenticide Act. Second, where hemp products are a food or animal feed, EPA will set tolerances or maximum pesticide residue limits, under the Food Quality Protection Act, or FQPA. Then third, EPA is coordinating with our Federal partners, State agencies, and others on hemp policy issues.

EPA has a long history of ensuring that pesticides used on U.S. crops are applied safely. EPA approves new pesticide uses in a timely fashion under the Pesticide Registration Improvement Act, or PRIA, so that the most cutting-edge and precise pesticides enter the marketplace and are available to growers, and we thank you, Senator, and the Committee, for your excellent work on PRIA's recent reauthorization.

I am pleased to tell you that EPA is committed to assisting hemp producers obtain the pest management tools they need to help them transition to commercial production of this crop. EPA's effective and long-standing methods for working with industry, grower groups, States, and other partners will ensure that producer requirements for pest management and environmental and public health protection can all be met and achieved.

First, as you know, for a crop to be sold the United States EPA must approve a pesticide use on that crop and associated pesticide labeling under FIFRA. EPA anticipates an increase in pesticide registrant interest in gaining approval to use pesticides on hemp under FIFRA, particularly thanks to the 2018 Farm Bill and the strong economic forecast for hemp production. In fact, since May 2019, EPA has received 10 requests to include hemp on existing pesticide labels. We already have an approach for reviewing these requests and are engaging the public in our process.

The pending requests notably involve biological and microbial chemicals, which tend to have very low environmental impact and can be approved on an expeditious basis, consistent with our authorities, and EPA completing review of these requests will be the

first of many actions I anticipate we will take to support growers in the new hemp industry.

Second, as mentioned, where hemp products are a food or animal feed, EPA will set tolerances or maximum pesticide residue limits under the FQPA. Notably, the biological and microbial chemicals that I mentioned earlier are exempt from the tolerance requirements, which makes them very available today. We look forward to working with our colleagues in the Food and Drug Administration on other tolerance-related issues. Our decisions are inter-related.

Third, coordination on hemp policy between Federal partners, States, growers, and other stakeholders is essential to our work. We are engaging with the Department of Agricultural, with FDA, and the Department of Justice, and our shared goal is, of course, to provide coordinated information and regulatory certainty. We are working also with our States as they have a co-regulatory role in administering and enforcing FIFRA.

In conclusion, over time EPA has proven to be a nimble and adaptive regulator, such that innovation in the pesticide marketplace is advanced while public health and the environment are protected, and we stand ready to ensure that EPA takes the pesticide registration actions and sets tolerances necessary so that hemp and hemp products can effectively and safely enter the marketplace.

I appreciate very much the opportunity to testify today and I would be happy to answer any questions. Thank you.

[The prepared statement of Mr. Dunn can be found on page 40 in the appendix.]

Chairman ROBERTS. I thank you very much for an excellent statement, more especially one of the first from any Federal agency to finish 30 seconds under the time limit.

[Laughter.]

Chairman ROBERTS. Dr. Abernethy. That does not mean that I am trying to restrict you, ma'am.

Dr. Abernethy. I thought you were handing it over.

STATEMENT OF AMY P. ABERNETHY, MD, PhD, PRINCIPAL DEPUTY COMMISSIONER OF FOOD AND DRUGS, OFFICE OF THE COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. ABERNETHY. Good morning, Chairman Roberts and members of the Committee. I am Dr. Amy Abernethy, Principal Deputy Commissioner of the Food and Drug Administration. Thank you for the opportunity to appear before you today to discuss the FDA's role in the regulation of hemp products. I am pleased to join my colleagues from the USDA and EPA to work together to ensure coordination across the Federal Government.

FDA is committed to advancing its regulation of hemp products through an approach that, in line with our mission, prioritizes public health, fosters innovation, and promotes consumer confidence. As a physician, I reflect that patients and consumers trust that the FDA will prioritize their health and protect public safety.

As this Committee knows, the 2018 Farm Bill unleashed a wave of interest and innovation in hemp agriculture. The Farm Bill removed hemp from the definition of marijuana in the Controlled

Substances Act and the Farm Bill explicitly preserved FDA's authorities over hemp products.

Hemp-derived products subject to the FDA's jurisdiction are regulated like any other products, enhancing consumer confidence in this growing hemp market. Hemp products that fall within FDA's responsibilities include food products like hulled hemp seeds, and also products that are extracted from hemp derivatives, like cannabidiol, such as foods, drugs, and cosmetics.

There is much interest in cannabidiol, otherwise known as CBD. FDA first approved a CBD drug product last year for the treatment of seizures associated with two rare and severe pediatric diseases, a significant milestone for these children and their families. In line with the Food, Drug, and Cosmetic Act, CBD is available to be marketed as this approved drug.

Meanwhile, there has been an explosion of CBD-based products like lotions, gummies, and chocolates. Providing clarity on the regulatory status of CBD products is an FDA priority. However, under the Food, Drug, and Cosmetic Act, adding CBD to food or marketing a CBD product as a dietary supplement is generally prohibited unless the agency makes an exception through rulemaking. The same rules applies to most active drug ingredients. It is common sense. We generally do not want drugs to be added to food.

FDA is a science-based agency. Americans expect the decisions made by FDA are informed by the best available information about safety, and CBD is no exception.

What data do we have? Through the approval of the CBD drug, Epidiolex, which was based on adequate and well-controlled clinical studies, FDA learned that CBD is not a risk-free substance. CBD can harm the liver, create a sense of exhaustion, and affect your appetite. When the medical provider prescribes an FDA-approved CBD drug product, the patient can be guided and monitored by the provider.

What about situations where CBD is in your morning cereal, you consume a CBD lozenge, or you apply CBD skin cream? What if you take these every day together, for months or for years? What is the risk if you are pregnant, breastfeeding, a child, elderly, taking other medicines, or suffering a major illness? What about pets and food-producing animals?

Prior to the Farm Bill, cannabis-derived CBD was a controlled substance which meant that research with CBD was very restricted. To our knowledge, the studies just have not been done. In sum, we lack the information for science-based decisionmaking about CBD.

What is the FDA doing to address this situation? First, we are moving as quickly as possible to learn what is known and develop a work plan to fill in the gaps. We have formed a working group, which I co-chair, to expedite FDA's work. We are reviewing the published medical literature, all data bases available to us, and any available information from industry sponsors.

On May 31st, we held a full-day hearing with over 100 speakers and 2,000 participants. A public docket just closed on July 16th, and we received 4,492 comments. We are meeting with our Federal partners, State governments, trade organizations, patient groups, and others. Throughout, we have asked for any available data that

is already available-—please send it to us—and we have committed to providing an update on our work by early fall.

Second, we are providing regulatory clarity whenever possible. FDA already provided clarity that certain hemp products—hulled hemp seed, hemp seed protein powder, and hemp seed oil—can be legally used in human foods. Similarly, the regulatory pathway for new CBD-based drugs is clear and we understand clinical studies are ongoing. Meanwhile, our working group is actively reviewing all potential regulatory pathways in order to determine the appropriate approach to CBD for other types of products that we regulate, like foods, dietary supplements, animal feeds, and cosmetics.

Third, we are taking appropriate steps to protect American patients and consumers. We have issued warning letters to companies marketing CBD with therapeutic claims like treating cancer, Alzheimer's, and opioid withdrawal.

Finally, we are working together with our Federal partners and State partners and communicating with the public. I cannot emphasize enough how important this is. This is what Americans expect of us, this is what the Committee expects of us, and this is what we, as FDA, expect of ourselves.

Thank you, and I invite your questions.

[The prepared statement of Dr. Abernethy can be found on page 46 in the appendix.]

Chairman ROBERTS. Well, thank you. Thank you, Doctor, for an excellent statement.

Mr. Vaden, I am not a scientist but it is my understanding that testing results for total THC, similar to other tests on agriculture products such as feed, have analytical variances, and they are due to random sampling error. Such variances mean that a hemp plant could be a 0.3 percent in actuality and measure 0.21 percent, or even 0.39 percent at a different credible lab.

In your opinion, as the General Counsel, would the USDA be legally required to implement any testing regime in the upcoming regulation to a strict 0.3 percent with no variations? To be clear, I understand that this is a legal opinion and there may be other policy considerations, about which I am not asking the Office of General Counsel for its opinion.

Mr. VADEN. Well, thank you, Mr. Chairman. As Supreme Court Justice Oliver Wendell Holmes observed, "The life of the law has not been one of logic; it has been one of experience." Thankfully, Congress gave USDA the tools it needs to draw from the experience of the States who have been participating in the 2014 Farm Bill pilot program on hemp in order to understand the best testing methodologies that are available, what their limitations are, and to factor that in with the discretion given to the agency to set up a testing program in order to ensure that the program that we put forward is farmer-friendly and does not unwittingly trap farmers who are doing their level best to abide by the 0.3 limit that Congress set in the statute.

Chairman ROBERTS. Mr. Vaden, this is a new and exciting crop. Thank you for that comment, and I underline the farmer-friendly emphasis that you put on that. I commend the RMA and Leader McConnell for all of their efforts to provide responsible risk management tools for hemp producers.

As we all know, good farming practices and actuarial soundness are pillars of the Federal Crop Insurance program. My question is, how will RMA develop or evaluate multi-peril policies that include practice standards for this new crop? How will RMA develop or evaluate revenue policies that are based upon crop yield and price data?

Mr. VADEN. Well, Senator, RMA will continue as it always has, in a way that, first and foremost, maintains program integrity. RMA will work with stakeholders to ensure that it has sufficient data to have an actuarially sound product. This includes stakeholders such as State Departments of Agriculture, industry, and the Agriculture Marketing Service, among others, as well as our States, and, of course, producers.

Furthermore, as was announced by Under Secretary Ibach in his opening remarks, hemp will be covered under a pilot program whole-farm revenue policy for the coming crop year in 2020. As a pilot, under the law, RMA can assess the program and make changes as needed to maintain program integrity, while also providing a product that is useful for hemp producers.

One final note that I will add, we take note of the fact that Congress put, in the 2018 Farm Bill, a non-discrimination provision, when it comes to hemp. What that means with regard to RMA is that should any private producer wish to have a policy focused on hemp, be evaluated by the Federal Crop Insurance Committee, it will be treated just as any other policy is that goes through that same process and will suffer no additional hurdles or detriments because it is for hemp.

Chairman ROBERTS. I thank you for that statement.

Greg, Mr. Under Secretary, thank you for all of your efforts over the past seven months regarding the implementation of the 2018 Farm Bill. Not an easy task. I greatly appreciate it, the members of this Committee appreciate it, and I know it requires tremendous staff effort.

I have asked other colleagues of yours at the Department a similar question regarding the bill as you make decisions in rulemaking. Will you commit to me and this Committee that the hemp authority within your mission area is going to be implemented in a farmer-friendly manner?

Mr. IBACH. As you are aware, Chairman Roberts, Secretary Perdue has charged the entire USDA team to be the most efficient, effective, and customer-focused agency in the Federal Government. Farmers, as well as processors, are part of our customers in this hemp production world that we are living in now. It is very much in our interest, and that is why we are working very closely with States to understand the experiences they have to be able to design programs that they know work for their farmers so that we can design a hemp program at USDA that will also be farmer-friendly.

Yes, I do pledge to you that we will have a farmer-friendly program as best we can.

Chairman ROBERTS. I appreciate that very much.

Administrator Dunn, reflecting the letter that I submitted in the hearing record, the Inter-Regional Research Project, or the IR–4 program, is intended to facilitate the development of conventional pesticides for minor use crops. When will EPA develop their re-

search protocol for hemp and when will these guideline documents be updated?

Ms. DUNN. Thank you for that question, Senator. EPA and IR–4 are working together now to identify the information that we need to support tolerance petitions for conventional pesticides that would be used on hemp. Coincidentally, a technical meeting on this topic between my staff and IR–4 will be held later today, and it was scheduled prior to this hearing.

We have some additional, more extended discussions coming up later this summer, and we believe that these continued discussions will result in a viable proposal from IR–4 about the technical details needed for field trials for sampling hemp plants. I think we are in a very good position to move forward with IR–4.

Chairman ROBERTS. I thank you for that and I wish you the very best.

Dr. Abernethy, there are significant questions that I have regarding the issues you have outlined in front of the FDA at this time. I promised Chairman Alexander that I would stay in my lane, or our lane, during this hearing. Instead, I will address those issues whenever appropriate on the HELP Committee. I am on that Committee as well.

However, I am wondering about the need for data regarding approval for hemp as animal feed. Does this data and needed information exist?

Dr. ABERNETHY. Thank you. Indeed, we do need data around animal feed. Importantly, now that hemp has been removed from the Controlled Substances Act we will have the ability to study cannabidiol and hemp better and understand the impact on animals.

With respect to animals and animal feed, we need to understand that the impact of hemp and cannabidiol on animals, on food-producing animals that ultimately have an impact on human health, and then also given the fact that animals typically eat the same feed every single day, the issue of continuous exposure and potentially accumulation, so there is a safety question there as well.

Critically, we understand, as FDA, that we need to get the data but we need to be very focused in the data that is ultimately sought after, so that we do not unduly take extra time or extra resources to get to the answers that American farmers and American public needs.

Chairman ROBERTS. I appreciate that.

Senator Smith?

Senator SMITH. Thank you very much, Chair Roberts, and welcome to all of you, to this Committee today. I am so happy to have this conversation.

You know, just earlier this week the Banking Committee, where I serve, talked about the banking challenges facing the cannabis industry, and I am also a member of that committee so I raised an issue that has—I have been hearing a lot about from Minnesota farmers. They have told me that it is tough to get loans, or even access to payment processing for hemp because farmers have not received the guidance that they need from the USDA. I am really happy to see representatives from all of your agencies on this panel—USDA, EPA, and also FDA.

In order to, as Chair Roberts says, have a farmer-friendly process here and to be able to support farmers and not hinder them as they want to start growing hemp, it is going to take cooperation across the Federal Government—DEA, Department of Transportation, DOI, the Small Business Administration, Treasury, banking regulators. All these Federal agencies need to be aware of the regulation that USDA is making, as well as the research that comes out of the Agricultural Research Service.

My question to all of you is this. When it comes to hemp, is there a formal dialog that is taking place across all of the Federal agencies, and how are you collaborating exactly when it comes to supporting our farmers on this issue?

Mr. IBACH. I might offer my thoughts first, and then everybody else can offer theirs as well.

Part of the interagency review process that we are going through right now with the interim final rule at OMB is allowing for that discussion process to begin. It gives all those Federal agencies the opportunity to look at the proposed interim final rule that USDA has put forth. It allows the opportunity to open a dialog that goes into many of these subject areas, and they can explore some of questions about how their program might be affected by our rule, and then we can have that discussion to be able to put forward an interim final rule that not only works for farmers and ranchers but also can work between the interagency cooperation that needs to take place as well.

Senator SMITH. Very good. Thank you. Mr. Vaden?

Mr. VADEN. I would add another important partner, who is not here today but nonetheless is very important to this effort, particularly because Congress required us to coordinate with it, and that is the Department of Justice.

Senator SMITH. Mm-hmm.

Mr. VADEN. We have been engaging in the statutorily required consultation with the Department of Justice at every level. I have been participating in those conversations, as well as other colleagues from the Office of General Counsel, individuals from the Agriculture Marketing Service, and that is critical so that law enforcement (a) can be assured that we are running this program as Congress expects us to, in a forthright and legal manner, and also so that law enforcement can have access to the information that Congress has asked us to provide, so that they can be assured that the farmer, the field of hemp that was mentioned earlier, that you drive by on the highway, is actually hemp, by checking with a data base that we will be required to maintain in coordination with the Department of Justice.

Finally, I would note that they are providing input into the testing as well, as they have a very important legal role to play should someone wantonly break that 0.3 limit.

Senator SMITH. Thank you.

Ms. DUNN. Thank you, Senator, for your question. With regard to the EPA, we are also engaged with our colleagues. Particularly, we have a unique dialog with the FDA. We have to work with the FDA on jurisdictional issues associated with CBD products in food. When it comes to food safety, EPA will be working with our Federal partners to ensure that the food supply is safe, and we will

work with FDA as they look at CBD, to inform our work. Then we are not waiting on another Federal agency necessarily but we are actively working together.

Senator SMITH. Thank you.

Dr. ABERNETHY. Thank you very much, Senator. In addition to what we have just said, ultimately, in my opening statement, as I highlighted, we see this as a critical issue, is working across government to start to solve the question of appropriate regulations around hemp and provide regulatory clarity so that ultimately are able to provide farmers the predictability that they need.

A few details about that from the perspective of the FDA—we are certainly working together with EPA, as you have just heard from Alexandra Dunn. We also work together in accelerating pace with USDA, and we have multiple interactions at all levels of FDA. We also are working together with States, and we had State governments represented in our full-day meeting on May 31st. There was a specific section where we heard what the State government needs were and we are considering about how do we make sure we accelerate the pace of our communication. We see that this is a critical issue across all this work.

Senator SMITH. I appreciate very much you devoting time to this, because I think sometimes Minnesota farmers feel a little bit like they are caught between a rock and a hard place, and they are feeling a real urgency to move forward, because given the current State of the farm economy in Minnesota and around the country, with, you know, trade disputes, low prices, and terrible weather, they are ready for—they are looking for new opportunities. There is a lot of urgency on their part. I am sure that you appreciate this. Your cross-agency collaboration is just really important.

Let me just ask one last question to Under Secretary Ibach and Mr. Vaden. Once the rules and regulations are out around—this is a question around the right hemp seeds to use—once those rules and regulations are out, how long will it take the ARS to set up a hemp research program, do you think?

Mr. IBACH. Actually prior to 2018, with hemp being a controlled Schedule 1 drug, ARS has engaged in very little research at this point. ARS has now started to take steps to get a research beginning on hemp. ARS has authorized the Geneva, New York, laboratory location to devote funds to establishing an infrastructure to support studies done in conjunction with Cornell University.

This research will take a look at destructive diseases, pests, weather extremes as they relate to hemp production. ARS is also exploring options to expand this research in conjunction with the 1914 Farm Bill is awaiting the AMS rule to guide development of additional projects.

In addition to what ARS is doing, there are a number of State universities that have participated in the 2014 Farm Bill research opportunities, and we look forward to being able to gather those different research projects and see what type of applications they have. You know, because there are many different growing environments across the United States, some of those research projects are going to be very specific to those States and their individual growing regions, but some of them may have some great application across the entire United States.

Senator SMITH. Great. Thank you very much. Thank you, Mr. Chair.

Chairman ROBERTS. Senator Braun.

Senator BRAUN. Thank you, Mr. Chair. I agree with Senator Smith. There could not be a better time for farmers, in general, as actively involved in farming as I can be and still doing this job. We need to find new markets, new things to compete with, I think, soybean and corn usage.

Can you give me an idea, Mr. Ibach, how big the hemp market is? I think from my information more than 30 countries produce hemp. It has got 22,000 different uses, from textile shoes, food, paper, rope, bioplastics, biofuel. Just generally speaking, how does this compare to soybeans and corn, in terms of the potential market out there, so farmers can actually have something that they could scale into something as big as their corn and soybean enterprises?

Mr. IBACH. Well, in terms of excitement there is probably more around the hemp industry right now than there is corn and soybeans, but maybe just to share a little bit of data from 2018. Forty-one States have passed legislation and hemp is being grown in 23 of those in the 2018 crop year. There were 3,546 State licenses issued and hemp was growing on about 78,000 acres. Again, that pales in comparison to corn and soybean numbers. Some States have quite a bit of acreage dedicated to that. Montana and Colorado have over 20,000 across in each of those States, so that shows that there are a number of producers that embraced it there.

I think one of the concerns that we have at USDA is with the excitement and number of acres that are moving to hemp production and will be planted to hemp in the 2019 crop year, that we want to make sure that producers are aware and have an outlet for their product—some place to sell it. We have encouraged producers all this spring to look for a partner, look for a customer, encouraged them to engage in a contract before producing hemp.

One of our big concerns is that production and consumption or processing will not align with each other, and so that is one caution that we have made to farmers as we have moved forward with our rule.

Senator BRAUN. Is there a rough, globally, soybeans, corn, hemp—can you give me any indication of what that would be, say, split percentage-wise?

Mr. IBACH. I would not be able to.

Senator BRAUN. It would be interesting to know that, because I think that would be helpful for farmers. Then when you talk about lining up production with customers, what does it look like currently in the U.S.? I cannot imagine many processors have been gung ho, due to the economy of scale.

Will you potentially have to export your product to a processor in another country? Do you think that is—you know, because a lot of infrastructure looks like it would have to get put in place before you can actually start to scale hemp production.

Mr. IBACH. Maybe in the first part of your question, there has been more interest in processing facilities that have focused on CBD, and so we see more of that in States across the United States. The fiber part of it has been slower to develop a processing

industry, so for those producers that are interested in fiber production there is probably less alternatives right now in the processing.

The export opportunities also have some concerns surround them, as to whether or not there are international treaties that may come into play, as exports that would hinder the exportability of hemp products for processing. You know, we will need to work with USTR, the State Department, as well, to help producers understand what kind of restrictions might be in place on the export side of things.

Senator BRAUN. Then currently, if somebody was looking at it for the fiber component, which looks like it is many of those 22,000 different uses, can you import hemp, since it could not be legally produced here until just recently? Or was it something where since you could not source it domestically that we basically have no industry in place?

Mr. IBACH. I think that the industry for fiber usage, there has been a lot of pilot projects, a lot of little research projects that have gone on, in universities across the United States that have identified some possible uses. I also know that in some States they have a more vigorous developing industry, some research parks and industrial parks that are focusing on hemp and hemp processing, especially on the fiber side, but very much developing.

I think the imports of hemp into the United States, we made provisions earlier this year to be able to bring seed in. APHIS put forward the regulatory process to be able to bring seed in from other countries. I do not think there is much attention been given to fiber.

Senator BRAUN. One final question. Is there any data on what the profit per acre would be from hemp versus soybeans or corn?

Mr. IBACH. I think that is very variable, depending on whether the hemp is for seed, for flour and food use, whether it is for CBD oil, or whether it would be for fiber. One of the reasons why—and as far as being able to track the market value of those crops, we really do not have good information there either. That is one of the reasons why, for the whole-farm crop insurance, RMA has put the requirement that producers have a contract, so it would indicate to us the value of their crop.

Senator BRAUN. Thank you.

Chairman ROBERTS. Well, thank you to the first panel. I appreciate your testimony. Very good testimony. Thank you.

I would like to welcome our second panel of witnesses before the Committee.

[Pause.]

Chairman ROBERTS. Our first witness on the second panel is Mr. Brian Furnish. Leader McConnell was planning to introduce Mr. Furnish and did, and did so very well. He is here with his daughter, Cindy, right?

Mr. FURNISH. Gracie.

Chairman ROBERTS. Gracie. Sorry to call you Cindy, Gracie.

I think it bears repeating. He is an eighth-generation farmer from Cynthiana, Kentucky. Who was Cynthia?

Mr. FURNISH. Colonel Harrison in the Civil War had two daughters, one named Cynthia and one named Anna, so they named the county Harrison and the city Cynthiana.

Chairman ROBERTS. Well, there you go. I had to ask.

Brian grows hemp, tobacco, corn, and raises beef cows, founder of GEN 8 FARMS, LLC, former president and board member of the United States Hemp Roundtable. He is accompanied by his daughter, Gracie. Welcome.

Then our next panelist is Mrs. Erica Stark, the Executive Director of the National Hemp Association, from Reading, Pennsylvania. Mrs. Stark is the Executive Director of the National Hemp Association, which represents farmers as well as processors, manufacturers in the hemp industry. Mrs. Stark was also involved with the industrial hemp program in Pennsylvania and has helped farmers manage help permits grown there since 2017. She is accompanied by the association's board chairman, Geoff Whaling, and her husband, Les Stark. We welcome you, and I turn now to Senator Smith to introduce her next witness.

Senator SMITH. Thank you very much, Mr. Chair. It is my honor to introduce Chair Darrell Seki of the Red Lake Nation, and welcome, my friend, to Washington. Chair Seki was raised by his grandparents. He was born in Red Lake, Minnesota, and has spent the majority of his life in the village of Ponemah on the Red Lake Nation.

Chair Seki is a proud veteran, having served in the Vietnam era. Chair Seki has served the Red Lake Nation in various capacities over 40 years, and is one of the longest-serving members of the Department of the Interior Tribal Budget Council, having represented the Midwest Region for 16 years.

Chair Seki has been a leader in the Native Farm Bill Coalition, which influenced many of the provisions in the Farm Bill last year that helped Native farmers. Red Lake Nation has, for many years, operated the Red Lake Tribal Farms and the Red Lake Nation Foods. The Red Lake Nation has actively marketed Native food products, like wild rice, in national and international markets.

Chair Seki was elected Council Treasurer in 2002, and served in that position until his election to Chairman in 2014, and he was re-elected in 2018.

I want to just also note, Mr. Chair, that the 23d annual Anishinaabe Spirit Run starts next week, and the Spirit Run is an intertribal community event co-sponsored by Red Lake. This is a 200-mile relay in northern Minnesota that travels through three Tribal Nations and promotes wellness and balance in mind, body, and spirit.

I am very happy to welcome Chair Seki to this Committee this morning.

Chairman ROBERTS. We thank you, Senator Smith.

Brian, why don't you start off.

STATEMENT OF BRIAN FURNISH, FARMER, CYNTHIANA, KENTUCKY

Mr. FURNISH. Thank you, Chairman Roberts and members of the Committee. I appreciate you having me here for this important testimony and important crop that is affecting Kentucky farmers and many farmers throughout the Nation.

My name is Brian Furnish, and I am an eighth-generation tobacco farmer. In the past seven years I have helped change hemp

laws in Kentucky and in Washington. I was the first licensed hemp grower in the United States since World War II. I was with you when Mr. President signed the 2018 Farm Bill in the White House.

I first started working with the political process with Senator Mitch McConnell back in 1999, when we first worked on the Tobacco Buyout that was finally accomplished in 2004. I was General Manager of the Burley Tobacco Growers Co-op in Lexington, Kentucky, and traveled to over 70 countries selling tobacco, and I realized that American tobacco farmers needed an alternative crop to tobacco.

Congressman Jamie Comer, who was than the Commissioner of Agriculture in Kentucky, asked me to help make this crop legal in 2012. That is when I started to work with Senator McConnell and you all, to make hemp legal in the US.

The 2014 Farm Bill made hemp legal in States that had a law that allowed research with the universities. At that time, I received the first grower license under the 2014 Farm Bill. I then proceeded to try to find a partner in the hemp business. I found an Australian man that was growing and researching hemp in Australia for 18 years. Now that company has a worldwide presence and a market cap of over $1 billion on the Stock Exchange in Australia, and they were just listed the first of April.

I was the first citizen chairman of the Kentucky Hemp Commission and a founder and first president of the U.S. Hemp Roundtable, the industry-leading national business advocacy organization that now has 80 members and serves as a leading advocate in the industry effort to make hemp legal.

My brothers and I have grown all three types of hemp, for seed, for fiber, and for CBD production. Each of these hemp categories uses a different genetic and growing method and different planting times throughout the season.

For the fiber, we plant about 50 pounds of seed per acre we want to grow hemp as tall as we possibly can. My first hemp crop got to over 23 feet tall, and I yielded 4 tons per acre. The average value of a ton of hemp fiber at this time is $185 a ton.

For seed, we plant approximately 30 pounds per acre, hoping to get a yield of 800 to 1,000 pounds per acre, and currently we sell that for $0.85 per pound.

For CBD production and full-spectrum hemp oil production, we set about 3,200 plants per acre and we plant it the same way we have always planted tobacco, for eight generations—one small plant at a time with manual labor. We harvest the CBD by only using the flower buds and leaves. You want the short hemp for CBD because it is harvested by hand or special machines like tobacco, and it is very labor intensive, so we do not want that plant very tall.

For the seed plants, we want those plants to be between 4 and 5 feet tall so we can combine them with a regular combine and a Draper head on the front of a combine.

The new hemp industry needs a lot of genetic research to make each of these uses profitable. As with most plants, the latitude must be consistent to get consistent production. In Kentucky, we learned early on that Canadian seed varieties do not do very well in Kentucky. Our day and nights are too different from theirs and

so we have to find genetics for the right latitude, and normally bringing southern genetics north works much better than taking northern genetics south.

Hemp seed for feminized seed needs certain periods of light and dark, so we need dark rooms for our genetic grow rooms for creating feminized seed for full-spectrum and CBD production, not green houses because they offer too much light at the wrong time of the year.

We have learned a lot over the past five years about the hemp industry and it has a long way to go before it is mainstream production agriculture. Having a certified seed program for hemp would be a huge benefit to hemp farmers, and I discussed this yesterday with members of the USDA staff, of how critical it is for farmers to have access to certified seed.

Now that hemp is legal we need to take a close look and remove, one by one, the barriers to success so that hemp can be on the same production playing field as all the other crops. Most folks in the government, and even in production agriculture, probably do not know or realize that hemp has no legal pesticide or herbicide or fungicide. A grower can lose its entire crop to weeds or pests.

Without an approved herbicide or pesticide we may have to pay a labor bill of $500 to $2,500 an acre just to get the weeds out of our hemp crop to make sure that it is still a pure crop when we harvest it. We need your help to encourage EPA and USDA to make those approvals happen as soon as possible.

Hemp growers have no USDA RMA crop insurance at this time. While I know and am part of the U.S. Hemp Farming Alliance, a group involved in the efforts to make that happen, we need to keep the pressure on for the creation of those necessary risk management tools, and make them readily available to farmers as soon as possible.

Also, without hemp processors knowing if FDA will make hemp a food or a dietary supplement, the unknown only complicates the downstream use of hemp. The current contracts for hemp growers are all over the place. Many times the grower provides the land and labor, and the processors provide the seed and the genetics and the expertise. By the way, there is no expert in the hemp business because they do not exist.

However, too often the growers are short-changed when the processor cannot come up with the money to pay the growers, or the specification for the final products have such varied results that both sides feel cheated and it is a bad experience for all involved.

In closing, myself, I have been, for better or worse, a farmer face for the hemp grower in an effort to finally make it a legal crop here in the United States. I thank you for making this wonderful crop legal, but now what the hemp growers need and want is for this new and valuable crop to be just that—a crop, with the same opportunities to grow and fill the marketplace with new and valued products. Corn, wheat, and soybeans all have hundreds and maybe thousands of product uses. Hemp can too. They need the barriers removed and the consistency and stabilization which come from the regulatory framework you all can give us.

On behalf of the hemp farmers, my family, and growers all over the Nation, I am asking for your help. Thank you for your time and

consideration and I would be pleased to answer any questions that you may have.

[The prepared statement of Mr. Furnish can be found on page 58 in the appendix.]

Chairman ROBERTS. Brian, we really appreciate your comments. Mrs. Stark, please.

STATEMENT OF ERICA STARK, EXECUTIVE DIRECTOR, NATIONAL HEMP ASSOCIATION, READING, PENNSYLVANIA

Ms. STARK. Thank you, Chairman Roberts, and the entire Committee and staff for affording us this opportunity to speak on the implementation of the 2018 Farm Bill.

The National Hemp Association is a nonprofit, grassroots organization supporting tens of thousands of farmers, businesses, and consumers. We have a particular interest in ensuring that this opportunity benefits small and medium-sized farmers who have been struggling and who form the backbone of America's rural and agricultural economies, and is the foundation upon which this country's hemp industry is being build.

Reasonable regulation will be instrumental in ensuring future success. One of the major components of these pending regulations is the testing protocol used for THC compliance. The language of the Farm Bill defines hemp as the plant, Cannabis sativa L, and any part of that plant with a Delta–9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

When the Farm Bill addresses the requirements for State and Tribal plans, it indicates that there must be a provision for testing using post-decarboxylation or other similarly reliable methods. This language raises many questions and concerns and changes the way many States were testing under their 2014 pilot programs.

One of the challenges the pilot programs revealed, and what we hope to prevent moving forward, is that if States implement too many different testing protocols we are left in a situation where what is legal is one State may be considered illegal in another State. That can create undue hardship for farmers selling across State lines, for trucking companies, for law enforcement, and for consumers.

Another of the challenges revealed by the 2014 pilot programs relates to the uncertainty of determining Delta=9 THC in hemp crops, including using post-decarboxylation or other similarly reliable methods. We would like to recommend an approach that creates a level playing field across the country while adhering to the law and providing the best possible protection for farmers and consumers. This can be accomplished by specifying using Gas Chromatography-Flame Ionization Detection, or High-Performance Liquid Chromatography to estimate the Delta–9 THC levels in post-decarboxylated hemp, and that that estimate resulting from those decarboxylation methods be divided by 3 in order to determine the Delta–9 THC.

The reason for dividing the test results by 3 is due to the relative difference in the concentrations of THC in post-decarboxylated hemp as compared to the concentrations in hemp on a dry-weight basis. Peer-reviewed research demonstrates that the ratio of THC

in post-decarboxylated hemp to the THC in hemp on a dry-weight basis is somewhere between 3-to–1 and 11-to–1.

Our recommendation to divide the post-decarboxylated test results by 3 is the most conservative end of that range, to assure that a crop will meet the legal requirement of 0.3 percent THC on a dry-weight basis. It also closes any loopholes that could even potentially allow marijuana to be introduced into the marketplace.

We further recommend that there be standards established for calibration methods, sample preparation, and control samples. What must be kept top of mind is that this is about the farmers, all of which want to stay compliant, and we are talking about one-tenth of one percent being the difference between a farmer making a profit or suffering a devastating loss.

The simple fact is there is no single or absolute way to determine those THC levels with that level of precision. Our recommendation provides compliance to the legal definition of hemp, satisfies the requirement for post-decarboxylation testing, while also providing protection to farmers and the public.

This is a difficult topic to cover in 5 minutes, so more details on the testing protocols, along with other important issues such as sample, personal eligibility requirements, cross-pollination, hemp flower, and importation of biomass are included in our written testimony.

To quote our chairman, Geoff Whaling, "This is a once in a life time opportunity and we need to get this right." We acknowledge that implementation of the hemp provisions of the 2018 Farm Bill is a challenging task for regulators, because it touches so many different Federal and State agencies, farmers, businesses, and the public.

At the very heart of what we need to move forward is simplicity and clarity. We need regulations that create an even playing field across the country. We need to eliminate the unintended consequences of legal gray areas caused by each State testing differently and operating under a different set of rules and regulations.

The hemp industry has been struggling with legal uncertainties for far too long and looks forward to reasonable regulations which will afford the opportunity for all to prosper within a clear legal framework.

Thank you again for your time and I am happy to answer any questions.

[The prepared statement of Ms. Stark can be found on page 61 in the appendix.]

Chairman ROBERTS. We thank you for an excellent statement, Mrs. Stark.

Chairman Seki, from one chairman to another, please.

STATEMENT OF THE HONORABLE DARRELL G. SEKI, SR., TRIBAL CHAIRMAN, RED LAKE BAND OF CHIPPEWA INDIANS, RED LAKE, MINNESOTA

Mr. SEKI. Chairman Roberts, Ranking Member Stabenow, my Tribe's Senator, Senator Smith, and other friends on this Committee, my name is Darrell G. Seki, Sr. I am Chairman of the Red Land Band of Chippewa Indians. Chi Miigwetch for the oppor-

tunity to testify today about the opportunities and challenges that the new Federal hemp law offers for Indian country.

Red Lake's 840,000-acre reservation is held in trust for my Tribe by the United States, and is home to over 12,000 Tribal members. It is remote with limited job opportunities. While unemployment in Minnesota is below three percent, ours remains close to 40 percent. Because of this, our Red Lake Tribal Government is constantly trying to create new jobs on our reservation.

Thanks to this Committee, and thanks to the work of many Tribes and organizations in the Native Farm Bill Coalition, the 2018 Farm Bill opened a door for Tribal governments to create new and sustainable opportunities for jobs and economic development by growing, processing, marketing hemp products.

Several years ago, our Red Lake Tribal Government began to develop necessarily legal logistics infrastructure to grow, process, and market hemp products. We set aside lands for hemp farming, developed Tribal law to guide the development of our regulatory plans. We issued a license to a Tribal member who made plans for a joint venture project with an experienced hemp grower, and we also explored our agreements with seed providers from Manitoba and Colorado.

We also sought significant levels of financial capital investment that are needed to turn our reservation into a competitive, productive growing and processing center for industrial hemp in our region. Red Lake, like some other reservations, is a great platform where large-scale growing and regional processing can take place in a business-friendly climate. We are excited by the possibilities.

However, our enthusiasm has been tempered by the significantly large startup costs of land preparation, seeds, cultivation, and testing equipment. These challenges are compounded by the regulatory uncertainty that Tribes are experiencing at the hands of the USDA. All our efforts are at risk of being wasted if USDA does not give Tribes like Red Lake a fair regulatory opportunity to compete on equal footing with States.

Earlier this year, USDA announced that they were developing 2018 Farm Bill regulations on hemp, which were initially expected to be released in early fall of 2019 to accommodate the 2020 growing season. Yes, USDA continues to push back its release date. That means Tribal producers are getting less and less time to prepare, plan, finance, and plan for the new crop year.

Meanwhile, States are forging ahead in the competition because they have 2014 Farm Bill authority on hemp seed cultivation processing that Tribes do not because Tribes were shut out of the 2014 Farm Bill hemp provisions. It is ridiculous and na?ve for USDA to suggest that Tribes should ask States if they would partner with us as a highly competitive stage of an emerging market.

Although Congress unlocked the door to Tribal hemp production, USDA's Chairman is jamming that door shut through delays that put Tribes at competitive disadvantages. I doubt it is what Congress intended.

Because of this, Red Lake is urging this Committee to work with Indian Country to compel USDA to take five actions right away.

First, USDA must negotiate with Tribes and determine what constitutes the territory of our Tribal Government that will define boundaries of each Tribe's jurisdiction over hemp production.

Second, USDA must partner with Tribal Government through direct consultation to develop a model plan for hemp that each Tribe can adapt to fit its own situation.

Third, USDA must guarantee Tribes equal access to credit, crop insurance, technical assistance for hemp production and processing.

Fourth, USDA must recruit FDA and together work jointly with Tribal governments in approving and marketing hemp products.

Fifth, and finally, USDA must issue its 2018 Farm Bill regulations in early fall, after robust negotiations with Tribes, so that Tribes are no longer disadvantaged by being left out of the 2014 authority.

Chi Miigwetch for inviting me to testify today, for your leadership in enacting the 2018 Farm Bill. Red Lake Nation looks forward to working with you to see that the law is implemented as you intended.

I will be available for questions, and I say again, Chi Miigwetch.

[The prepared statement of Mr. Seki can be found on page 66 in the appendix.]

Chairman ROBERTS. I want to thank you, Mr. Chairman, and rest assured, when the USDA has its final rule ready, and we do not want to hurry this up too much but we want to get it right, but we know we have to expedite this and that language with regards to your concerns that you have outlined will be addressed.

Mr. Furnish, your experience as a grower with more than one business model for hemp production on your operation brings a valuable perspective. Do you have any suggestions regarding how the RMA can determine good farming practices when hemp varieties are changing and producers are learning more about the crop every year, such as best planting dates and crop rotations?

Mr. FURNISH. Yes, Mr. Chairman. I think it would be very beneficial if members of all agencies come to a working hemp farm in Kentucky and get to experience all the different scenarios that play out on our farm.

I would also encourage the different agencies to get in touch with the Kentucky Department of Agriculture, to Mr. Ryan Quarles and Doris Hamilton, who is the Hemp Director, and ask them how they managed and accelerated the Kentucky program from 33 acres in 2014 to 60,000 acres in 2019.

The groundwork has been laid in Kentucky. We have a tremendous amount of data available through the Kentucky Department of Agriculture and through our hemp growing program. I would encourage anybody that wants to learn about hemp and what has happened in the—this is my sixth crop. All the data has been kept by the Department of Agriculture, Commissioner Ryan Quarles, and it is all available to agencies to take a look at.

There is data on production. There is data on profitability. There is data on how many crops have been destroyed because of weeds. There is data on how many crops have been planted that were not harvested. There is tons of data available in Kentucky if people will just ask us for it.

Any agency or any member of this Committee is invited to my farm at any time to have the experience of what we are doing within the hemp industry, as well as to see the processing side. We built a processing facility from the ground up, went from the shed in the side of a barn into a $35 million facility to process hemp and ship it all over the world, on our farm in Cynthiana, Kentucky.

It is quite an experience, and if anybody wants to come or if you want to hold a field hearing at my farm, that would be most welcome, Chairman.

Chairman ROBERTS. You discussed the need for an effective herbicide. Can you tell the Committee about the agronomic challenges for hemp growers in the absence of any crop protection tools?

Mr. FURNISH. Mr. Chairman, I would say the first couple of years in Kentucky that 80 to 90 percent of the acres planted were destroyed by weeds, at planting. The challenge with hemp seed is when you plant it directly into a field the seed is not very vigorous and it is very hard to get out of the ground. The soil conditions and the rain has to be almost perfect to get the current hemp varieties to germinate in the field.

I have planted one hemp field seven times, one summer, just to try to get it to live. It was either too dry or too wet or it rained the day I planted it, it was too crusted, it was too deep, it was too shallow.

We have perfected that. Over six crops we have perfected that, but it is still a challenge. Weeds are a very big problem. In all other commodities I have weed killers available that I can put on pre-plant or even post-plant. Right now, we go to extensive lengths to make sure that weeds do not get in our crop.

The reason we went to the tobacco model of planting the crop is because we have weed control systems already set up with cultivation equipment from tobacco, and so we are able to keep the weeds out of the hemp the same way we can the tobacco, with cultivation. It would be much easier if I could, when I put my fertilizer on preplant, that I could come through with a herbicide that has an effect over the entire length of the crop, the same way we do for any other crop.

Many farmers lost all their money the first year due to weeds. Luckily, on our farm, we have planted about 1,000 acres and only destroyed 5. That is a pretty good track record for a new crop. I was lucky enough to have a gentleman from Australia who had 18 years of experience. Even though we have different growing models, he was able to bring his experience to me and we were able to perfect that experience in Kentucky.

Chairman ROBERTS. I appreciate that very much. What part of your hemp crop is 23 feet high?

Mr. FURNISH. The fiber crop is planted to get as tall as possible. We plant it in May and we hope by August it is 22 to 23 feet tall. We had to buy specialized equipment from Germany and Australia just to mow it, because it was so big. Once we mow it with this mower from Germany, we can actually handle it very easily at that point, because it cuts it into two-foot sections, lays it on the ground in a windrow, and then we can bale or chop it. It is very easy at that point. Many farmers have tried to use hay equipment to bale fiber and it is an absolute disaster.

Chairman ROBERTS. I thank you for your testimony and very practical advice.

Mrs. Stark, your testimony regarding sampling and testing is extremely insightful. What is the most important issue on testing affecting farmers and the interState movement of the crop, hemp?

Mrs. STARK. The largest issue there is consistency that what tests legal in one State will also test legal using the same or a different method in another State, and that is why we make the recommendation of reconciling the difference between decarboxylation testing and testing on a dry-weight basis. That ensures that just a little bit of wiggle room, so to speak, in order to make sure that no matter which protocol a State is using for testing, or what law enforcement is using to test for compliance, will be consistent from State to State. There is no risk of a consumer purchasing a product in another State and bringing it home and having it test uncompliant in that State.

Like I said, when you are talking about one-tenth of one percent being the difference between legal and illegal, it is important. I think that the spirit of the language in the Farm Bill mandating post-decarboxylation testing is to close any potential loophole that could let marijuana escape into the market under the guise of the hemp program, but certainly even with a few points over 0.3 post-decarboxylation there is zero risk of that happening with our recommended protocols.

Chairman ROBERTS. Mrs. Stark, finally, I should have started with the most basic question. Does your association support implementation of the rule of the Department of Agriculture in a farmer-friendly manner? Obviously you do, I think.

Ms. STARK. Yes.

Chairman ROBERTS. Would availability of an option for crop protection help this industry expand with any future expansion?

Ms. STARK. Certainly. I mean, you know, certainly we are very, very supportive of organic practices for hemp, and one of the things that is attractive about hemp to a lot of like smaller farmers is its propensity to do well in organic practices. We have not done this yet on a full commercial scale. When we start seeing thousands, if not millions of acres of hemp being grown, particularly for fiber production, for manufacturing purposes, absolutely, I anticipate that that is going to be an important issue.

I think, from some of the researchers I have talked to, we just do not know what pests are going to become problematic. It seems like once hemp starts to be grown right next to other more traditional crops it could be that certain pests that are a problem in those, like rye or wheat crops, might figure out that they have a taste for hemp as well.

Certainly the research should be done now in anticipation of moving forward, to make sure that it does not ever become extremely problematic. There is definitely a need for that, and definitely a need for the specific testing protocols for food products, because hemp does tend to be a hyperaccumulator and absorb more toxins than traditional plants. It is definitely going to be a large need.

Chairman ROBERTS. I appreciate that very much.

Senator Smith?

Senator SMITH. Thank you, Chair Roberts, and thanks to all of you for being here today.

Chair Seki, I would like to start with you. I very much appreciate your testimony and I appreciate Chair Roberts' comments also that we hear you loud and clear on how important it is that USDA do the kind of consultation with Tribal governments, just as they would with State governments or other governments.

You know, I want to say that, you know, for those of you that do not know Minnesota so well, the Red Lake Nation is over 260 miles from Minneapolis and St. Paul, and as you say, because of the remoteness, unemployment is a significant issue. I remember when I first met you, in 2014, we talked about many things, but your particular passion was economic development in Red Lake Nation and what we could do. I appreciate how important this opportunity could be for Red Lake.

Let me ask you, Chair Seki, in your testimony you talked about the idea—you know, we talked about various ways that USDA could consult with and assist Tribal governments as they pursue this opportunity, and you talked about the idea of maybe if USDA could create a model plan for Tribal governments. Could you talk about that and just expand a little bit more on how we could be better partners with the Tribes as they work forward this opportunity?

Mr. SEKI. OK. Before I start, the first panel, it is concerning to me, to us, that only USDA mentioned Tribes. See, this is the problem I see, we see, is because we were not included in the 2014 Farm Bill, and now that we are included in the 2018 Farm Bill, and there are many obstacles that the Tribes are running into. That model for all Tribes, that everyone works together as partnership to make this hemp production work in Indian Country is very, very important, because you, as your Committee, as I stated in my oral statement, I gave you five—I recommended five steps to be done to work for our Tribal Nations. You can do it. It is the right way and the model for the other Tribes that are interested in doing hemp production.

Senator SMITH. Thank you very much, Chair Seki, and it is a great point. It is not only USDA. It is all the Federal agencies that interact. We will followup specifically to make sure that we address this.

Let me ask Mr. Furnish—I am so interested in all the practical experience that you have and that we have in Kentucky, and I appreciate that there is still a lot of research that we have left to do on the best varieties of hemp seed, what is most suitable for different regions, and you talked about this in your testimony.

As a seasoned hemp grower, could you give—what advice would you have to give to new hemp growers about ensuring that the hemp crop is at the 0.3 percent THC when the plant is harvested?

Mr. FURNISH. Senator, it all starts with the genetics. You have to find a reputable genetic source who will tell you the truth and tell you what the actual C of A's are, which is Certificate of Analysis, and you have to try to find one that is as close to being certified as possible. The problem is there are very few reputable seed source farms available in the United States at this point. Most of the varieties for CBD production and for full-spectrum hemp oil

production came from bad marijuana varieties, and so that is what we are dealing with.

Many farmers are buying genetics from suppliers who are told, in the beginning, that the only way to keep it below 0.3 is to harvest it early. Well, that creates a huge problem because then your cannabinoid content is also less because you harvested it early.

Senator SMITH. Mm-hmm.

Mr. FURNISH. My brothers and I have been trying to come up with varieties that we do not have to harvest early, and that we can let go to full maturity but still stay below 0.3. We have had pretty good success at that.

I would encourage any farmer that wants to start in this industry, first talk to someone who has done it for a while. Do not believe people who say they are experts, and do not believe a company who comes and says, "I am going to provide everything. You just provide your land and labor and I am going to give you hundreds of thousands of dollars," because that is not reality.

The reality is you can make a living growing hemp, but you will not become rich growing hemp in one year. Many farmers are being told by companies, "If you grow hemp for me, and grow my genetics, you are going to be rich in a year." I do not know anything legal in the United States that you can become rich in a year.

I would encourage anybody—you know, come to Kentucky. We have field days. University of Kentucky has field days. Murray State is doing great work on hemp. They have a field day. We will do farm tours for farmers. I do not have enough time in my schedule to answer every farmer that calls me but I try to do a good job of working with other State, Federal, and regional organizations to get the word out about what hemp is.

I would encourage anybody here, or listening to this, to join is the U.S. Hemp Roundtable as a supporter. It is very effective. We have helped change a lot of laws throughout the country. There is a lot of useful information that is generated on a daily basis to members of that group, and that is a good networking opportunity for everybody in the industry—political figures, government officials, farmers, producers, researchers. It is a hub that everybody ought to be using.

There are other organizations. Vote Hemp, the National Hemp Associations. There are many organizations out there. I am just familiar with the U.S. Hemp Roundtable because I was a founding member and president, but that is not the only one. Join these organizations. Go to these trade shows and conferences.

Enter hemp with caution, extreme caution. I know multi-million dollars lost every day in the hemp business in Kentucky and across the United States.

Senator SMITH. Thank you very much. Mr. Chair.

Senator BOOZMAN.

[Presiding.] No, thank you. That was, again, very interesting. This is a topic of discussion right now, and Mr. Furnish, you are kind of one of the guinea pigs. You have been in this for quite a while compared to most. It sounds like, you know, if you do not have time for all the calls, at some point when you get tired of working the fields you can become a hemp consultant. There is probably money to be made in that regard.

Mr. FURNISH. I already am a hemp consultant, sir.

Senator BOOZMAN. Very good.

Mr. FURNISH. It pays better than farming.

Senator BOOZMAN. Exactly.

I would like to talk a little bit about some of the nuts and bolts, as far as getting in the business. I used to have a bunch of cows. I understand that business very well. I have grown to understand all of these things. Tell us about the expense of getting in. Is it costly to do that? All of farming is costly these days.

Mr. FURNISH. Yes sir, Senator. I think it depends on what part of the country you are in as to what type of hemp you will grow. It is my belief that the CBD full-spectrum hemp oil production will take place where tobacco and vegetables have been grown, because the farmers are used to having labor-intensive crops with a lot of machinery, and they are used to farming that way.

Now, I will never be good at growing fiber and seed from hemp because I am not in a row crop area and I do not have large acreage that I can run huge machines across. It is my belief that the seed production and the fiber production will take place in the Corn Belt where you have flatter land, and you don't need as much water to grow hemp, so I anticipate in the future that is where those crops will go.

For a tobacco farmer getting into hemp production it is very simple. We did not have to spend any money to start growing hemp on our farm. We owned a lot of equipment, a lot of tobacco equipment, a lot of wagons, a lot of tobacco barns. We use—one acre of hemp requires 25 rails in a tobacco barn. That is how we do it. It is very efficient. It is very cheap.

We already had the assets in Kentucky that we needed to do this crop, and that is one reason I think Kentucky has done so well, so far, with the acreage, is because we already had the infrastructure.

The biggest challenge we have is H–2A labor. We will have 60 workers on our farm this year and we are dealing with H–2A and it is almost a full-time job for one of my brothers just to keep the paperwork straight. Between the hemp regulation and the H–2A regulation it is a full-time job. It should not be that complicated to bring in legal workers to work on our farm, considering they have been helping us for 18 years. We should not have to go through the same paperwork and the same housing inspections every single year.

A three-year visa program through H–2A for workers who have never caused a problem would be excellent for us, so we could do paperwork every three years instead of every year.

Senator BOOZMAN. Right.

Mr. FURNISH. You know, it is farming. We have a lot of challenges. Weather is a challenge. The biggest challenge right now is good genetics and companies buying from you that will tell you the truth and pay you on time and pay you what they are supposed to pay you.

Senator BOOZMAN. You mentioned about seed. It sounds like you are developing your own seed varieties. Is the seed—do most people sell the seed as a crop, or part of the crop?

Mr. FURNISH. Every scenario you can imagine is taking place in the country right now. You have a lot of experts who have done

this their whole lives, who just started three months ago, who are trying to sell seed to farmers.

Senator BOOZMAN. Right.

Mr. FURNISH. The biggest challenge farmers have right now for what is most in demand is for CBD. You need high-CBD varieties and low-THC varieties. The challenge is that seed is not available, so the majority of farmers in the United States are using clones from mother plants. Clones is a very expensive way to farm. It is not good for agriculture. It is good for greenhouse production but it is not good for agriculture.

A clone right now, delivered to my farm from a supplier in Kentucky or Colorado or California, would cost me $4 a piece—$3 to $4 a piece. It requires us 3,200 plants per acre. You take 3,200 times $4 and I have already got $13,000 invested in plants. OK? That is not the reality of farming moving forward.

The price of CBD will fall. Once there is more production, the price will fall. The only way for farmers to sustain that is to have a good source of seed. We try to plant feminized seed because the male will pollinate the female and create seed in the female, which creates problems for the extraction. We try to eliminate the males by using feminized seed.

Well, if I buy feminized seed right now I have to pay $1 a seed to have it delivered to me. Odds are the germination will be 20 to 30 percent lower than the company says it is, and when I plant it, it will be 20 to 30 percent higher in the amount of males in the field than what they told me it is.

The only way to remedy that is to create, with USDA, a PVP program for seed certification and breeding, a feminized seed through a true research partner and a farmer, because we know what needs to take place and we move faster than government and universities. We are trying to develop a project now to speed up this process, with the help of the 2018 Farm Bill. Now we can go after a PVP, which is Plant Varietal Protection, for genetics, which does not exist.

People claim to own genetics in this country right now for hemp, and they make you sign a contract that says you cannot re-propagate that variety. The truth is nobody owns the genetics. They have stolen the genetics from somebody else.

Senator BOOZMAN. Right. Thank you very much.

Senator Hoeven?

Senator HOEVEN. Thank you, Mr. Chairman. Is this kind of an early takeover, or what is going on here today?

[Laughter.]

Senator SMITH. Senator Hoeven, I had a rapid rise to power here today.

Senator HOEVEN. I am impressed.

Thanks to all of you for being here.

Ms. Stark, talk about the market size. I mean, you know, I know there is a lot of interest in growing hemp and developing the market. Talk to me about the market size, the market potential for all of the different potential products that go with hemp, whether it is the CBD, or making clothes, or whatever it is. Just kind of take me through the market opportunities, market size and scope.

Ms. STARK. Well, certainly right now CBD is the largest segment of the marketplace. It is where the demand is right now. It is where the money is right now.

Senator HOEVEN. Well, that is kind of important when you are deciding which crop and product to go with, isn't it?

Ms. STARK. Cultivation for CBD versus fiber and grain are two very different business models. They are cultivated differently. The genetics are different. The input costs are dramatically different. They really are—it is the same plant but they almost are kind of different industries.

The infrastructure for processing CBD exists right now. It is where all the investment has been so far. Right now CBD is definitely where the markets are. Now the future of that is largely going to depend on how FDA handles this and what type of regulatory framework we have to move forward.

The longer-term vision for hemp, in looking, you know, maybe 5, 10 years down the road, hopefully faster than that, would be the fiber markets. That is where we are going to have the opportunity to create manufacturing jobs, and have the need to grow hemp on a massive scale. When we talk about supplying the auto industry, and looking to replace single-use plastics, replacing, you know, some of the paper pump we use for paper plates and for papermaking and things of that nature.

There is a lot of infrastructure that still needs to be built there, but the long-term potential of that is tremendous. I often say that I think that fiber is going to be the future of hemp. It has the most potential. It is also going to be what is going to help us realize the most positive environmental impacts as well. There is so much benefit to it, but we are still a little bit behind on building the infrastructure to get there, as opposed to CBD, which is very popular and in demand right now. I expect it will continue to be for the foreseeable future, assuming that we get a clear regulatory framework.

Senator HOEVEN. Is that it—oil and fiber are the two? Are there other aspects of it?

Ms. STARK. Well, the word "oil" is confusing for a lot of people. Hemp oil is not CBD oil. Hemp oil, by strict definition, is cold-pressed from the seed, and that type of oil is what is used to make cooking oil. It is a popular basis for soaps, lotions, and shampoos. That has always been perfectly legal. That has always been exempted from the Controlled Substances Act from the beginning, which is why we have the market for hemp hearts and hemp soaps and lotions, from oil that we have been always able to import from Canada or other places.

CBD oil, on the other hand, is extracted from the plant material, primarily the flower. I always like to use the analogy of thinking of it as like a lavender essential oil. It is just an extract from the cannabis plant, the hemp plant, as opposed to lavender or other types of essential oil.

Senator HOEVEN. The hemp oil is from the seed——

Ms. STARK. Yes.

Senator HOEVEN [continuing]. and the CBD oil is from pressing the flower?

Ms. STARK. It is not necessarily pressing, but there are different methods of extractions. There is CO2 extractions, there is butane. Yes, it is an extract from the flower.

Senator HOEVEN. You knew all that, right, Mr. Chairman? You are fully aware of that? OK.

Talk about those two markets, the CBD oil versus the hemp oil, and can you take both? If you grow the plant, do you have to make a choice there, and then do you have to make a separate choice on fiber? Or are the opportunities to have multiple products?

Ms. STARK. Most people who are cultivating it for CBD right now only want female plants and do not want them to be pollinated and produce seed, because it reduces the volume of the flower material that you have for extraction and lowers the total CBD content of that biomass, of that acreage.

Now, conversely, if you are growing it for fiber and grain, you can save the leftover flower material and the leaves and that can be used for CBD extraction. Fiber and grain varieties tend to have 2 or 3 CBD content whereas specific CBD varietals are 10 percent or higher, therefore generating a lot more revenue per acre.

You can take fiber and grain crops and extract CBD from them on a much smaller scale, but if you are growing a really large volume it is still a good value-add to that crop. If you are growing it for CBD specifically, which is what is going to get you the higher profit margins per acre, you definitely want to grow CBD-specific varietals and not have them get pollinated, if that makes sense.

Senator HOEVEN. It does. It makes it complicated.

Ms. STARK. This is a very complicated world. Yes, it is complicated. The potential is so tremendous. The thing that is great about the CBD production, the way it is now, is that if you are a small farmer and you only have a 20-acre farm, what other crop can give you that type of revenue in that kind of small acreage? You know, and then when you talk about——

Senator HOEVEN. Twenty acres is more in the large garden.

Ms. STARK. Well, not in Pennsylvania, it is not. Again, so there is something for everybody. There is a business model that works for every type of farmer, and I think that is what is really beautiful about it, is that there is room for everybody. We have room for huge, commercial-scale production, but we also have room for even urban farmers to be able to, you know, generate a little bit of revenue. This crop can be totally inclusive, and there is a niche for everybody.

Senator HOEVEN. Thank you. Very interesting. I appreciate that very much.

Can I ask the indulgence of the Chair for one more question? I will try to keep it—OK.

Chairman Seki——

Senator SMITH. Seki.

Senator HOEVEN [continuing]. Seki. I am sorry. Chairman Seki, just in terms of from a Tribal standpoint, just your thoughts in terms of opportunities but also challenges in terms of getting going. It has got to be kind of brief. I do not want the Chairman to come down on me too hard.

Mr. SEKI. OK. The challenges we have is in my oral presentation, the five steps, and also the things we need for a model for tribes,

according to their own situation. Like in Red Lake, our economic development and our Red Lake, Inc., engage in planning, and due diligence, regarding our lands, where we can plant the hemp. Also due diligence, what kind of equipment we need to start this production.

For example, say the market out there, or say we started planting 500 acres, and like this lady is saying about the flowers, this is where you get the CBD oil and other products. Now our first year we figure we could make $3 to $4 million, and it is going to take three to four years to get everything going to maximize this opportunity Tribes are given on this 2018 Farm Bill. Again, I want to say Chi Miigwetch to this Committee for implementing that for Tribes to do the same thing as other States are doing.

Senator HOEVEN. Absolutely. We want to try to help you realize that opportunity. Thank you. Thanks to all of you for being here. I appreciate it very much.

Thank you, Mr. Chairman——

Senator BOOZMAN. Thank you, Senator Hoeven.

Senator HOEVEN [continuing]. and Ranking Member.

Senator BOOZMAN. Thank you all for being here. That concludes our hearing. I do want to thank you. This has been a very informative conversation, sharing some of the upside and downside, you know, what is lurking out there. We appreciate you taking the time to be with us today.

To my fellow members, we ask that any additional questions you may have for the record be submitted to the Committee Clerk five business days from today, or 5 p.m. next Thursday, August 1st, and with that the Committee is adjourned.

[Whereupon, at 11:29 a.m., the Committee was adjourned.]

A P P E N D I X

JULY 25, 2019

Statement by

Greg Ibach

Under Secretary for Marketing and Regulatory Programs

Before the Senate Committee on Agriculture, Nutrition, and Forestry

July 25, 2019

Chairman Roberts, Ranking Member Stabenow, and other members of the committee, thank you for the opportunity to appear before you today to discuss the U.S. Department of Agriculture's (USDA) implementation of the hemp provisions contained in the Agriculture Improvement Act of 2018 (2018 Farm Bill). I am Greg Ibach, Under Secretary for USDA's Marketing and Regulatory Programs mission area, which includes the Agricultural Marketing Service (AMS), the agency charged with implementing the core hemp provisions of the bill. With me today is USDA General Counsel Stephen Vaden. The Office of the General Counsel has been a valuable partner to AMS as we work to provide guidance around allowable activities under the existing authority of the 2014 Farm Bill and as we make progress toward implementing provisions contained in the 2018 Farm Bill.

Today I would like to provide you with a synopsis of all USDA's activities related to hemp since the Farm Bill was signed into law on December 20, 2018. I will also provide the committee with Department's plans for moving forward.

BACKGROUND

The 2018 Farm Bill authorized the production of hemp (defined as *Cannabis sativa L.* and derivatives of cannabis with concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC) of 0.3 percent THC on a dry weight basis or less) and removed hemp and hemp seeds from the Drug Enforcement Administration's (DEA) schedule of Controlled Substances. USDA is required to issue regulations and guidelines to implement a program for the commercial production of industrial hemp in the United States. The rulemaking will outline provisions for the USDA to approve plans submitted by States and Indian Tribes for the domestic production of hemp as set forth by the Farm Bill. It also establishes a federal plan for producers in States or territories of Indian Tribes that do not have their own USDA-approved plan. The program includes provisions for maintaining information on the land where

hemp is produced, testing the levels of THC (the principal psychoactive constituent of cannabis), disposing of plants that are not in compliance with program requirements, licensing requirements, and ensuring compliance.

States or Tribes who submit plans will need to include procedures and information collections regarding: land to be used for planting; testing procedures; effective disposal of plants and products that are not in compliance with the program; information sharing and compliance with law enforcement; annual inspections; submission of information to USDA; and certification that resources and personnel are available to carry out the practices and procedures described above. Individuals who have been convicted of a felony relating to a control substance will not be able to participate in the domestic hemp production program under a State, Tribal, or USDA plan for 10 years after the conviction with a limited exception for those who currently produce hemp under the 2014 Farm Bill. As required by law, USDA is committed to completing its review of plans within 60 days; however, USDA is not able to review or approve State plans until regulations have been promulgated.

For the 2019 planting season, the 2018 Farm Bill provides that States, Tribes, and institutions of higher education can continue operating under authorities of the 2014 Farm Bill which permitted these entities to produce hemp under pilot programs for research purposes. The 2018 Farm Bill extension of the 2014 Farm Bill authority expires 12 months after the effective date of the AMS rule.

In addition to the activities of AMS, the 2018 Farm Bill hemp provisions impact other USDA agencies as well:

Farm Service Agency (FSA)

Producers growing industrial hemp in accordance with the hemp research provisions of the 2014 Farm Bill are eligible for certain FSA farm loans and the agency is working closely with AMS to review provisions in the 2018 Farm Bill.

Natural Resources Conservation (NRCS)

Currently, producers growing industrial hemp in accordance with the hemp research provisions of the 2014 Farm Bill are eligible for NRCS programs and the agency is working closely with AMS and other impacted USDA agencies to review provisions in the 2018 Farm Bill.

Risk Management Agency (RMA)

H.R. 2157, the Supplemental Appropriations for Disaster Relief Act, 2019 directed the Federal Crop Insurance Corporation to offer coverage for hemp through a Whole Farm Revenue Protection plan beginning in 2020. Covered hemp must be grown in accordance with state and federal regulations. In addition, the producer must have a contract with a buyer. Earlier this year, RMA issued guidance to permit hemp to be grown without voiding the Whole Farm Revenue Protection Policy for 2019. RMA is researching options to offer crop insurance coverage for hemp production.

USDA ACTIVITIES

Following passage of the 2018 Farm Bill, AMS participated in hundreds of meetings and consultations with interested parties, in both Washington, D.C. and in the states. These entities include states, Congress, tribes, other Federal agencies, private businesses, industry organizations, and producers. In addition to these meetings, USDA has provided a number of informational documents as well as engaging the public through information gathering sessions. Here is a list of activities to date:

- A Notice to Trade was issued on February 27, 2019 which confirmed that AMS is the agency tasked with this rulemaking and that States and Tribal nations do not need to submit plans until the rulemaking is completed. This notice also clarified that for the 2019 planting season, the 2018 Farm Bill provides that States and institutions of higher education can continue operating under authorities of the 2014 Farm Bill.
- A USDA Hemp Farm Bill Listening Session was held March 13, 2019. This was a three-hour webinar where approximately 2,100 connected and 46 individuals shared their perspectives and ideas on hemp production with USDA officials. The webinar was recorded and is available on our website along with the comments that were submitted to AMS.
- A Notice to Trade was issued on April 18, 2019 which provided assistance to U.S. producers and hemp seed exporters on providing an avenue for hemp seed exports to the United States.
- AMS participated in a USDA Tribal Consultation on Implementing Title X on May 1, 2019. Approximately 30 tribal representatives were in attendance. Over 90 percent of the consultation was devoted to the Farm Bill's hemp provisions.

- A Notice to Trade was issued on May 28, 2019 in which USDA's Office of General Counsel issued a legal analysis concerning provisions pertaining to the interstate transportation of hemp and who may obtain a license to produce hemp.
- A Notice to Trade was issued on May 28, 2019 in which USDA clarified avenues for Tribal participation under authorities in the 2014 Farm Bill to grow industrial hemp for research purposes during the 2019 growing season.
- An Interim Final Rule is currently undergoing interagency review and we hope to issue regulations in the Fall of 2019 to accommodate the 2020 crop year.

NEXT STEPS

Once the regulation is published and becomes effective, AMS will move quickly to establish the program. AMS will begin accepting and reviewing state and tribal plans as well as license applications submitted by individuals who are located in States or territories of Indian Tribes that will not operate their own State or Tribal plan, and who wish to be licensed under the USDA plan.

USDA has worked diligently to establish the program and issue regulations in time for the 2020 crop year. Thank you for the opportunity to be here today and I look forward to any questions you may have.

TESTIMONY OF

ALEXANDRA DAPOLITO DUNN, ESQ.

ASSISTANT ADMINISTRATOR, OFFICE OF CHEMICAL SAFETY AND POLLUTION PRENVENTION

U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE

SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

JULY 25, 2019

Good morning Chairman Roberts, Ranking Member Stabenow, and members of the committee. I am Alexandra Dunn, Assistant Administrator of the Office of Chemical Safety and Pollution Prevention at the U.S. Environmental Protection Agency (EPA). It is a privilege to be here with my federal colleagues to discuss the EPA's role in and plans for regulating hemp.

Safe pesticide use is extremely important to our society, particularly in the production of U.S. food and fiber. Innovation in pesticide use has greatly increased U.S. agricultural productivity and contributed to a predictable food supply and stable food prices. The EPA estimates that pesticides used to control various insects, weeds, and fungus diseases add billions of dollars per year to the U.S. economy, translating into a bolstered workforce of American jobs. Additionally, the pesticide industry accounts for meaningful aspects of the U.S. economy -- a dozen major pesticide producers; another 100 small producers; 1,700 pesticide formulators and 25,000 distributors; 23,000 commercial pest control firms; more than two million farms; and

more than 88 million households.[1] There are more than 17,000 registered pesticide products containing more than 1,200 active ingredients, with uses ranging from insect repellents, household sanitizers, lawn and garden chemicals, hospital and restaurant disinfectants, biotechnology products, and a broad range of agricultural crop protection chemicals used to provide an abundant food supply. The wide range of entities intersecting with pesticides yields challenges for EPA's administration for an efficient and equitable regulatory program. Over time, the EPA has proven to be a nimble and adaptive regulator, such that innovation in the pesticide marketplace is advanced while public health and the environment are protected.

I am pleased to provide an overview of how the EPA regulates pesticides to protect human health and the environment while making valuable tools readily available to provide a safe and abundant food and crop supply.

PESTICIDE REGULATION

The EPA regulates pesticides under the authorities of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food Drug and Cosmetic Act (FFDCA); the Food Quality Protection Act of 1996; the Endangered Species Act (ESA); and the Pesticide Registration Improvement Extension Act (PRIA).

The EPA has developed a highly regarded program for evaluating pesticide safety and making regulatory decisions. Our approach to decision-making is based on the best available science and public transparency. Using these approaches, the agency makes decisions consistent with information that is peer-reviewed and protective of human health and the environment.

[1] EPA Pesticide Industry Sales and Usage: 2008-2012 Market Estimates

Credibility is at the core of meeting the requirements of pesticide registration and reevaluation activities. The EPA has integrated efficiencies into our risk assessment process, enabling the agency to successfully meet the requirements and decision-making goals of PRIA. We have done this in a collaborative manner with our regulatory partners and stakeholder community.

Under FIFRA, the EPA ensures that, when used properly, pesticides provide significant benefits to society, such as controlling disease causing organisms, protecting the environment from invasive species, and fostering an affordable, safe and abundant food supply. FIFRA's safety standard requires the EPA to weigh these types of benefits against risk to the environment that might result from using a pesticide.

FIFRA generally requires that before any pesticide may be sold or distributed in the United States, the EPA must license its sale through a process called "registration." During registration, the agency examines every pesticide product that is intended to be distributed or sold in our country. In addition, under FFDCA, the EPA sets "tolerances" (maximum residue limits) for pesticides used on food or animal feed. The EPA may establish a tolerance or a tolerance exemption for a pesticide residue in food or feed only if the agency finds that there is a "reasonable certainty of no harm" from consumption of the pesticide-treated food and from other non-occupational sources of exposure.

FIFRA also requires the EPA to reexamine previously approved pesticides every 15 years through a program called "registration review." Any changes to the use of a pesticide identified through registration or registration review, as necessary for safe use, appear on product labels. The EPA is statutorily required to complete review of all pesticides by October 1, 2022.

2018 FARM BILL AND HEMP

On December 20, 2018, President Trump signed into law the 2018 Agricultural Improvement Act, also known as the Farm Bill. Section 10113 of the Farm Bill provides for the cultivation, transport, and sale of hemp, a variety of Cannabis sativa that contains 0.3% tetrahydrocannabinol (THC) or less on a dry weight basis.

Again, FIFRA provides that the EPA must approve the use of a pesticide on crops and its labeling in order for that product to be sold in the U.S. Therefore, before a pesticide can be used on hemp, it must first be approved by the EPA. Thanks to the 2018 Farm Bill and the strong economic forecasts for hemp production, the EPA anticipates that pesticide registrants will intensify their interest in gaining crop protection approvals for use on hemp under FIFRA. Starting with an initial registration application we received in May 2019, I can report that the agency has recently begun to receive a number of registration requests seeking to add hemp to pesticide labels. Currently, there are 10 product registration requests under review at the EPA. We have developed an approach for reviewing these actions; and we plan to engage the public in the context of our decision-making on these initial actions by requesting public comment via *Federal Register* notice of receipts.

The pending requests involve biological and microbial chemicals, which tend to be very low impact on the environment. The EPA is prioritizing these requests and reviewing them on an expedited basis consistent with our authorities. I anticipate these will be the first of a group of decisions that will support growers and this new industry. Moreover, the statutory scheme and the agency's regulatory policies offer a strong basis for the EPA to support this developing industry. For instance, minor crops or niche crops may be eligible for a PRIA fee exemption,

since the costs of the registration process may be a barrier for registrants to support labels for low acreage crops. The EPA is also having discussions with our partners at USDA's Inter-regional Research Project #4 (IR-4 Project) who support minor and specialty crop growers through the generation of field residue trial data, which are the critical data needed to support tolerance petitions submitted to the EPA under FFDCA. Hemp projects are currently advancing through the IR-4 system for research and we are working with them and other data developers to ensure that the needed information can be efficiently generated. Moving forward, as registrants submit applications, the EPA stands ready to evaluate and make timely registration decisions for submitted hemp labels.

COLLABORATION

The EPA recognizes the importance of effective collaboration with our federal partners and co-regulators in achieving our mission of protecting public health and the environment. We value our strong partnerships, not only for implementing and enforcing regulatory decisions, but also for the collaboration and input we receive while working through challenging issues. The 2018 Farm Bill requires coordination on hemp between federal partners. The EPA is engaged in an interagency hemp working group with the Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Department of Justice (DOJ). The agency is also in discussions with the Health Canada Pest Management Regulatory Agency about their approved pesticide labels and approaches to regulating hemp. A theme that cuts across the work of the federal partners is our recognition of the definitional limitation for hemp in the 2018 Farm Bill concerning the quantification of the hemp plant's THC content. Marijuana with THC levels higher than 0.3 percent remains a regulated item under the Controlled Substances Act. Therefore,

FIFRA regulatory approvals for this crop would be limited to hemp cultivation for harvested crops with a low concentration of THC, defined in the law as no more than 0.3 percent on a dry weight basis.

State agencies have a co-regulatory role in administering and enforcing FIFRA, and the EPA is working with states on hemp related issues through the State FIFRA Issues Research and Evaluation Group (SFIREG), a committee of the Association of American Pesticide Control Officials (AAPCO).

In addition, the EPA sought input on hemp issues from the Pesticide Program Dialogue Committee (PPDC) during a meeting in May. The PPDC is a chartered forum for stakeholder representatives from commodity groups, registrants, and nongovernmental organizations to provide input on pesticide regulatory, policy, and program implementation issues.

CONCLUSION

The EPA has a history of working in strong collaboration with our federal partners, co-regulators, the grower community and stakeholders to address potential pesticide risks while still providing growers with the necessary tools to meet their pest management needs. We are committed to assisting hemp producers with obtaining the pest management tools needed to help them transition to commercial production of this crop. The agency's effective and long-standing methods for working with industry, grower groups, states and other partners will ensure that producer requirements for pest management and environmental protection can both be achieved.

Thank you for the opportunity to testify today. I will be happy to answer any questions you and the other members may have.

STATEMENT

OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

UNITED STATES SENATE

"HEMP PRODUCTION AND THE 2018 FARM BILL"

JULY 25, 2019

RELEASE ONLY UPON DELIVERY

Introduction

Good morning, Chairman Roberts, Ranking Member Stabenow, and Members of the Committee. I am Dr. Amy Abernethy, Principal Deputy Commissioner of the Food and Drug Administration (FDA or the Agency), which is part of the U.S. Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss FDA's role in the regulation of hemp products. I am also pleased to appear with Greg Ibach from the U.S. Department of Agriculture (USDA) and Alexandra Dunn from the Environmental Protection Agency (EPA). FDA works collaboratively with USDA and EPA on a day in and day out basis across the Agency's programs to ensure coordination across the Federal government.

First, I would like to thank this Committee for explicitly preserving FDA's authority over hemp products in the Agriculture Improvement Act of 2018 (2018 Farm Bill, PL 115-334). We recognize the substantial potential that hemp has for our nation's farmers and agriculture sector. FDA's approach to cannabis and cannabis derived products, including hemp products, is to treat these products just like we do any other. FDA is committed to advancing hemp products through the Agency's existing regulatory pathways, and we are further exploring whether it would be appropriate to make additional regulatory pathways available to hemp products such as those containing cannabidiol (CBD). FDA believes taking this approach protects patients and the public health, fosters innovation for safe and appropriate products, and promotes consumer confidence.

The Current Regulatory State of Play

In December of 2018, the 2018 Farm Bill was signed into law. It removed hemp, defined as cannabis (*Cannabis sativa* L.) and derivatives of cannabis with extremely low concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC) (no more than 0.3 percent THC on a dry weight basis), from the definition of marijuana in the Controlled Substances Act (CSA).

The 2018 Farm Bill explicitly preserved FDA's authorities over hemp products. Therefore, hemp products must meet any applicable FDA requirements and standards, just like any other

FDA-regulated product. For example, FDA's existing authorities over foods, dietary supplements, human and veterinary drugs, and cosmetics apply to hemp products to the extent such hemp products fall within those categories. These safeguards help ensure that Americans have access to safe and accurately labeled hemp products, and, in the case of drugs, that patients can depend on the effectiveness of these products.

In late 2018, FDA advanced three hemp seed derived food products through the Agency's Generally Recognized as Safe (GRAS) process.[1] Hemp seeds do not naturally contain cannabidiol (CBD) or THC, which are cannabinoid compounds that are found in other parts of the cannabis plant. The hemp seed products – hulled hemp seed, hemp seed protein powder, and hemp seed oil – can be legally used in the U.S. food supply. Any food products made with these hemp seed ingredients are subject to the same FDA requirements as any other food, such as those related to ingredient and nutrition labeling, as well as the risk-based, prevention focused Food Safety Modernization Act (PL 111-353) safeguards.[2]

The current regulatory state of play is more complex when it comes to hemp products that contain CBD.

It is unlawful under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to introduce into interstate commerce a food (including any animal food or feed) to which has been added a substance that is an active ingredient in an approved drug product or a substance for which substantial clinical investigations have been instituted, and the existence of such investigations has been made public.[3] Similarly, these types of substances are outside of the statutory definition of a dietary supplement. These provisions in our statute exist to protect patients and to preserve American patients' access to the most safe and advanced pharmaceutical system in the world. I think everyone on this Committee can understand why, in general, adding drugs like

[1] *https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food*
[2] *https://www.govinfo.gov/content/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf*
[3] See FD&C Act Section 301(ll) and Section 201(ff)(3)(B)

blood pressure medicines or chemotherapeutics to foods, or to products marketed as dietary supplements, may not be in the best interests of American consumers and patients.

In June 2018, FDA approved the drug Epidiolex[4] for treatment of seizures associated with two very rare and severe pediatric diseases. The approval of this medicine was a significant milestone for these patients and their families. The active ingredient in this drug is CBD. Based on both the approval of this drug, as well as previous substantial clinical investigations of CBD, CBD cannot be marketed as a dietary supplement, and foods to which CBD has been added cannot be introduced into interstate commerce under the FD&C Act. The FD&C Act provisions that prohibit adding an active drug ingredient to foods or marketing an active drug ingredient as a dietary supplement contain an exception if the drug was marketed in foods or dietary supplements before the drug was approved and before it was subject to substantial clinical investigations. The Agency is not aware of any evidence that CBD was marketed in foods or dietary supplements prior to it being subject to substantial clinical investigation. Therefore, FDA has concluded this exception does not apply to CBD.

The FD&C Act further allows for the Agency to make an exception through notice and comment rulemaking to one or both of the provisions that prohibit adding active drug ingredients to foods or marketing them as dietary supplements. It is important to note that it can take three to five years to complete even an expedited notice and comment rulemaking process that complies with the Administrative Procedure Act and other requirements. Completing a rulemaking requires the Agency to develop a robust record to support the rulemaking, including economic analyses, and to consider public comments, which can be voluminous when rulemakings concern substantive topics for which there is extensive public interest, as in the case of CBD.

Creating an exception for an active drug ingredient to be used in either foods or dietary supplements would make sense only if we could determine that products would be able to meet the other relevant safety standards in the FD&C Act, such as the food additive safety standards for human or animal foods, or the New Dietary Ingredient standards for dietary supplements. If

[4] https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms

we were to create an exception under one provision of the FD&C Act, but other provisions of the statute still barred products from coming to market, our action could end up generating additional confusion in the marketplace – a result the Agency believes all stakeholders would prefer to avoid.

FDA recognizes that three to five years is a long time to wait for regulatory clarity, particularly given the significant public interest in hemp products, and CBD in particular. That is why, as I discuss in greater detail later in my testimony, the Agency is exploring options to reach a resolution more quickly and efficiently.

Cannabidiol (CBD)

It has only been seven months since the 2018 Farm Bill removed hemp, which includes low-THC derivatives of cannabis, such as CBD products, from the definition of marijuana in the CSA. I cannot overstate how significant of a policy sea change this has been. Prior to the enactment of the 2018 Farm Bill, the CSA did not differentiate between marijuana and hemp, and all cannabis (with certain exceptions, e.g. sterilized seeds and mature stalks of the plant) was a Schedule I substance and therefore controlled by the Drug Enforcement Administration (DEA). Early interest in clinical research was focused on the development of drugs using THC rather than CBD. More recently, interest in CBD as a drug is increasing, and, as discussed above, FDA approved Epidiolex in 2018, a drug for the treatment of two severe forms of childhood seizures.

The passage of the 2018 Farm Bill has led to the misperception that all products made from or containing hemp, including those made with CBD, are now legal to sell in interstate commerce. The result has been that storefronts and online retailers have flooded the market with these products, many with unsubstantiated therapeutic claims. FDA has seen CBD appear in a wide variety of products including foods, dietary supplements, veterinary products, and cosmetics. As this new market emerges, we have seen substantial interest from industry, consumers, and Congress. However, in the midst of the excitement and innovation, FDA's role remains the same: to protect and promote the public health.

At present, any CBD food or purported dietary supplement products in interstate commerce is in violation of the FD&C Act due to the statutory provisions discussed above. However, FDA's biggest concern is the marketing of CBD products that make unsubstantiated therapeutic claims to prevent, diagnose, mitigate, treat, or cure serious diseases, but have not obtained new drug approvals. For example, FDA has seen various CBD products with claims of curing cancer or treating Alzheimer's disease. The proliferation of such products may deter consumers from seeking proven, safe medical therapies for serious illnesses – potentially endangering their health or life. FDA's commitment to protect consumers from these unsubstantiated therapeutic claims does not just apply to CBD products – it is a longstanding commitment of the Agency across all the products we regulate.

FDA has issued numerous warning letters to firms selling unapproved CBD drug products with claims to treat or prevent serious diseases, and in fact, the Agency began doing this in 2015, prior to the passage of the 2018 Farm Bill[5]. It is also worth noting that, while investigating these unapproved CBD drug products, FDA identified other concerns. For example, laboratory analysis of some of these products revealed they did not contain the amount of CBD that was claimed on a product's label, and/or the products contained other substances that were not on the product's label, such as other cannabinoids like THC.

Through the approval of the CBD-containing drug Epidiolex, which was based on adequate and well-controlled clinical studies, FDA has learned that CBD is not a risk-free substance. During our review of the marketing application for Epidiolex, we identified certain safety risks, including the potential for liver injury[6]. In that context, the risks are outweighed by the benefits of the approved drug to the particular population for which it was intended.

The drug approval process offers significant benefits to prescribers and patients, including those who seek to prescribe or use hemp products for therapeutic purposes. Drug approvals generally

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[5] *https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products.*

[6] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf*

are based on adequate and well-controlled clinical studies, which gives prescribers and patients confidence in the drug's safety and effectiveness for its indicated use. In addition, approved drugs have uniform strength and consistent delivery that support appropriate dosing needed to treat patients, particularly patients with complex and serious conditions such as the epilepsy syndromes that Epidiolex was approved to treat. Moreover, patients using an approved prescription drug are under medical supervision to monitor any potential adverse effects of the drug. But for consumers purchasing the types of CBD products that are proliferating throughout the marketplace, these protective factors are generally not present.

FDA's Commitment to Sound, Science Based Policy on CBD

Given the substantial public, industry, and congressional interest in CBD, FDA has formed a high-level CBD Policy Working Group, which I co-chair along with Lowell Schiller, who is the Agency's Principal Associate Commissioner for Policy. The goal of the CBD Policy Working Group is to coordinate the Agency's approach to CBD policy making, including considering the appropriateness of potential pathways for dietary supplements and/or conventional foods containing CBD to be lawfully marketed.

The first priority of the CBD Policy Working Group has been to obtain and assess safety data for CBD, given the Agency's public health mission. Although FDA has approved one drug, Epidiolex, that contains CBD, Epidiolex is approved for use in a limited population at a specific dose, was studied for safety and efficacy in rigorous randomized clinical trials, and is available only by a prescription from a licensed medical professional. When considering the use of CBD in non-drug products, such as conventional foods and dietary supplements, FDA must evaluate different factors than for a prescription drug product. CBD food and dietary supplement products would be directly available to a wide range of consumers, which could potentially include pregnant or nursing mothers, children, the elderly, those with chronic illnesses, and those taking medications that might interact with CBD. CBD products could also be given to a wide variety of animal species, some of which are used for food. These would also be available without discussions with a doctor or other medical professional. Given this, FDA must consider

the potential safety implications of long-term use of CBD by different human and animal populations.

FDA is wrestling with questions not only about the intrinsic safety of CBD, but also about potentially unsafe manufacturing processes for products containing CBD. FDA knows from CBD products it has tested that they may not contain the amount of CBD indicated on a label, or they may contain other potentially dangerous compounds that are not listed on the label. Therefore, FDA must consider questions related to good manufacturing practices for CBD products and potential labeling that might be appropriate for these products to address any potential risks to consumers.

FDA has made it a priority to address these questions, and we are working diligently to make progress. However, FDA will only consider creating legal pathways for CBD to be marketed as a dietary supplement or in a food if the Agency is confident that it can develop a framework that addresses safety concerns. Another issue that FDA plans to consider is whether allowing CBD to be marketed as a dietary supplement or in a food will deter clinical research to substantiate additional therapeutic uses for cannabis-derived compounds. Less research into the promise of cannabis-derived compounds and fewer drug approvals in this area would be a significant loss for American patients.

Listening to and Learning from Stakeholders

As part of the Agency's commitment to engage the public on cannabis products and their derivatives, we held a public hearing on May 31, 2019. The goal of the public hearing was to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. The hearing was attended in person by more than 600 people, with over 2,000 more viewing it on line, and included presentations from more than 100 speakers, representing a broad and diverse array of stakeholders, including patients, consumers, and their advocacy groups; health care providers; academia; manufacturers, retailers and distributors; agricultural coalitions; and state, tribal, and local government representatives.

The public hearing raised many issues, including the need for more and better data regarding the benefits and risks of CBD, concerns related to manufacturing, adulteration, and unlawfully marketed products, and even as simple as the need for consistent terminology related to cannabis products. We opened a public docket to collect comments as part of the public hearing, and it just closed on July 16, 2019. We received 4,492 comments submitted to the docket, which we have been reviewing. As this issue progresses, we are committed to being transparent with the public about our path forward and providing information that is based on sound science and data.

We recognize that hemp producers, the food and supplements industry, the pharmaceutical industry, retailers, academic institutions, patients, and consumers all want and need regulatory certainty in this area. The Agency has also put out several statements since the passage of the 2018 Farm Bill to keep the public informed about the current regulatory landscape and our efforts to consider the appropriateness of potential new pathways for cannabis products[7]. We also maintain a Questions and Answers page on cannabis products to help address questions from the public and our stakeholders[8]. We are committed to keep the public updated on this evolving area.

Working with our Federal, State, Tribal, and Local Partners

FDA recognizes that our approach to regulating hemp products must occur in close collaboration with our Federal, state, tribal, and local regulatory partners.

First, I would like to thank my counterparts from USDA and EPA who are also testifying today. FDA has strong relationships with these agencies, and we are working closely with them as USDA and states implement the hemp provisions in the 2018 Farm Bill.

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[7] *https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd; https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation; https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys.*

[8] https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers.

FDA and USDA staff and leaders have participated in numerous meetings and conversations regarding cannabis issues. These include a recent conference with senior leaders from the USDA Agricultural Marketing Service Specialty Crops Program to discuss the agencies' respective roles and responsibilities. FDA and USDA remain in close communication on this issue.

FDA and EPA are engaged in sustained information sharing. For example, earlier this spring, FDA provided EPA's Office of Pesticide Programs with information regarding FDA's regulation of cannabis and cannabis-derived products, including information regarding the recent public hearing. FDA and EPA remain in communication on this issue and plan to further discuss together moving forward.

FDA has been working closely with our state, tribal, and local partners to assist them in navigating the regulation of hemp products, including those that contain CBD. A number of states, tribes, and local jurisdiction have enacted various laws that decriminalize or allow different types of cannabis compounds or products under state law. FDA is also aware that products that contain CBD have become available in these jurisdictions, as well as in jurisdictions that have not enacted any cannabis legalization-related legislation

We remain committed to moving forward on the regulation of hemp products in close coordination with our federal, state, and local partners.

Preserving Incentives for Research and Drug Development

While FDA is considering the possibility of new legal pathways for CBD products, we know that it is important to maintain adequate incentives for drug research and development. Drugs have important therapeutic value and are approved after rigorous scientific studies that provide important new information about therapeutic uses. It is critical that we continue to do what we can to support the science needed to develop new drugs from cannabis. To date, FDA has approved four drugs that contain active ingredients that are cannabinoids found in or related to

the cannabis plant. In addition to Epidiolex, which contains plant-derived purified CBD, and was approved for treating two rare forms of pediatric epilepsy, FDA has approved three drugs containing other cannabinoids for treating the side effects of chemotherapy, such as nausea[9]. Among these three products, two contain synthetically-derived dronabinol, which is chemically identical to THC, and the third contains nabilone, a synthetic chemical analogue of THC, not naturally occurring in cannabis.

FDA has also received feedback from stakeholders interested in conducting research with cannabis and CBD. FDA is committed to doing what we can to facilitate and preserve incentives for clinical research. We are concerned that widespread availability of CBD in products like foods or dietary supplements could reduce commercial incentives to study CBD for potential drug uses, which would be a loss for patients.

To conduct clinical research that could potentially lead to an approved new drug, researchers need to submit an Investigational New Drug application to the FDA's Center for Drug Evaluation and Research. For use as an animal drug product, researchers would establish an Investigational New Animal Drug file with the FDA's Center for Veterinary Medicine.

Because the 2018 Farm Bill removed hemp from the definition of marijuana in the CSA, this change may streamline the process for researchers to study certain cannabis derivatives that have no more than 0.3% THC by dry weight, including cannabinoids such as CBD, which could advance the development of new drugs from those substances.

Conclusion

The 2018 Farm Bill made tremendous changes to the regulation of hemp products, and FDA is fully committed to the work that lies ahead in this space. We are, and will continue to work quickly and efficiently. We recognize the significant interest and potential this crop has for farmers across the United States. FDA looks forward to keeping Congress and stakeholders

[9] *https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers.*

updated on our work to bring appropriate hemp products to market through existing regulatory pathways, as well as our efforts to determine whether additional regulatory frameworks are appropriate for products containing CBD. Our work on hemp products will continue to be founded in our public health mission and our commitment to making sound, science-based policy.

Thank you for the opportunity to discuss FDA's regulation of hemp products. I would be happy to answer any questions.

Brian Furnish Statement to the Senate Ag committee

July 25, 2019

My name is Brian Furnish, and I am an 8th generation tobacco farmer from Kentucky. In the past 7 years I've helped change hemp laws in Washington. I was the first licensed hemp grower in the United States since WW2. I was with many of you when President Trump signed the 2018 Farm bill.

I first started working with the political process with Senator McConnell back in 1999 when we first worked on the Tobacco Buyout that was finally accomplished in 2004. I was General Manager of the Burley Coop in Lexington KY and traveled all over the world selling tobacco and realized that the American tobacco farmers needed an alternative to their cash crop.

Congressman Jamie Comer, who was than the Commissioner of Agriculture in KY, asked me to help him make hemp a legal crop. That's when I started to work with Senator McConnell and you all, to make hemp legal in the US.

The 2014 Farm Bill made hemp legal in states that had a law that allowed research with the universities. At that time I received the first grower license under the 2014 farm bill. I then proceeded to try to find a partner in the hemp business. I found an Australian mate that was growing and researching hemp in Australia. Now that company has a worldwide presence and a market cap of over 1 billion dollars.

I was the first citizen chairman of the KY Hemp Commission and a founder and first president of the US Hemp Roundtable – the industry's leading national business advocacy organization that now has 80 members and serves as a leading advocate in the industry effort to make hemp legal.

My brothers and I have grown all three types of hemp, for seed, for fiber, and floral production to make CBD. Each of these hemp categories uses a different genetic and growing method.

For fiber we will plant about 50 lbs of seed per acre and grow the tall hemp, and we can grow it over 18-20 feet tall. We expect a 3 – 4 ton per acre yield and will get about $185 per ton.

For seed we plant about 30 lbs. per acre, hoping to get a yield of 800 – 1000 pounds per acre and sell it for $.85 per pound.

For CBD we will set about 3200 plants per acre and set or plant them in the same way as we do tobacco, one small plant at a time. We harvest the CBD by only using the flower buds and leaves. You want the short hemp for CBD because it is harvested by hand or special machines like tobacco.

The new hemp industry needs a lot of genetic research to make each of these uses profitable. As with most plants, the latitude must be consistent to get consistent production. In Kentucky

we learned early on that Canadian seed doesn't work very well. Our day and nights are too different.

Hemp seed for feminized seed needs certain periods of light and dark. so we need dark rooms for our genetics, not the green houses that are light whenever the sun comes up.

We have learned a lot over the past 5 years but the hemp industry has a long way to go before it is mainstream production agriculture. Having a certified seed program for hemp would be a huge benefit to the hemp farmers.

Now that hemp is legal we need to take a close look and remove, one by one, the barriers to success so hemp can be on the same production playing field as all the other crops. Most folks in the government and even in production agriculture probably don't know or realize that hemp has no legal pesticide or herbicide or fungicide. A grower can lose its entire crop to weeds or pests. Without an approved herbicide or pesticide we may have to pay labor between $500 - $2500 an acre to pull the weeds to keep our hemp crop pure and healthy. We need your help to encourage EPA and USDA to make those approvals happen.

Hemp growers have no USDA RMA crop insurance, while I know and am part of the U.S. Hemp Farming Alliance, a group involved in the efforts to make that happen, we need to keep the pressure on the creation of those necessary risk management tools, and make them readily available.

Also, without hemp processors knowing if FDA will make hemp a food or a dietary supplement, the unknown only complicates the downstream use of hemp. The current contracts for the hemp growers are all over the place. Many times the grower provides the land and labor, and the processors provide the seed and expertise. However, too often the growers are short changed when the processor can't come up with the money to pay the growers, or the specification for the final products have such varied results that both sides feel cheated and have a bad experience.

Currently there are no industry wide specifications or standards for hemp crops or products. The laboratory testing methodologies have not been standardized so that consumers can be confident of the products they are receiving. The US Hemp Authority has started the process to made hemp and hemp products consistently safe with their Guidance Program but the need for laboratory consistency is real and immediate

The labor necessary to successfully plant and harvest hemp is much the same as tobacco. That's why hemp is and can be a great replacement for the dwindling tobacco production. But, hemp, as with tobacco, is very labor intensive. In the 5 years we have been growing hemp we have found that using the same seed-to-plant process in the greenhouse or dark house in the case of hemp, and then planting the plant in the field as we do with tobacco, is the most productive method. Just last week we had three planters going and it took 23 workers on the planter plus 8 people including myself to keep the planting process going. Over 20 of those workers were our H2A help. We need revisions to the H2A program so our valued labor supply can be maintained.

In closing, I have been for better or worse a farmer face of the hemp grower in the effort to finally make it legal here in the United States. I thank you for making this wonderful crop legal. But now what the hemp growers need and want is for this new and valuable crop to be just that, a crop, with the same opportunities to grow and fill the marketplace with new and valued products. Corn, wheat and soybeans all have hundreds and maybe thousands of product uses. Hemp can too, but they need the barriers removed and the consistency and stabilization which come from the regulatory framework you all can give us. On behalf of the hemp farmers & growers, I'm asking for that help.

Thank you for your time and consideration. I'd be pleased to answer any questions you may have.

Testimony for The Committee on Agriculture, Nutrition, and Forestry of the United States Senate, titled "Hemp Production and the 2018 Farm Bill." July 25, 2019

Submitted by: Erica Stark, Executive Director, National Hemp Association

Thank you, Chairman Roberts, Ranking Member Stabenow and to all committee members for affording NHA this opportunity to speak on the implementation of the new hemp provisions enacted by the Agricultural Improvement Act of 2018. We are appreciative of this committee and its wonderful staff, and to Secretary Sonny Perdue, Under Secretary Greg Ibach, General Counsel Stephen Vaden, Deputy Administrator, Sonia Jimenez and other USDA officials that have long been supportive of the hemp industry.

The National Hemp Association is a D.C. based non-profit, grassroots organization supporting tens of thousands of farmers, businesses and consumers. We have a particular interest in ensuring that this opportunity benefits small and medium-sized farmers who form the backbone of America's rural and agricultural economies and the foundation upon which this country's hemp industry is being built. The passage of the 2018 Farm Bill has brought a lot of hope to a lot of people as we now have the chance to bring to life all of the potential this crop has to offer: for farmers; for economic development in rural communities; for increased sustainability of products we all consume on a daily basis; and for American leadership in global industries and markets that are rapidly evolving to deliver the many valuable benefits of hemp to people all around the world.

Among the many issues surrounding the implementation of the hemp provisions of the 2018 Farm Bill, the National Hemp Association would like to focus today on the following issues of prime importance to our industry: testing protocols; sampling; personnel eligibility requirements; cross-pollination; hemp flower; and importation of biomass.

TESTING PROTOCOLS

Proper and reasonable testing protocols will be instrumental in ensuring the hemp industry's success, particularly with respect to the testing protocol used to determine whether hemp crops meet the legal standard enacted by the Farm Bill:

''SEC. 297A. DEFINITIONS. ''In this subtitle: ''(1) HEMP.—The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives...with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

Hemp is defined in this way because delta-9 tetrahydrocannabinol ("D9-THC") is the only one of at least 113 different biochemical compounds produced in the Cannabis sativa plant species ("cannabis") that can have an intoxicating effect on humans. Cannabis that is relatively high in D9-THC concentrations remains a controlled substance under Federal law, while cannabis that is relatively low in D9-THC—specifically under 0.3% on a dry weight basis—is what the law now defines as "hemp," and is no longer considered a controlled substance under Federal law as a result of the 2018 Farm Bill.

The Farm Bill further enacted a requirement for Federal, state and tribal hemp programs to include "a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels."

One of the challenges that the 2014 Farm Bill-authorized pilot programs revealed in this respect, and what we hope to prevent in the forthcoming USDA regulations, is that if states implement too many different testing protocols, then the industry is left in a situation where what is legal in one state may not be legal in another. This can create undue hardship for farmers selling across state lines, for trucking companies, for law enforcement, and for consumers.

Another of the challenges revealed by the 2014-era pilot programs relates to the uncertainty of determining D9-THC in hemp crops, including 'using post-decarboxylation or other similarly reliable methods.'

After consultations with scientists, state Departments of Agriculture and industry stakeholders, we'd like to recommend an approach that creates a level playing field across the country while adhering to the law and providing the best possible protection for farmers and consumers. This can be accomplished by specifying procedures to be used nationwide for testing D9-THC concentrations.

Specifically, the National Hemp Association recommends that these procedures call for using Gas Chromatography-Flame Ionization Detection (GC-FID) or High-Performance Liquid Chromatography (HPLC) to estimate D9-THC concentrations in post-decarboxylated hemp, and that the estimates resulting from those post-decarboxylation methods be divided by 3 in order to determine the D9-THC concentrations on a dry-weight basis, thus determining whether the crop meets the legal definition of hemp.

GC-FID and HPLC are the most commonly used testing methods by states.

GC-FID is the most common method for testing "using post-decarboxylation" and calls for equipment and skills already possessed by most state Departments of Agriculture, thus keeping costs down for the states, and, therefore, in the form of licensing fees levied by the state (to recoup the costs of administering the hemp program), for farmers.

By contrast, HPLC testing requires skills and equipment that some states possess while others do not, but farmers and processors often prefer HPLC testing for their regular course of business because it provides a wider range of useful analyses to assess the quality of their crops. Therefore, though administrative costs can be higher, farmers in states that utilize this method benefit from efficiencies in satisfying compliance requirements alongside their own quality control needs at the same time.

The reason for dividing the D9-THC concentrations in post-decarboxylated hemp by 3 is due to the relative difference in the concentration of D9-THC in post-decarboxylated hemp as compared to the concentrations in hemp on a dry-weight basis. Peer-reviewed research (Small and Cronquist, 1976; Dussy et al., 2005; UN Office on Drugs and Crime, 2009; Taschwer and Schmid, 2015, Iffland et al., 2016; and others) demonstrates that the ratio of D9-THC concentrations in post-decarboxylated hemp (0% moisture) to the concentrations of D9-THC concentrations in hemp on a dry-weight basis (8-13% moisture) is somewhere between 3:1 and 11:1. Our recommendation to divide the post-decarboxylated D9-THC concentrations by 3 reflects the most conservative end of that range (3:1), so as to obtain the greatest assurance that a crop will not exceed 0.3% on a dry-weight basis.

We further recommend that standards be established for calibration methods, sample preparation and control samples. This would ensure that we do not potentially face a scenario where what is legal by one method is illegal using another accepted method or even another test using the same method.

SAMPLING

How the crop is sampled plays a major role in the results. This is also an area where it is important that the federal regulations are clear and that every state is using the same sampling procedure to ensure test results are consistent from state to state. Some states just sample the flower material while other states take samples from the flower, leaves and small lateral branches. This difference in sampling can produce dramatically different results from the same plant. The scientific research from which the 0.3% D9-THC distinction between hemp and marijuana originated (Small and Cronquist, 1976) adopted that concentration specifically for "young, vigorous leaves of relatively mature plants as a guide to discriminating [the] two classes of plants." Given that, we recommend that all samples are a composite taken from the whole plant including the flower, leaves and small lateral branches.

TIME BETWEEN SAMPLING AND HARVESET

Another important issue is the time allotted between testing and harvest. THC levels have the potential to rise towards the end of harvest making it is important from a regulatory position to have limits between the time a sample is tested to ensure compliance and when the actual harvest takes place. Some states allow for up to 30 days while some provide a more narrow time frame. The challenge becomes what is the right balance from a regulatory perspective while also taking into account practical considerations such as weather conditions and the logistics of a State Department of Ag being able to get to the farms for sampling in a timely manner. This could be handled by the permit holder submitting their target harvest date to the Dept of Ag 30 days prior to that target date. This would give ample time for the Dept. of Ag, or other licensed person or entity authorized to take samples, to make arrangements to visit that farm 14 days prior to the harvest date to collect the samples. In the event that the sample collectors are unable to visit the grow site in that time frame, or in the scenario where adverse weather conditions or other extenuating circumstances prevent the farmer from harvesting on their target date, there should be a provision to allow for testing to be conducted post-harvest and prior to the crop leaving the farm. While field testing is the more ideal scenario from a regulatory viewpoint there can be a separate sampling protocol to ensure that representative samples can be taken from the harvested crop by requiring samples to be taken from each super-sack or other storage container.

FELON BAN

''(B) FELONY.—

H.R.2—423 ''(i) IN GENERAL.—Except as provided in clause (ii), any person convicted of a felony relating to a controlled substance under State or Federal law before, on, or after the date of enactment of this subtitle shall be ineligible, during the 10-year period following the date of the conviction— ''(I) to participate in the program established under this section or section 297C; and ''(II) to produce hemp under any regulations or guidelines issued under section 297D(a). ''(ii) EXCEPTION.—Clause (i) shall not apply to any person growing hemp lawfully with a license, registration, or authorization under a pilot

program authorized by section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) before the date of enactment of this subtitle.

We would like to see this provision implemented only as a restriction on applicants for licenses and not applicable to employees of hemp operations. The principle behind the criminal justice system is rehabilitation and for those who have served their time to be able to assimilate back into society and lead productive lives. With the goal of making hemp a widely used commodity crop, and there being no such restrictions or bans for anyone who works in the industries of corn, soybeans and the like, NHA wishes to see this right extended to all non-permit holders. The Exemption Clause allows this ban to not apply to those that held a license under section 7606 of the Agricultural Act of 2014, supporting the recommendation that this felon ban should only apply to those holding the permit and not those that may be working under the licensed person or entity.

CROSS POLLINATION

While cross pollination concerns are an issue that cannot be practically regulated on a federal level, NHA recommends that there be a regulation that states should collect data pertaining to the type of hemp each permit holder intends to grow and for what end purpose. That information should be made available to the other permit holders in the state in order for them to coordinate with each other based on location and/or for each permit holder to be able to make decisions based on risk assessment.

HEMP FLOWER

While it is unclear at this time where the jurisdiction will be, whether it remains within USDA or is transferred to ATF or another agency, the issue of hemp flower is important and needs to be considered.

Demand for hemp flower has been rapidly increasing over the past year. Many consumers smoke hemp flower as their preferred delivery method of CBD, many smoke hemp flower as an aid in quitting smoking tobacco, and others like to add raw flower into their juicing or other recipes. We have seen an alarming rate of states and cities moving to ban hemp flower despite its clear legality as "All parts of the plant", under the provisions of the 2018 Farm Bill. While it is understandable that law enforcement may have a difficult time determining the difference between hemp flower and marijuana, it should not be a justification to ban it. While it may within each state's rights to impose restrictions that the federal government does not impose, based on other case law, an argument could be made that a state banning something that is expressly federally legal could be unconstitutional. Perhaps there could be some guidance for states with recommendations for labeling requirements, certificates of analysis or other means to protect this portion of the industry. Not only does this type of boutique hemp provide a great way to ensure small and diverse cultivators and businesses continue to have a niche in this industry as it grows, it is also important to provide some protection for consumers that may purchase product online or in other states that are unaware of any local or state bans.

IMPORTATION OF BIOMASS

The issue of CBD imports will be outside of USDA's purview, but the issue of biomass imports will remain within USDA. NHA believes that there should be a ban on foreign imports of biomass from outside of North America. As this industry grows the opportunity to supply the industry should go to American

farmers. In addition, since this crop is only now going to be grown on a true commercial scale, it is still unknown what pests or diseases may become problematic without exposing our farmers to the risks of non-native pests or pathogens.

CONCLUSION

To quote our NHA Chairman, Geoff Whaling, "This is a once in a lifetime opportunity. We will only grasp the staggering potential of hemp if we empower ALL people to participate, regardless of background. We need to get this right!" We acknowledge that implementation of the hemp provisions of the 2018 Farm Bill is a challenging task for regulators as it touches many different federal and state agencies, farmers, businesses and the public.

At the very heart of what we need to move forward is simplicity and clarity. We need regulations that create an even playing field across the country. We need to eliminate the unintended consequences of legal 'gray areas' caused by each state testing differently and operating under a different set of rules and regulations. The hemp industry has been struggling with legal uncertainties for too long and looks forward to reasonable regulations which will afford the opportunity for all to prosper within a clear legal framework.

Thank you for this opportunity to present our positions and for your consideration.

RED LAKE BAND
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Testimony of the Honorable Darrell G. Seki, Sr.
Tribal Chairman
Red Lake Band of Chippewa Indians
Before the
U.S. Senate Committee on Agriculture, Nutrition, and Forestry
Hearing on "Hemp Production and the 2018 Farm Bill"
July 25, 2019

Chairman Roberts, Ranking Member Stabenow, and members of the U.S. Senate Committee on Agriculture, Nutrition, and Forestry, my name is Darrell G. Seki, Sr. and I am Chairman of the Red Lake Band of Chippewa Indians in what is now, northern Minnesota.

Chi Miigwetch for the opportunity to provide testimony on the challenges and opportunities for Tribal governance and the production, processing, and marketing of industrial hemp in Indian Country.

Background on the Red Lake Nation and Reservation

Red Lake's 840,000 acre Reservation is held in trust by the United States and is home to over 12,000 Tribal members. While diminished in size over time, our Reservation was never broken apart or allotted. Thus our Tribal government is responsible for a large land area over which we exercise full governmental authority, jurisdiction and control, in conjunction with the United States.

There are far too few job opportunities available on our Reservation, due to our remote location, our lack of good roads, reliable communications systems, and other necessary infrastructure. These challenges make it difficult to provide public safety services, promote economic development, and create employment opportunities at Red Lake. While unemployment in Minnesota is below 3 percent, ours remains close to 40 percent.

Our Red Lake Nation has a rich tradition of agricultural production along with our fish, harvesting, wildlife and service economies. Red Lake Reservation has the only commercial fishery for walleye in the United States, annually catching, processing and marketing about a million pounds of fish. Red Lake is the only Tribe in the U.S. that grows and harvests our own wild rice on Tribal lands. Red Lake Nation Foods has expanded our natural foods line with unique hand harvested wild fruit jellies, jams & syrups, handcrafted gift items, all natural batter mixes, popcorn & herbal teas. We are pleased to export into the domestic American and international trade markets the bounty of our Reservation harvest produced by Native people. Red Lake Nation Foods is a proud and active member of the Intertribal Agriculture Council and the Native Farm Bill Coalition, and with pride we place the "Made/Produced by American Indians" trademark on our products.

Our Tribe has long operated the Red Lake Tribal Farms on the western side of our Reservation. We are using fish waste from our Walleye processing facility to fertilize our land and help our crops grow. Our interest in hemp production, processing and marketing stands well within our strong food production and processing traditions. When the 2018 Farm Bill provisions on hemp emerged, Red Lake began the process of developing the necessary legal and practical infrastructure. We adopted a Tribal law to guide our ongoing development of our regulatory plan for hemp production, processing and marketing. We are seeking significant levels of financial capital investment that are needed to turn our relatively vast land area into a competitively productive growing and processing center for industrial hemp in our region. There is great opportunity for Red Lake in this field, if we are given a *fair* opportunity to compete.

Tribal Perspective on the 2018 Farm Bill

The enactment of the 2018 Farm Bill, the Agriculture Act of 2018 (Pub. L. No. 115-334), represented an incredible paradigm shift in federal law, both in its acknowledgment of Tribal government sovereignty and its promotion of parity for Tribal producers. Because of the 2018 Farm Bill's recognition of Tribal sovereignty, Tribal producers across Indian Country will have improved access to the programs and authorities at the U.S. Department of Agriculture (USDA). These historic changes for Indian Country in the 2018 Farm Bill are owed in part to the work of the many Tribal leaders, Tribal organizations, Native youth, and allies who joined together to form the Native Farm Bill Coalition (NFBC) in October 2017. The NFBC today counts over 170 Tribal governments as members with 78 Tribes passing resolutions of support, 15 national and regional Tribal organizations/entities, and two national ally organizations. In addition to the dedication of the NFBC members, the support that Indian Country finds in the 2018 Farm Bill is also owed in large part to this Senate Committee, whose members and staff worked with NFBC members throughout the entire legislative process. In the end, our combined efforts cemented 63 new provisions across 11 of the 12 Farm Bill titles. These 63 provisions are aimed specifically at supporting Tribal self-governance, food, and agriculture, infrastructure, research, and education for Tribal governments and Tribal food producers, all of which will assist Tribes and Tribal producers in continuing to promote economic development, job creation, and healthy, sustainable food systems.

Hemp's Growing Potential for Tribes

Of the 63 significant Tribal provisions in the 2018 Farm Bill, one of the clearest illustrations of its many acknowledgments of Tribal sovereignty appears in the Horticulture Title, where Congress legalized the production of industrial hemp and expressly included Tribes alongside states as regulators of hemp production. While the 2014 Farm Bill only offered Tribes the opportunity to grow industrial hemp through an agreement with a state institution of higher education, the 2018 Farm Bill specifically recognizes that Tribes have separate and independent legal authority to regulate industrial hemp production in the same manner as states. This provision represents remarkable respect for Tribal government sovereignty and parity. It also offers Tribes federal protection for an incredible economic development opportunity.

The Tribal regulation and production of industrial hemp holds great promise to build strong, sustainable agricultural economic development through Indian Country, creating jobs and building strong Tribal economies in some of our nation's most rural and remote areas where local economies have stagnated, and unemployment remains high. Tribes and Tribal producers are ready to enter this new market as soon as possible. Many Tribes, like the Red Lake Nation, have access to the land and water necessary to be leaders not only in the cultivation of industrial hemp, but to engage in lucrative value-added agriculture for hemp products as well.

The 2017 Census of Agriculture data indicates that 58.7 million acres of land throughout Indian Country are already supporting some type of food or agriculture production, at a total value of $3.5 billion. Today's robust Tribal agriculture sector reflects only the beginning of what is the bourgeoning potential of Indian Country to feed itself and provide food, fiber, and jobs throughout America. Expanding Tribal agriculture production to include industrial hemp cultivation will certainly help grow Tribal economies and create Tribal jobs, but only if the 2018 Farm Bill hemp provisions are implemented in a way that truly allows for Tribal self-governance. Tribal producers must be free to pursue these new market opportunities without unnecessary administrative burdens from USDA, or our producers will continue to struggle to access a market that the 2018 Farm Bill made clear was open to them. Tribes insist on a fair opportunity, on par with states in ways that make up for the many years Tribes have lost due to legal disadvantage and neglect.

Support for Tribal Authority to Regulate Hemp in the 2018 Farm Bill

In the 2018 Farm Bill, Congress unequivocally recognized the ability of Tribal governments to exercise our sovereignty and regulate industrial hemp produced within our jurisdictions, on par with state governments.

Tribes and states who want to regulate industrial hemp are authorized to submit a regulatory plan to USDA who has 60 days to review and approve it. The 2018 Farm Bill provides relatively few criteria that a Tribal (or state) plan must meet in order to regulate industrial hemp, and the Red Lake Nation thanks this Committee for that parity of treatment in the statute, and especially the fact that the law you authored applies exactly the same criteria for both Tribal and state governments. We are grateful that the law now makes no distinction between Tribes and states for regulatory management of industrial hemp.

Because the Farm Bill put Tribes on equal footing with states, it is all the more disappointing that USDA's current regulatory process leaves Tribal governments and Tribal producers lagging behind the states. Despite significant progress in the Farm Bill itself for Tribal sovereignty, USDA decisions to delay regulations are threatening to cripple Tribal industrial hemp projects before they can even begin.

If Tribes had always been on the same footing with states in terms of growing and regulating industrial hemp, this regulatory delay would merely be a source of frustration. Instead it poses a serious threat to competitive Tribal agribusiness. Unfortunately, the 2014 Farm Bill authority only allowed hemp production as part of a research pilot program authorized under state law in partnership with a higher education state institution or state department of agriculture. Our 1994 Land Grant Tribal colleges and Tribal universities and Tribal departments of agriculture and Tribal regulatory authorities were excluded from the hemp research authority in the 2014 Farm Bill unless we were able to persuade a state competitor to partner with us. This was simply not an option for many Tribes. Even for Tribes who maintain good relationships with their state universities or departments of agriculture, the 2014 law was still essentially asking Tribes to subordinate our sovereignty to states just to do research. This legal background is unfortunately still relevant to Tribes and Tribal producers today: the USDA's regulatory delay on its implementation of 2018 Farm Bill hemp authorities means that state governments today continue to be able to take competitive advantage of the unfair 2014 Farm Bill authorities on hemp research while Tribes are left to wait on USDA to implement the 2018 parity provisions.

Earlier this year, the USDA Agricultural Marketing Service (USDA-AMS) announced that AMS was developing hemp regulations which it expected would be released in early Fall 2019 to accommodate the 2020 growing season. As the months have passed, AMS has continued to push back this expected date. The more the AMS delays, the less time Tribal producers are given to prepare, plan, finance, and plant for the new crop year. Because there are no regulations, USDA takes the position that it cannot review and approve any proposed regulatory plans, whether from a Tribe or a state. However, states are still able to continue growing hemp under the 2014 law—and Tribes are not. Right now, the only way for Tribes to begin hemp production is to use the extremely limited 2014 Farm Bill industrial hemp authority, which as I have stated does not acknowledge Tribal sovereignty and requires a state competitor to become a willing partner. While USDA-AMS has sought to clarify its interpretation of the 2014 Farm Bill authority and how it will apply to Tribes in the 2019 growing season, it *still* limits and requires Tribal sovereignty to take a backseat to state authority. This is *not* what this Committee intended to be the outcome of the 2018 Farm Bill. I find it deeply frustrating that although the 2018 Farm Bill unlocked the door to Tribal parity in this area, USDA has blocked Tribes from opening that door through delayed implementation that places Tribes at a distinct competitive disadvantage.

Under federal law, the allocation of state and Tribal jurisdiction varies widely throughout Indian Country. At Red Lake Nation, our Reservation is solely under Tribal and federal jurisdiction. The State of Minnesota has no jurisdiction, civil or criminal. So for the Red Lake Nation, there is no legal framework that would permit us to enter into an agreement subjugating us to the State of Minnesota under 2014 Farm Bill authorities, even if we were to want to – which we do not. For many Tribes, the negative impacts and effects of a Tribe or Tribal producer starting production of hemp under a state law in 2019 not only exposes deep wounds from historically

competitive battles with states, but it also creates new concerns. Despite the bedrock federal Indian law cases of the Marshall Trilogy of the early 19th century, states have continually, consistently and wrongly attempted to assert jurisdiction over Tribal lands, especially policing powers. Given that the 2018 Farm Bill hemp provision hinges on a Tribe's ability to regulate and enforce its own laws, the USDA-AMS is shoving Tribes backwards by saying Tribes should simply start hemp production under state authority as an interim measure under the 2014 Farm Bill. Heeding that message would be a dangerous step back. It would not only set a wrong standard but also provide states an unwelcome foot in the door to exercise state jurisdiction and competitive control over Tribal lands. As we have seen countless times in Indian Country, once the federal government opens that door for states, it is extremely difficult, if not impossible, to walk the state back out the door and shut it again.

Tribes see this new market opportunity for hemp as one that has the potential to provide badly needed jobs and spur economic development in many of our remote and rural Tribal lands, but Tribes' unequal footing while the USDA-AMS delays implementation of the 2018 Farm Bill provisions will leave that potential wholly unrealized.

Need for Improved Consultation with Tribal leaders

Although USDA has held two Tribal consultations on the 2018 Farm Bill as a whole, this issue of hemp is so new, and so complicated, that we should have meaningful Tribal consultation focused on hemp alone. AMS has had a few "listening sessions" on hemp, but there is a significant difference between a consultation, where there is government-to-government dialogue between decision-making government representatives, and a listening session, where Tribal leaders raise concern after concern and the federal government is not really able to respond beyond a series of prepared talking points. Tribal governments need better engagement and communication from USDA on the development of industrial hemp regulations, especially as those regulations look to address Tribal regulatory jurisdiction over hemp.

One key issue that requires consultation is the growing concern among Tribal leaders about the definition of our jurisdiction in these developing regulations. We are unsure what the boundaries of that jurisdiction are because of the way it is defined in the Farm Bill. The new law defines a Tribe's jurisdiction to be the "territory of an Indian Tribe." Now for the Red Lake Indian Reservation, that should be quite clear. Our Reservation is intact. It was never allotted. Virtually all of the land within our Reservation boundaries are held in trust by the United States for the Red Lake Band of Chippewa Indians. Our Reservation was excluded from Public Law 83-280, preventing all state jurisdiction. I am concerned, however, that USDA-AMS is not openly addressing the wide variety of jurisdictional differences throughout Indian Country.

Unlike Red Lake and some other Tribes, many Tribes[1] have many different types of land within their jurisdictional boundaries: fee land, restricted fee land, individual trust land, or Tribal trust land. All of those legal categories can have different jurisdictional rules, yet hemp could

[1] Public Law 83-280 imposed varying state laws on many lands within Indian reservations and Tribal communities in Alaska, California, Minnesota (except for Red Lake Nation), Nebraska, Oregon, Wisconsin, as well as Florida, Idaho, and Washington. Other federal laws have imposed state law on other Tribal reservation lands (e.g., Oklahoma).

reasonably be grown on any of those lands within the "territory of an Indian Tribe." Given USDA's limited legal expertise in Tribal lands, this Committee should insist that Tribal leaders be welcomed by USDA, along with their technical advisors, to partner with USDA in guiding the regulation-writing process that will shape the federal regulations regarding our Tribal jurisdiction over our Tribal territory, and how the term "Tribal territory" is best defined in the regulation of hemp. If USDA does not take steps to define "territory of an Indian Tribe" in the regulations in meaningful and direct consultation with Tribes, I and other Tribal leaders are concerned that we will end up in a space where everyone involved in growing hemp on Tribal lands has to work out whether or not they can grow hemp on a parcel-by-parcel basis. That would be a huge barrier to Tribal regulation of hemp and to the Tribal producers trying to grow hemp. It would also be a paralyzing challenge to Tribal governments seeking to regulate consistent and uniform hemp production structures. To ensure this is not an additional barrier to Tribal economic development, USDA must work with Tribes on developing more precise definitions, or we need clarity in subsequent legislation. Here's the bottom line – Indian Tribes will *not* go backwards. Given that federal recognition of our jurisdiction has suffered calamitous erosion for more than two centuries, many Tribes will join the Red Lake Nation in insisting that Tribal authority to produce and process hemp within the "territory of an Indian Tribe" means that Tribes have the authority to regulate, produce and process hemp within "Indian country" as defined in Section 1151 of Title 18, United States Code.[2] While there may be additional views on how to define the statutory phrase – "territory of an Indian Tribe" – my point here today is that USDA should develop its views only in negotiation with Tribal leadership.

If USDA is going to give us that clarity in the regulations, however, then USDA needs to communicate better with Tribal leaders on this issue through a meaningful, government-to-government consultation on hemp alone. Tribal leaders understand the jurisdictional complications of the phrase, "territory of an Indian Tribe," because we deal with those complications every day. That is why I recommend that phrase be defined based on the territorial bounds of our Tribal reservations and jurisdictional service areas, which would keep us from having all parties involved considering their land status on a parcel-by-parcel basis. This definition is clear and recognizes Tribal sovereignty in a manner that is consistent with the inherent authority we have exercised since time immemorial. For these reasons, Congress must insist that the USDA deal with Tribal leaders as its technical and political advisors on this and many other issues regarding industrial hemp. The Committee should demand that the USDA invite Tribal leaders to sit at the regulatory-writing table as governmental partners not special interest groups or "stakeholders." The appropriate vehicle for that is through agency-specific, government-to-government negotiation consultations not listening sessions.

Another issue that requires Tribal consultation is the interstate commerce protections provision and issues with the testing certification process. Section 10114 of the 2018 Farm Bill safeguards the transportation and shipment of legally produced hemp under an approved Tribal or state plan

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[2] *"[T]he term 'Indian country' ... means (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state, and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same."* Title 18 U.S.C. § 1151.

when a crop leaves Tribal jurisdiction and enters another jurisdiction where hemp production might be illegal as a matter of state or Tribal law. There currently exists no efficient manner by which law enforcement in the field can scientifically determine whether a hemp crop is below the prescribed THC level of 0.3 percent on a dry weight basis without laboratory testing (which by definition now requires delay and impoundment). To complicate the matter more, the currently available tests yield different results, and hemp THC percentage levels can vary in the harvest, packing, and shipping processes. Therefore, you can have legally produced Tribal hemp that tests at the proscribed limit when harvested, but then tests above 0.3 THC when, inevitably, the truck carrying it is stopped in a state where the hemp production is illegal. This can create extensive inefficiencies, logistical shipping delays, and product loss, and can lead to personally burdensome arrests and bonds while a crop undergoes testing. It can also be exploited by states as a competitive means to thwart Tribal hemp production and it could deter third parties from doing business with Tribal producers and processors, thereby negatively compounding the economic disparities already faced by Tribes.

Tribal leaders have requested a formal consultation with USDA-AMS to discuss the hemp industry's unique regulatory issues in the context of Indian country. This request was made to the USDA-Office of Tribal Relations (OTR) at the most recent 2018 Farm Bill Tribal Consultation, which took place in Reno, Nevada, at the end of June 2019. So far, notice of a scheduled consultation has not reached Tribal leaders. I would like to underscore the need for this consultation before this Committee. We simply must have a meaningful consultation with USDA-AMS on these hemp issues that I have brought before the Committee today, or Tribes will continue to be left out of this process and regulatory decisions will be made that make it more difficult for Tribes to access this new market opportunity.

The fear of Tribes being left behind by USDA is not unsubstantiated. On many separate instances in meetings and listening session, high-ranking officials within USDA-AMS have frequently mischaracterized the sovereignty of Indian Tribes in the context of industrial hemp regulation under the 2018 Farm Bill, often not understanding that Tribal authority to regulate hemp production on our lands is not predicated on any state action and exists on-par with states in every aspect and that Tribes have their own policing powers and authorities. I believe effective consultation could provide clarity to all parties, but especially to USDA-AMS officials who are charged with crafting regulations that will affect Tribes for years to come.

Such a consultation would mark the first standalone government-to-government consultation concerning industrial hemp since the passage of the Farm Bill last December. This consultation would serve as a platform to clarify these recurring misunderstandings of Tribal authority and offer Tribal leaders an opportunity to provide USDA-AMS with technical advice on Indian country jurisdiction that will prove invaluable to the Department in crafting regulations that make sense and promote, rather than stifle, Tribal hemp production and processing. It is deeply concerning that regulations implementing these provisions will be released in a matter of months when meaningful consultation has not occurred as is required by USDA Departmental Regulation 1350-002. While I do not wish to delay the release of regulations further, I also know that regulation crafted without the necessary Tribal input could have negative impacts that last even longer than the problems arising from USDA's delay. A standalone consultation on hemp with Tribal leaders should be scheduled immediately.

Need for Technical Assistance and Risk Management Tools for Hemp Production

The 2018 Farm Bill also authorizes USDA-AMS to provide technical assistance to Tribal governments as we begin developing our regulatory plans. A form of technical assistance that would most benefit Tribes like the Red Lake Nation would be for USDA-AMS to issue a "model plan" for us to modify and adapt for our own governmental needs. This would lessen the amount of Tribal resources expended to enter this market and potentially expedite the review process for USDA when we submit plans. I know the Tribal members of the Native Farm Bill Coalition stand ready to provide their technical experts to help USDA-AMS draft such a "model plan."

The 2018 Farm Bill also assures Tribes that industrial hemp producers in our Tribal communities are eligible to receive the benefits of federal crop insurance administered by the USDA-Risk Management Agency (USDA-RMA). Despite that assurance in the law, we had no clear pathway to receiving this coverage until Congress passed the Additional Supplemental Appropriations for Disaster Relief Act of 2019 (H.R. 2157). That law finally made it clear that industrial hemp producers may purchase coverage for their crop through a Whole Farm Revenue Protection policy beginning in the 2020 reinsurance year. We appreciate that assurance from Congress, but now we look to USDA to implement it. USDA-AMS and USDA-RMA must work together in implementing this provision as Congress intended so that our Tribal producers, and investors from outside Indian country, can enjoy a necessary degree of security in their investments and reap the full benefits of this growing market.

Need for Access to Credit for Hemp Production

While Congress has identified a clear pathway to accessing federal crop insurance for hemp, questions remain about how Tribal producers can access credit assistance. It is unclear right now if industrial hemp producers will be able to access capital through additional USDA programs and farm loans like those many Native producers receive from Farm Service Agency (FSA), since the 2014 Farm Bill authority does not allow for it. For example, FSA State Directors are in the position to have to tell local farmers that they cannot provide FSA loans for the 2019 growing season because they are producing hemp under the 2014 Farm Bill which is just supposed to be a stop gap while we await new regulations. This FSA position is delaying the access to credit products that hemp producers need and will create a huge problem in Indian Country where access to credit is typically scarce. Credit deserts exist throughout Indian country and as a result, Tribal producers rely on FSA as a lender because there either are no commercial banks in our remote communities, or because the commercial banks refuse to adequately lend to our producers. FSA must honor the changes that the 2018 Farm Bill made and not further burden Tribal producers who are looking to expand into hemp production in this growing cycle and beyond.

Additionally, the regulatory delay is inevitably limiting other agriculture lenders from releasing guidance for lending to industrial hemp producers, leaving us with more questions than answers about credit access for Indian country. Further hesitation to lend to hemp growers will only make it even harder for Tribal producers to access credit, something that is such a challenge overall that the 2018 Farm Bill requested a special study from the GAO on the topic. Clear

guidance from policymakers is needed so that these items do not further compound the economic obstacles plaguing our communities.

Regulatory Issues Impacting Marketability of Hemp Products

I would like to raise one final regulatory issue which has the potential to have a serious negative impact on the marketability of hemp products, specifically hemp-based food products. Shortly after the 2018 Farm Bill was signed into law, the Commissioner of the U.S. Food & Drug Administration (FDA) released a statement that the agency would still retain the authority to regulate THC- and CBD-based food and drug products as FDA interprets these types of products to still be illegal under federal law. FDA's statement has created much confusion among our Tribal producers who want to grow hemp and also develop and process value-added hemp food products.

There are clearly many questions surrounding the new hemp provisions, and this incongruent regulatory interpretation between the USDA hemp cultivation side and FDA hemp-based food and drug products side is adding great uncertainty to the legal landscape. We need clarity as to when each federal agency is properly exercising jurisdiction and what is permissible under the law. Thus, we ask the Committee to instruct the federal agencies to work closely together in developing a federal regulatory framework to avoid a patchwork of conflicting state and Tribal regulations in this area and simplify the marketplace for cultivators, producers, processors and purchasers alike.

Conclusion

The industrial hemp provisions of the 2018 Farm Bill hold vast potential for sustainable economic development throughout Indian country. These remarkable provisions recognize the inherent sovereignty of Indian Tribes, and our proper governmental role in developing this new agricultural market as partners on par with the federal and state governments. In its implementation of the 2018 Farm Bill, however USDA is not reflecting the spirit and letter of this new law. The Committee should aggressively exercise its oversight responsibility to ensure that the USDA consistently and actively engage with Tribal governments throughout the implementation process.

The legalization of industrial hemp production marks a potential landmark economic opportunity for Tribes and Tribal producers through value-added agriculture. Because of this, it is vital that federal policymakers and agency officials negotiate with Tribal leaders, in robust government-to-government consultation, in shaping the federal regulatory structure implementing the industrial hemp provisions of the 2018 Farm Bill. This commitment must be made real from top to bottom at USDA. Otherwise, there is a high risk of this turning into yet another missed opportunity for Indian Country.

I would like to thank the Committee – Chi Miigwetch -- for holding this hearing and offering me an opportunity to focus on these issues and urge that Indian Country be restored to an equal footing and competitive opportunity in hemp cultivation, production, processing and purchasing, just as this Committee envisioned it in the 2018 Farm Bill.

DOCUMENTS SUBMITTED FOR THE RECORD

JULY 25, 2019

July 23, 2019

The Honorable Pat Roberts
Chairman
Committee on Agriculture, Nutrition & Forestry
United States Senate
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
Committee on Agriculture, Nutrition, & Forestry
United States Senate
Washington, DC 20510

This letter is submitted on behalf of the members of the Association of American Pesticide Control Officials, Inc. (AAPCO). Members of AAPCO consist of the officers charged by law with the execution of the state, territorial, provincial, and federal pesticide laws in the United States, including all its territories, and in Canada.

It is commonly recognized that hemp may be grown for a variety of purposes. These include, but are not limited to: as a protein or oil source utilizing the seed; as a source of fiber; and also for derivatives that contain no more than 0.3 percent delta-9-tetrahydrocannabinol (THC). There are currently many agricultural crops classified as food crops that are grown exclusively to extract oils or other substances. These include oils from seeds such as canola, oils extracted or distilled from foliage such as mint, or substances extracted from cones (flowers) such as hops. After extensive requirements are met, including the establishment of food tolerances, pesticides are eligible to be registered for use on these food crops.

It is the opinion of AAPCO that hemp should be treated similarly to other crops and regulated as a food crop, with the recognition that it may be grown for food products and its byproducts may be fed to livestock. Pesticides used on agricultural food and feed crops are heavily regulated by both federal and state agencies, using an established framework that is familiar to agricultural producers. For these reasons, AAPCO has provided comments to the Food and Drug Administration (FDA), urging them to classify hemp as a food crop and not as a supplement.

Prior to a pesticide being registered for use on a food or feed crop, a tolerance needs to be established by U.S. Environmental Protection Agency (EPA)[1]. AAPCO has been working with EPA to encourage the development of food tolerances that would cover hemp seeds and/or derivatives extracted from hemp flower buds and leaves. EPA has indicated to AAPCO, that pesticide residue data have not been submitted to them by pesticide registrants or by the IR-4 Project[2] (IR-4) for their review. Therefore, they have not been able to establish tolerances or approve pesticide registrations for use on hemp.

[1] Unless exempted from the requirement of a tolerance

[2] The IR-4 Project is a national agriculture research project that is funded by the federal government and state Ag. Experimental Stations to facilitate the registration of crop protection products for specialty crops and minor uses.

In order to collect some of the data necessary for establishing tolerances, pesticide residue trials and sampling need to be conducted by pesticide registrants or by IR-4, under a highly specific and well-defined research protocol. The lack of such a protocol for hemp has been one of the barriers to data generation and therefore product registration. When EPA's Residue Chemistry Test Guidelines were developed decades ago, hemp was not a crop grown in the U.S. AAPCO is very supportive of EPA conducting a review and assessment of which fractions of the hemp plant need to be sampled, and how many samples need to be collected in each region. This information is critical for the development of a standard protocol, and can be used to update the Residue Chemistry Test Guidelines.

AAPCO has also been in contact with IR-4 and is aware that several states have requested IR-4 assistance in registering new crop protection products for hemp. Research activities have not been able to move forward until EPA updates their test guidance documents that clarifies what type of data are required.

An additional complication associated with hemp relates to the potential that substances or derivatives will be extracted from hemp plants using various methods (butane, CO2, etc.). These extraction methods need to be examined to assess whether certain methods preferentially "pull-out" specific types of pesticides, thereby possibly resulting in the exceedance of an established tolerance level. It is hoped that IR-4 has the financial resources needed to examine this issue of potential concern, and also fund pesticide trials and the necessary laboratory analyses.

The needs identified by AAPCO to support hemp production in our states include:

- Pesticide registrants need to support registration of their products, which includes supporting efficacy and residue trials.
- EPA needs to provide an assessment of which fractions of the hemp plant need to be sampled, and how many samples need to be collected in each region.
- Standardized research guidelines in data collection and analysis need to be developed by EPA and implemented by IR-4 and registrants
- Pesticide residue trials need to be conducted.
- Extraction methods used by hemp processors need to be examined.
- Data necessary to allow EPA to assess a chemical to determine if a pesticide can be used with "reasonable certainty of no harm" must be available.
- Residue data need to be submitted to EPA for review and tolerance determinations made.
- Revised pesticide labels listing hemp as a crop need to be submitted to EPA.
- Adequate funding needs to be provided for IR-4.

On behalf of the Association of American Pesticide Control Officials, thank you for your interest in this matter. AAPCO is willing to serve as a source of subject matter expertise, when appropriate. AAPCO, EPA and IR-4 will continue to have discussions on issues regarding pesticide use on hemp.

Sincerely



Rose Kachadoorian
AAPCO President (March 2019 - March 2020)

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June 14, 2019

The Honorable Stephen Alexander Vaden
General Counsel
Office of General Counsel
U.S. Department of Agriculture
1400 Independence Avenue SW
Whitten Building – Suite 107W
Washington, D.C. 20250

Dear Mr. Vaden:

We write concerning a provision[1] enacted as part of the Agriculture Improvement Act of 2018 (P.L. 115-334) that makes any person convicted within the past ten years of a felony relating to a controlled substance under State or Federal law ineligible to produce hemp in accordance with a State, Tribal or Federal plan and Federal regulations. We urge the USDA to implement the hemp felony ban to apply only to individuals seeking a license or authorization to produce hemp in accordance with a state, tribal or USDA plan.

Although Congress specified that the hemp felony ban should apply to producers, there are many occupational roles that could be interpreted to be involved in hemp production. Should the provision be interpreted in an inappropriately broad manner, state agricultural authorities and the private sector would be required to conduct costly background checks, screen and track workers involved in hemp production operations such as cultivation, processing, packaging and transporting hemp products. Application of the hemp felony ban in this manner through USDA rulemaking would impose unnecessary hardship on states, the agriculture industry and individual farmers to comply with the rule.

We believe a fair reading of the Agriculture Improvement Act of 2018 and the accompanying conference report indicates that Congress intended for this provision to only apply to individuals seeking a license or authorization to produce hemp in accordance with a state, tribal or USDA plan.

The conference report[2] accompanying the Agriculture Improvement Act of 2018 specifies "negligent and other types of producer violations that require enforcement under a state or tribal plan. One such producer violation includes the felony ban regarding individuals that cannot "participate in state or tribal plans." The conference report then states that the felony ban "shall not apply to producers" who were lawfully participating in a state hemp pilot program prior to enactment. The felony ban clearly applies to producers.

The Agriculture Improvement Act of 2018 further specifies requirements[3] that must be fulfilled before a producer can participate in a State, Tribal or Federal plan including:

- Providing a legal description of land on which the producer produces hemp;
- Obtaining a license or other required authorization from the state department of agriculture or Tribal government (or USDA); and
- Producing hemp containing less than 0.3 percent THC on a dry weight basis.

These requirements that a producer must meet to lawfully participate in a State, Tribal or Federal plan are consistent with the roles and responsibilities of an individual seeking a license or authorization from the government. The hemp felony ban therefore applies to individuals seeking to obtain and maintain a license or authorization from the government to produce hemp. The hemp felony ban should not apply to any other individuals engaged in lawful hemp production under a State, Tribal or Federal plan, including any individuals employed by a producer.

We therefore urge USDA to follow congressional intent and limit the application of the felony ban only to individuals seeking to obtain a license or authorization to produce hemp in accordance with the Agriculture Improvement Act of 2018.

To further discuss our views, please contact Aline DeLucia with the National Association of State Departments of Agriculture at (202) 296-9680 or aline.delucia@nasda.org; or Scott Bennett with the American Farm Bureau Federation at (202) 406-3722 or scottb@fb.org; or Eric Steenstra with Vote Hemp at (703) 729-2225 or eric@votehemp.com; or Grant Smith with the Drug Policy Alliance at (202) 683-2984 or gsmith@drugpolicy.org.

Thank you for considering our perspective,

American Farm Bureau Federation
Drug Policy Alliance
National Association of State Departments of Agriculture
Vote Hemp

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[1] See P.L. 115-334, Agriculture Improvement Act of 2018, 132 Stat 4911 and 132 Stat 4912
[2] See "Conference Report to Accompany H.R. 2, Agriculture Improvement Act of 2018," December 10, 2018, p. 737
[3] See P.L. 115-334, Agriculture Improvement Act of 2018, 132 Stat 4911

QUESTIONS AND ANSWERS

JULY 25, 2019

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Hemp Production and the 2018 Farm Bill
July 25, 2019
Questions for the Record
Under Secretary Greg Ibach

Chairman Pat Roberts

1) Mr. Ibach, what length of time does USDA envision as farmer-friendly when providing for producers an opportunity to sign up under the USDA federal plan to raise hemp?

Response: Once the rule is effective, AMS intends to begin processing applications for USDA hemp production plan licensees immediately.

2) Building upon the hemp research pilot authorized in the 2014 Farm Bill, the 2018 Farm Bill authorized hemp cultivation in the United States. There is a scarcity of data and research to sufficiently support this new industry. What is USDA doing to meet the rapidly growing needs of producers, the hemp industry, and related input and service suppliers in terms of data, analysis, and research?

Response: USDA continues to support advances in research in several ways. The research pilot program created in the 2014 Farm Bill continues to allow growers, in conjunction with Land-Grant Universities to grow hemp for research purposes. Additionally, the National Institute of Food and Agriculture (NIFA) has awarded grants, through both competitive and capacity programs, aimed at addressing and identifying potential issues that growers may face. For instance, the NIFA funded IR-4 project has engaged with EPA to assist in data collection needed for pesticide registrations. The 2018 Farm Bill added language that added hemp to the list of supplemental and alternative crops (Sec. 7129). This change was made within NIFA immediately and is in effect. Many NIFA programs are currently evaluating applications for FY19 funding. Once any awards are made in the hemp space, NIFA would be happy to inform the Committee of these awards.

In addition, the Agricultural Research Service (ARS) has authorized its Geneva, NY location to devote funds to establishing the infrastructure (e.g., modular growth chambers, analytical equipment) which would be needed to support the Industrial Hemp (IH) germplasm collection once the collection was assembled. It also authorized the Geneva, NY location to work with Cornell University cooperators to hire term/temporary Cornell personnel to conduct some preliminary research regarding the genetic diversity of IH, to help identify the critical germplasm which should be acquired, and establish genetic analytical capacity to identify different IH types, maintain trueness-to-type, etc. ARS is currently developing internal procedures and policies in order to expand hemp research under the authorities of both the 2014 and 2018 Farm Bills.

The Economic Research Service (ERS) and National Agricultural Statistic Service (NASS) have been collecting and analyzing data relating to hemp. This work will continue and ERS will be providing the Committee with the report mandated in Sec. 7605 of the 2018 Farm Bill by the end of the year.

Ranking Member Debbie Stabenow

1) This past December, Michigan passed State laws that legalized both the production of hemp and the production of marijuana. Michigan producers will be required to get a separate license to grow either type of cannabis. One of the major concerns I've heard from potential hemp farmers in my state is how the new Federal and State regulations will address issues of cross pollination between hemp and marijuana. Please explain how USDA will address this concern and how farmers can manage this risk.

Response: USDA cannot comment on the contents of the rule while it is under interagency **review.**

Once a rule is promulgated, States are required to collect information regarding land on which hemp will be grown. Nothing precludes States from using this information to inform state-level decisions to mitigate cross-pollination risk.

Additionally, if States elect to administer a State hemp production plan, they may adopt additional requirements to mitigate cross-pollination risk.

As with other crops with cross-pollination considerations, farmers should also understand best practices to manage this risk.

2) There have been many questions about the different testing methods being used to determine levels of THC in hemp products. How will USDA ensure flexibility for States and Tribes to conduct accurate testing for THC while at the same time providing consistency across the hemp industry nationwide?

Response:

As required by the statute, hemp must be tested to ensure it does not contain a delta-9 THC concentration level greater than 0.3 percent on a dry weight basis. The 2018 Farm Bill requires USDA to set forth testing procedures that must be followed when conducting THC testing; for example, using post-decarboxylation or other similarly reliable analytical methods.

While the rule is under interagency review, **USDA cannot comment on the contents of the rule..**

Senator Joni Ernst

1) Ingredient refinement is a common practice in food production today and is used to develop consistent, concentrated ingredients for foods. As you know, the Farm Bill sets out a 0.3% THC limit for plants. Can you clarify how your agency is interpreting this limit as it relates to ingredient refinement? Specifically, does this limit apply to only plants, or both plants and any product derived from hemp plants (e.g. CBD oils, tinctures, foods)? Further, is this an issue your agency is concerned with and discussing more broadly?

Response: As required by the statute, hemp must be tested to ensure it does not contain a delta-9 THC concentration level greater than 0.3 percent on a dry weight basis. This concentration level is specific to plants or parts of plants only. Please note that section 10113 of the 2018 Farm Bill does not amend the Federal Food, Drug and Cosmetics Act or the Secretary of Health and Human Services and the Commissioner of Food and Drugs authorities under that Act. As such, HHS and FDA retain regulatory authority over products covered under that Act.

2) Like many states, Iowa has been working hard to adopt new state rules since the passage of the 2018 Farm Bill. As they proceed, questions have come up in regard to USDA's timelines and its coordination with other departments.

    a. What is the USDA's understanding of the FBI databases' capability to handle an influx of background requests from across the country? This information is important in understanding how quickly they will be to move in their state license application process and provide clarity to producers.

Response: USDA has been coordinating closely with other federal agencies, including the FBI, regarding the implementation of the provisions set forth by the 2018 Farm Bill. We have not heard concern from our agency partners about processing an influx of background checks.

    b. Once USDA releases the federal program, is there a timeline for how long states will have to decide if they would like to use the federal program or submit their own proposal?

Response: The Farm Bill does not establish a deadline by which States and Tribes must submit plans. Producers located in States and territories of Tribes who elect to not administer their own hemp production plans may apply for a USDA hemp production license. States and Tribes may initially choose to have producers operate under the USDA plan while they develop their own regulations, and once a State plan is in place require producers to migrate their respective State or Tribal plan.

    c. Is the agency prepared and staffed to administer these state applications in a timely manner?

Response: AMS has currently detailed staff from other activities to work on the hemp regulation for FY19. The hemp program is not currently listed among the activities specifically funded by appropriations.

Senator David Perdue

1) Mr. Ibach, as stated in your testimony, you mentioned that the Farm Bill requires states to submit a business development and regulatory plan to USDA before launching a commercial hemp program.

    a. As a part of this submittal, is USDA requiring states to demonstrate that they have sufficient resources and capabilities to implement the program before obtaining approval? Can you please expand upon the requirements of each State?

Response: The 2018 Farm Bill requires States and Tribes to certify that they have sufficient resources to support their plans. While the rule is under interagency review, **USDA cannot comment on the contents of the rule.**

2) Under what circumstances would USDA deny a state to move forward to implement a commercial hemp program?

Response: The 2018 Farm Bill authorizes the Secretary of Agriculture to provide technical assistance to States and Tribes to aid in the development of a State or Tribal plan.

The USDA will work with States and Tribes to support them throughout the development of their plans. During the review process, USDA will reach out to States and Tribes and communicate any deficiencies in the plans submitted to enable States and Tribes to resubmit adequate plans. The 2018 Farm Bill outlines certain components that all plans must contain. The USDA cannot approve plans until all requirements are met. All plans must describe how their respective hemp production program will administer the following:

- **Land used for Production**
- **Sampling and testing for delta-9 THC**
- **Disposal of non-compliant product**
- **Compliance with enforcement procedures**
- **Information sharing**
- **Certification of resources**

    a. Would USDA prefer to regulate all hemp farming activities directly?

Response: USDA is committed to developing a successful program with clear guidelines and protocols for farmers interested in growing hemp. To this end, USDA is supportive of whichever model makes this program most successful.

Senator Patrick Leahy

1) The Farm Bill requires states to create a procedure for testing THC levels "using postdecarboxylation or other similarly reliable methods." Although many in the hemp sector are using the gas chromatography flame ionization detector method to test THC, some stakeholders, including those in Vermont, believe that an alternative procedure known as "high pressure liquid chromatography" (HPLC) is the most reliable method of detection.

    a. As it writes regulations for hemp production, how will USDA provide states flexibility to determine the most effective and efficient testing procedures?

Response:

As required by the statute, hemp must be tested to ensure it does not contain a delta-9 THC concentration level greater than 0.3 percent on a dry weight basis. The 2018 Farm Bill requires USDA to set forth testing procedures that must be followed when conducting THC testing; for example, using post-decarboxylation or other similarly reliable analytical methods.

While the rule is under interagency review, **USDA cannot comment on the contents of the rule.**

    b. How does USDA intend to evaluate the reliability of testing methods?

Response: USDA has undertaken an extensive research and outreach effort in order to draft the hemp regulation. In addition to talking to States and learning about the methods they are currently using, USDA has commissioned its own scientists within AMS to research and evaluate the applicability of the primary methods currently used. USDA will continue to engage with industry and scientists as new methods are developed.

2) While the Farm Bill tasks the Agricultural Marketing Service (AMS) with rulemaking regarding the production of hemp, many other agencies and programs can significantly impact hemp producers, particularly in these critical first few years. For instance, guidance to Farm Service Agency staff can influence access to capital; programs like Value Added Producer Grants through Rural Development could help address the current processing bottleneck impacting the industry; and research through agencies like the National Institute of Food and Agriculture and the Agricultural Research Service is critical to both regulators and producers alike. At this time there appears to be a lack of consistency and coordination among the USDA agencies with some having adopted 2018 Farm Bill compliant programs

while others continue to work under the much more restrictive 2014 Farm Bill.

a. How is USDA coordinating across its agencies ensure hemp producers have access to the full range of 2018 Farm Bill programs?

Response: USDA agencies will continue to follow guidance under the 2014 Farm Bill until AMS finalizes the hemp production rule. Once the rule is promulgated, USDA will ensure hemp producers have access to the full range of 2018 Farm Bill programs.

USDA is conducting weekly meetings with mission areas to ensure a unified approach to rulemaking and to updating department guidance. USDA agrees that intramural and extramural research at NIFA and ARS will be vital to regulators and producers. USDA also recognizes that mission areas like Farm Production and Conservation, Rural Development, Food Safety Inspection Service, and Trade and Foreign Agricultural Affairs will play an important role in assisting the hemp industry once the AMS rule is finalized.

b. What guidance and training has already been provided to USDA field staff to support growers in the field?

Response: USDA is committed to developing a successful program with clear guidelines and protocols for farmers interested in growing hemp. While no official guidance has been issued out to field staff, USDA is working across the department to have guidance ready for field staff once the rule is published.

Senator Amy Klobuchar

1) Tribal leaders have expressed concerns about being comparatively disadvantaged by USDA during the implementation of the hemp provisions from the 2018 Farm Bill. It is my understanding that they have requested consultation with USDA's Agricultural Marketing Service to discuss the unique challenges of regulating hemp production and cultivation on Tribal land.

a. How has USDA been communicating and working with Tribal governments to address regulatory issues related to hemp production from the Farm Bill?

Response: USDA has taken multiple opportunities to engage Tribes, and we understand they have unique concerns relating to establishing programs for industrial hemp. Our Office of Tribal Relations (OTR) hosted a tribal consultation for the 2018 Farm Bill implementation on May 1-2, 2019 at the National Museum of the American Indian in Washington, DC. Hemp was a major topic. Secretary Perdue, Deputy Secretary Censky and a number of Under Secretaries, myself included, participated in this event to engage in a dialogue with more than 45 tribal leaders and proxies. Additionally, almost 20 business, law firm, corporation or nonprofit representatives and at least 25 individuals were on the call-in conference line to listen to the proceedings. OTR also hosted a listening session prior

for the 2018 Farm Bill implementation on June 26, 2019 at the National Congress of the American Indian Mid-Year Conference in Sparks, NV. OTR and other mission area heads participated in this event to engage in a dialogue with more than 20 tribal leaders and tribal representatives; 12 business, law firm, corporation or nonprofit representatives for tribal interests. Lastly, OTR posts a bi-weekly newsletter on its website and emails the newsletter to all federally-recognized tribes [on the Bureau of Indian Affairs posted list] and other interested parties that request to be on that mailing list. The newsletter includes information of interest to tribes about USDA programs. USDA is committed to maintaining a dialogue with tribes, and we welcome additional feedback they may have.

Senator Michael Bennet

1) Currently, when an individual's hemp crop contains a higher concentration of THC than is legally allowed, the grower often has to destroy a crop they worked on all year. Existing regulations do not allow for the use of this hemp as a marketable product. Farmers in Colorado would like the option to recover some of their commodity's value and have suggested appropriate uses could include livestock bedding, fiber, or animal feed.

    a. Will the USDA regulations provide the option for farmers to recoup some of their crop's value when their hemp exceeds the legal limit for THC?

Response: While the rule is under interagency review, **USDA cannot comment on the contents of the rule..**

2) Despite passage of the 2018 Farm Bill, hemp producers and processors continue to have trouble accessing financial services. In response to a letter I sent on June 13 to federal financial regulators on this topic, the National Credit Union Administration said that "until the Department of Agriculture completes their regulations and guidelines for this program, the uncertainty for financial institutions will likely remain."

    a. What is the current timeline for the completion of regulations?

Response: Secretary Perdue has stated it is the intent of USDA to issue the regulations by Fall 2019. A draft rule is currently undergoing interagency review. USDA will work quickly to address any questions or concerns raised through this interagency process.

    b. Is the USDA consulting with financial regulators to ensure that institutions do not categorically exclude hemp businesses from accessing financial services?

Response: The 2018 Farm Bill removed industrial hemp from schedule I of the Controlled Substances Act, and as such hemp is no longer a controlled substance. This change is self-executing and not contingent on enactment of the rule by USDA. USDA has engaged in extensive outreach and consultation with public- and private-sector partners to clarify

these changes and to ensure hemp producers are not categorically excluded from programs and services for they would otherwise be legally eligible.

c. Does the USDA have plans to issue interim guidance, or is it taking other steps, to ensure that individuals currently growing and processing hemp legally can access financial services?

Response: AMS issued a Notice to Trade clarifying that the 2018 Farm Bill removed industrial hemp from schedule I of the Controlled Substances Act, and as such hemp is no longer a controlled substance. This change is self-executing and not contingent on enactment of the rule by USDA. USDA does not have authority to issue additional guidance specific to financial services.

3) The 2018 Farm Bill requires that a state or Indian tribe desiring to have primary regulatory authority over the production of hemp must test for delta-9 THC using post-decarboxylation or other similarly reliable methods. We have heard from Coloradans that private industry may favor High Performance Liquid Chromatography as a technique of choice because they can evaluate the entire cannabinoid profile.

a. What is your plan for working with states, Indian tribes, and industry to ensure all of the appropriate methods are considered "similarly reliable methods" under the 2018 Farm Bill?

Response:

As required by the statute, hemp must be tested to ensure it does not contain a concentration of THC greater than 0.3 percent on a dry weight basis. The 2018 Farm Bill requires USDA to set forth testing procedures that must be followed when conducting THC testing, for example, using post-decarboxylation or other similarly reliable analytical methods.

While the rule is under interagency review, **USDA cannot comment on the contents of the rule.**

4) The way that hemp is sampled often determines the level of THC measured, as a result of a number of variables such as seed vs. flower or mature vs. young plans. These factors create uncertainty and can prove extremely challenging for a farmer if the sampling method results in incorrect measurements and they are forced to destroy their entire crop.

a. How will the USDA establish clear, fair guidelines on sampling protocol?

Response: USDA statisticians and chemists have been collaborating to develop recommended sampling procedures that are consistent, reliable, and not overly burdensome for producers.

b. Will the USDA harmonize the sampling protocol that should be followed prior to testing? If so, what stakeholders are you working with on this effort?

Response: While the rule is under interagency review, **USDA cannot comment on the contents of the rule.**

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Hemp Production and the 2018 Farm Bill
July 25, 2019
Questions for the Record
The Honorable Stephen Alexander Vaden

Chairman Pat Roberts

1) Mr. Vaden, there appears to be a variety of hemp-derived CBD contracts between producers and processors. Some contracts are tied to quantity measured by pounds of flowers, others on quality measured by the percent of CBD in the raw material, or a mix of both quality and quantity. RMA allows quality adjustments for other crops to compensate farmers for their economic loss, which may be greater than their loss as measured simply in yield. However, accurately assessing quality adjustments can be challenging even for crops with well-understood and well-publicized quality discounts. In light of the above, how would RMA insure quality on hemp while still serving the purpose of the federal crop insurance program—risk management for farmers?

   Response: RMA utilizes industry grading standards to establish quality adjustments for crops that currently are eligible for quality adjustments. RMA is actively engaged with the hemp industry to ensure that future quality adjustments for hemp are adequate.

2) Mr. Vaden, in the Department's testimony, it mentions "...the producer must have a contract with a buyer" for hemp crop insurance coverage through a Whole Farm Revenue Protection plan. I note that this requirement may have the unintended consequence of incentivizing growers to contract with processors instead of developing and selling into an open market. Does RMA expect for the requirement to have a contract with a buyer to continue in future crop years for Whole Farm coverage and in future developed hemp specific crop insurance policies?

   Response: Given the current availability of price data along with need to ensure that producers have a market to sell hemp, RMA determined that a contract was the most effective way to both establish a price and to ensure producers have a market to sell hemp. RMA will evaluate this requirement as the hemp industry matures.

3) Mr. Vaden, it is my understanding that the Rural Development mission area has considered all applications regarding hemp to be ineligible for RD programs. Is this still the policy of the Department? Will Value Added Producer Grant hemp applications for the upcoming NOFA this month be disqualified solely because the project involves hemp? If yes, please provide the legal authority for the subject-matter based disqualification.

   Response: USDA's Agricultural Marketing Service is currently drafting regulations to implement the 2018 Farm Bill provisions on industrial hemp. It is USDA's goal to have

regulations in effect by the fall of 2019. Until plans can be approved and licenses issued under such regulations, growing industrial hemp remains illegal unless done in compliance with section 7606 of the 2014 Farm Bill (certain limited research purposes) or with a DEA permit. While Rural Development has not encountered an eligible project under the 2014 Farm Bill authorities, the mission area is awaiting the imminent publication of the hemp production regulation so that it may begin considering financing projects that comply with the licensing rules. Additionally, Rural Development intends to clarify in its upcoming funding Notice for Value-Added Producer Grants, that projects related to Industrial Hemp will be eligible for funding as soon as the USDA hemp regulations are published in the Federal Register.

4) Mr. Vaden, how will the Farm Service Agency balance individual credit risk with the novelty of hemp based enterprises as it underwrites any direct or guaranteed lending activity?

Response: Farm Loans anticipates that existing regulations are sufficient to ensure that sound underwriting decisions will be made on hemp-related loans. Specifically, 7 CFR 761.104(c) requires farm operating plans be based on accurate and verifiable information that utilize historical information when available. Additional guidance to employees expands on this regulation to specify when grower/forward contracts may be required, how to address operations that lack an actual production history, and how to analyze operations when minimal enterprise data exists. Concerning the guaranteed loan program, banks that want to use this program to finance hemp production may seek to do so until risk factors become more mitigated.

With the exception of limited hemp production under the 2014 Farm Bill, hemp is a new covered crop for USDA programs and has been grown only for a niche market. Farmers' production, the growth of their operations, and financial success will be an evolutionary process as market networks develop, historic cost of production and commodity prices are available, and grower/forward contracts with reputable buyers proliferate.

Ranking Member Debbie Stabenow

1) This past December, Michigan passed State laws that legalized both the production of hemp and the production of marijuana. Michigan producers will be required to get a separate license to grow either type of cannabis. One of the major concerns from potential hemp farmers in Michigan is how the new Federal and State regulations will address issues of cross pollination between hemp and marijuana. Please explain how this concern will be addressed and how farmers can manage this risk.

Response: While the rule is under interagency review, **USDA cannot comment on the contents of the rule.Once a rule is promulgated, States are required to collect information regarding**

land on which hemp will be grown. Nothing precludes States from using this information to inform state-level decisions to mitigate cross-pollination risk.

Additionally, if States elect to administer a State hemp production plan, they may adopt additional requirements to mitigate cross-pollination risk.

We note that USDA has authority to regulate hemp, as defined in the 2018 Farm Bill. The Drug Enforcement Agency retains its authority under the Controlled Substances Act to regulate marijuana.

2) The Michigan Department of Agriculture, as well as other stakeholders, have raised questions about the different testing methods being used to determine levels of THC in hemp products. How will USDA ensure flexibility for States and Tribes to conduct accurate testing for THC while at the same time providing consistency across the hemp industry nationwide?

Response:

As required by the statute, hemp must be tested to ensure it does not contain a delta-9 THC concentration level greater than 0.3 percent on a dry weight basis. The 2018 Farm Bill requires USDA to set forth testing procedures that must be followed when conducting THC testing; for example, using post-decarboxylation or other similarly reliable analytical methods.

While the rule is under interagency review, **USDA cannot comment on the contents of the rule.**

3) How is USDA going to ensure that States and Tribes provide a fair and equitable process for issuing State or Tribal licenses to all eligible hemp producers and a fair and equitable process for testing hemp products?

Response: Under the 2018 Farm Bill, States and Indian Tribes that seek to have primary regulatory jurisdiction over hemp production must submit a plan that meets the requirements in the 2018 Farm Bill. USDA's role is to review and approve their hemp production plan and to conduct period audits over the implementation of those plans.

4) The recently passed Farm Bill includes a provision that any person convicted within the past ten years of a felony relating to a controlled substance under State or Federal law renders them ineligible to produce hemp. Please describe specifically how USDA will implement this provision and to whom it will apply.

Response: A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under the Agricultural Marketing Act of 1946. An exception applies to a person who was lawfully

growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

More specific details are part of the draft hemp production that is currently under review at OMB. While the rule is under interagency review, **USDA cannot comment on the contents of the rule.**

5) Throughout my career and over the course of several Farm Bills, I have sought to expand the opportunities and protections for specialty crop, beginning, and veteran farmers. This effort has included expanding crop insurance options to more crops and counties. While I am encouraged that USDA is looking for ways to bring crop insurance to hemp farmers as quickly as possible, USDA should not lose sight of the needs of specialty crops more broadly.

   a. What actions is USDA taking to speed the availability of crop insurance coverage for hemp, particularly for beginning and veteran farmers?

      Response: For the 2020 crop year, hemp will be insurable under Whole Farm Revenue Protection provided the producer has a contract with a buyer to purchase the hemp and the producer has a permit to grow hemp under either a state, Tribal, or USDA permit pursuant to the 2018 Farm Bill or if a producer is growing under the authority of section 7606 of the 2014 Farm Bill. In addition, USDA promptly implemented the provisions of the 2018 Farm Bill that expanded the definition of beginning farmer or rancher for Whole Farm Revenue Protection as well as the Veteran Farmer provision, which makes crop insurance more affordable for beginning farmers, ranchers and veterans. These provisions were made effective for most 2019 crop year policies.

   b. To what extent can or are these tools and flexibilities being used more generally for beginning farmers and local food system farmers who are seeking to obtain crop insurance for crops other than hemp who may have similar barriers to accessing crop insurance?

      Response: In addition to promptly implementing the items outlined above, RMA is making several other changes to the 2020 Whole Farm Revenue Protection program that will benefit specialty growers. These changes include: 1) new history smoothing options to help producers moderate the impacts of disaster years on historical revenue, similar to what is allowed on traditional crop insurance programs, 2) NAP for Whole Farm Revenue Protection is now treated like other non-RMA insurance payments and not as revenue to count, 3) increased nursery limits as well as livestock limits that will help with issues that have been brought forth by smaller dairy operations, 4) revising the records requirement for commodities that have no underlying yield coverage (Multi-Peril Crop Insurance) from a 6 year records requirement to three years

preceding the insurance period. RMA is also moving forward with the feasibility study on Local Foods as outlined in the 2018 Farm Bill.

6) At a Senate Agriculture, Nutrition, and Forestry Committee ("the Committee") briefing on the second Market Facilitation Program, USDA indicated that it would not share several important details regarding the program with the public or the Committee. Specifically, at that time USDA indicated that it would not share the calculations and estimates of the trade harm by commodity/tariff line or the corresponding national rate by commodity that was used to calculate the per-county trade damage.

   a. Will USDA provide to the Committee these calculations and estimates? If not why not? What authority are you using to decline to provide this information?

      Response: USDA's Office of the Chief Economist (OCE) has prepared a report that explains how trade damages resulting from retaliatory tariffs were estimated and the data used to calculate the Market Facilitation Program (MFP) payment rates for non-specialty crops, hogs, milk, and specialty crops.

   b. Will USDA provide to the public these calculations and estimates? If not why not?

      Response: The report will be published on the OCE website on Friday, August 23. USDA will notify the Senate when the report is published.

7) On July 31, 2019, the Committee received responses to questions submitted for the record from Under Secretary for Trade and Foreign Agricultural Affairs Ted McKinney. Under Secretary McKinney did not respond to several questions regarding the Market Facilitation Program (MFP), citing that the MFP regulations were currently under review by the Office of Management and Budget (OMB). However, the OMB review had already concluded and the MFP regulations had been published in the Federal Register prior to the submission of these answers. As the rule is not currently under OMB review, please provide an answer to the following questions asked previously:

   a. Will a producer determined to have "lack of good faith effort" [in the first Market Facilitation Program] be eligible for the second Market Facilitation Program?

      Response: All producers who have not been suspended or debarred from participation in government programs are eligible to submit an application to participate in the program.

   b. $14.5 billion is a significant expenditure. What safeguards has USDA put in place to ensure that this second Market Facilitation Program is free of waste, fraud, and

abuse?

Response: As with any program implemented by USDA, we already have producers of record on file for the majority of farming operations nationwide. For producers who have not participated in programs, FSA creates a farm record and ensures the land identified is not previously identified previously by another producer. Benefits will be determined based on previously filed acreage reports for 2018 and 2019 crop years. Those acreage reports are subject to being spot checked and if acres are late filed because they did not timely file, field visits must be completed to document the crop intent.

8) Although the "Trade Mitigation Rule" published on July 29, 2019 stated that the Office of Management and Budget had reviewed this rule, summarized the costs and benefits of this rule and had provided the full cost benefit analysis in the docket on regulations.gov, the full cost benefit analysis was not posted in the docket (CCC-2019-0003) on regulations.gov as of August 1. Please provide to the Committee the full cost benefit analysis and publish it in the docket on regulations.gov.

Response: Unfortunately, there was a technical glitch in posting the Market Facilitation Program rule, which has since been corrected. The cost benefits analysis was posted to regulations.gov on August 9 and is available for viewing at the following link: https://www.regulations.gov/document?D=CCC-2019-0003-0007

9) USDA justified the need for the proposed rule "Revision of Categorical Eligibility in the Supplemental Nutrition Assistance Program" with the need "to create a clearer and more consistent nationwide policy." Similarly, in the Regulatory Impact Analysis accompanying the proposed rule "Revision of Categorical Eligibility in the Supplemental Nutrition Assistance Program," USDA indicated that it did not adopt several alternatives because these alternatives would allow "inconsistencies in the eligibility determination across States" to remain. However, Congress has provided explicit flexibility in the Food and Nutrition Act for states to adapt many aspects of their programs to meet the needs of low-income households in their states, including some flexibility regarding eligibility determinations.

Response: See the response to question 10 below.

10) In light of this, how is USDA's justification for the proposed rule – to create "a more consistent nationwide policy"—consistent with the intent of Congress?

Response: Food and Nutrition Service accepted public comments on its proposed rule revising Categorical Eligibility in the Supplemental Nutrition Program (SNAP) (84 FR 35570) until September 23, 2019. All comments will be fully considered in developing the final rule.

11) USDA's state options report indicates that "SNAP's statutes, regulations, and waivers provide State agencies with various policy options. State agencies use this flexibility to adapt their programs to meet the needs of eligible, low-income households in their States." Does USDA intend to restrict or eliminate any other longstanding state options? If so, please indicate which options.

Response: USDA reserves its right to pursue rulemaking within its legal authorities as it determines appropriate to administer SNAP and other Federal programs within its jurisdiction.

12) In the proposed rule "Revision of Categorical Eligibility in the Supplemental Nutrition Assistance Program," USDA justified the changes to categorical eligibility in part because the replacement of AFDC with TANF in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) provided states with "significant flexibility in TANF-funded program administration, resulting in a wide array of programs designed to further TANF's four purposes, including ones that may not have meaningful eligibility criteria." PRWORA also made numerous changes to SNAP (then food stamps), including conforming changes to confer categorical eligibility to households that received benefits under the new TANF program. However, Congress declined at the time to limit the type of benefits that households must receive through TANF in order to be considered categorically eligible. In light of this, does USDA believe that it was the intent of Congress when replacing AFDC with TANF to limit the types of TANF benefits that confer categorical eligibility?

Response: Food and Nutrition Service accepted public comments on its proposed rule revising Categorical Eligibility in the Supplemental Nutrition Program (SNAP) (84 FR 35570) through September 23, 2019. All comments will be fully considered in developing the final rule.

13) Executive Order 12866 states, "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people." Neither the proposed rule "Supplemental Nutrition Assistance Program: Requirements for Able-Bodied Adults without Dependents" nor "Revision of Categorical Eligibility in the Supplemental Nutrition Assistance Program" were required by law. Additionally, both rules proposed major changes to longstanding interpretations of the Food and Nutrition Act. Does USDA believe that these proposed rules are "necessary to interpret the law," despite the longstanding policies established in regulation and Congress consistently rejecting changes to these policies through the legislative process?

Response: Food and Nutrition Service will consider all public comments timely received in developing these final rules for the Supplemental Nutrition Assistance Program.

14) Executive Order 12866 states, "In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating." Why did USDA not consider the possibility of not regulating in the Regulatory Impact Analysis accompanying the proposed rule "Revision of Categorical Eligibility in the Supplemental Nutrition Assistance Program?"

Response: Food and Nutrition Service accepted public comments on its proposed rule revising Categorical Eligibility in the Supplemental Nutrition Program (SNAP) (84 FR 35570) though September 23, 2019. All comments will be fully considered in developing the final rule.

15) The current Administration has used the flexible authorities under the Commodity Credit Corporation (CCC) Charter Act more frequently and to a greater extent than in the past. Moreover, it has used these authorities for multiple rounds of programs (e.g. Cotton Ginning Cost Share and Market Facilitation Program) even after claiming during the first round that the assistance was "one-time."

a. Is the CCC authority limited to only tariff-related trade assistance?

Response: No. The authority that CCC is using to implement the Trade Mitigation Program (TMP) is found at section 5(b), (d), (e) and (f) of the CCC Charter Act.

b. If not, could USDA provide assistance through the CCC related to other trade related harm such as dumping or artificial trade barriers? If yes, which please identify which CCC authorities would allow this assistance.

Response: Yes. Section 5 of the CCC Charter Act could be used to design programs similar to the TFP.

c. Would the CCC authorities allow USDA to provide assistance immediately following a natural disaster such as the flooding? Would this include harm from prevented planting or the damage to stored grain? If yes, which please identify which CCC authorities would allow this assistance.

Response: No. The CCC Charter Act does not provide authority to conduct any type of indemnification program for losses of agricultural production, thus the enactment of numerous ad hoc disaster programs by Congress over the past thirty years. Some of these programs are funded by CCC and some are funded by appropriations.

I have been advised that this issue was raised several times between the prior Secretary of Agriculture and senior officials of the prior Administration, including the Secretary of State, with regard to the potential to use CCC funds

for an indemnification activity outside of the United States. In each instance the conclusion was that the CCC Charter Act could not be used for indemnification programs.

d. Could the authorities under the CCC be used to supplement disaster assistance provided by Congress either through an existing permanent program or an ad-hoc appropriations? If yes, which please identify which CCC authorities would allow this assistance.

Response: There is no authority under the CCC Charter Act that could be used. The following disaster assistance programs are permanently authorized and are carried out using CCC funds: Noninsured Crop Disaster Assistance Program (NAP), 7 USC § 7333 et seq; Livestock Indemnity Program (LIP), 7 USC § 9081(b). Livestock Forage Disaster Program (LFP), 7 USC § 9081(c); Emergency Assistance for Livestock, Honey Bees, and Farm-raised Fish (ELAP), 7 USC § 9081(d); Tree Assistance Program (TAP), 7 USC § 9081(e).

e. Taking into account the expected payments under Farm Bill authorized programs (ARC/PLC, CRP, livestock disaster programs) and the ad-hoc trade assistance announced under a new round of the Market Facilitation Program (MFP), what is unallocated balance of the CCC available for unexpected expenses or emergencies?

Response: The Commodity Credit Corporation (CCC) has authority to borrow up to $30 billion from the United States Treasury to finance programmatic activity, including the Farm Bill's authorized programs as well as programs implemented using the CCC Charter Act authorities. As of August 7, 2019, CCC had a total of $10.5 billion in available borrowing authority.

f. What actions would USDA take should the price of a major crop like soybeans fall below the marketing loan rate due to escalating tariffs or another market shock and trigger significant loan deficiency payments and market loan gains that exceed the available CCC balance?

Response: If such a situation arose again, CCC would cease to expend funds.

g. What protections has USDA put in place to prevent the promised $16 billion in additional trade assistance from violating the Anti-Deficiency Act? Despite the claims by the President on twitter that the $16 billion has already been provided to farmers, does USDA not consider the funding for the second and third tranches of MFP to be obligations?

Response: The authority to obligate funds is not restricted by its limitation to borrow funds from the Treasury of the United States. No additional precautions are necessary to ensure that CCC abides by the Anti-Deficiency Act when administering the trade mitigation payment program. The MFP portion of the

TMP provides that a second or third tranche of payments will be made to producers if CCC determines further payments are warranted. An obligation would not arise until that determination is made.

Senator Deb Fischer

1. There seems to be a fair amount of concern with uncertainty amongst testing methods and testing facilities.

    a. Will the USDA require states to be uniform in their methods?

Response: The draft hemp production regulation will address these questions. While the rule is under interagency review, **USDA cannot comment on the contents of the rule.**

    b. Can you clarify or offer guidance as to what states should be requiring of testing facilities and what methods should be used?

Response: The draft hemp production regulation will address these questions. While the rule is under interagency review, **USDA cannot comment on the contents of the rule**

    c. Will any variance in THC levels be considered acceptable or will states be required to make the determination from an enforcement position?

Response: The draft hemp production regulation will address these questions. While the rule is under interagency review, **USDA cannot comment on the contents of the rule**

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Hemp Production and the 2018 Farm Bill
July 25, 2019
Questions for the Record
Assistant Administrator Alexandra Dapolito Dunn

Ranking Member Debbie Stabenow

1) Your written testimony indicates that EPA began receiving registration applications for pesticides to be applied to hemp in May of this year, and that there are now 10 such requests pending at EPA. Acknowledging that there are very important statutory and regulatory requirements that the agency needs to comply with to protect human health and the environment, and that these steps can take time, can you please give the committee your best estimate as to when we'll see approved crop protection tools for hemp farmers?

Response: We anticipate taking next steps in the coming months to complete a regulatory decision on each of those actions by the end of 2019.

Senator David Perdue

1) Has EPA approved a label for any restricted use pesticide for hemp?

    a. Is EPA currently considering any applications for such a product? If so, how many?

Response: The Environmental Protection Agency (EPA) has not approved and is not currently considering any applications for restricted-use pesticides for hemp.

2) Does EPA anticipate using the same protocols for establishing future pesticide tolerances for hemp as they would for any other agronomic or food crop?

Response: The EPA will review any pesticide registration application on its merits and in accordance with the pesticide laws and their implementing regulations. Additionally, the EPA and the Inter-regional Research Project #4 (IR-4) are working together to identify the information needed to support tolerance petitions for hemp for conventional pesticides. The EPA and IR-4 met in August 2019 and discussed how to apply these criteria to hemp. We also discussed alternate approaches, including the use of surrogate data from similar crops. We plan to continue to meet with IR-4 to address these issues.

3) Will all risk procedures be followed? Can EPA assure members of this committee that regulators will not relax these procedures simply because of the novelty of this new crop?

Response: The EPA is reviewing applications for use on hemp as we would any other application.

The EPA has received requests for labeling amendments to add hemp as a use site to existing products that have established tolerance exemptions. The products have very low toxicity and do not require updates to the human and ecological risk assessments. In the future, if the EPA receives requests under the Pesticide Registration Improvement Act (PRIA) for products that require a more extensive evaluation, the EPA will ensure that any new uses will meet the safety standards as defined for new registrations in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and for pesticide tolerances on foods (such as hemp seed) in the Federal Food, Drug, and Cosmetic Act (FFDCA).

4) How long do you expect the approval process to be for a hemp-approved pesticide? Is this time period standard for any other crop?

Response: The time period is the same as it would be for any other new use.

The length of time for approving a new use on any crop varies, but is generally defined by PRIA and depends on the extent of review needed. Some applications, however, such as the 10 amendments currently undergoing EPA review, do not fall under PRIA because they have an existing tolerance exemption. If the risk profile lends itself to an expedited review, we will do so, as we would for any pesticide registration application. Information on the length of time for reviews may be found at https://www.epa.gov/pria-fees/fy-2019-fee-schedule-registration-applications.

Senator Deb Fischer

1) We have towns that are concerned about materials that might be released from hemp storage areas or processing facilities.

    a. Will any guidance be provided for processor and/or growers regarding effluents or other waste materials?

Response: Existing regulations on waste management from pesticide products would apply to any registration we approve. Pesticide labels typically have disposal instructions related to the pesticide product. The EPA has no current plans to issue guidance on hemp processing effluent. If hemp processing involves a process wastewater discharge, then the permitting authority would implement the appropriate National Pollutant Discharge Elimination System (NPDES) permitting process. Hemp processing could fall under Category Eleven (xi) – light manufacturing – for industrial stormwater. If storage or other activities were exposed to precipitation and there were stormwater discharges to waters of the U.S., then industrial stormwater permit coverage could be appropriate.

Senator Michael Bennet

1) One of the biggest barriers to hemp production is the lack of EPA-approved pesticides and herbicides. Colorado hemp farmers would like EPA to work quickly to identify products that can be applied to their crops safely.

    a. What steps is the EPA taking to approve hemp pesticides and herbicides quickly?

Response: The EPA is working on a variety of approaches so that we can quickly approve crop protection tools for hemp growers. The EPA is encouraging the submission of requests for products that have a favorable risk profile and therefore have a much shorter review period under PRIA. With respect to potential use of conventional pesticides that require a more extensive evaluation of risk, the EPA is working with states, registrants, and our federal partners to learn more about pest concerns, how and where hemp is grown, and how it is processed, so that we can quickly assess requests while still ensuring that the products meet the applicable regulatory standards.

    b. What steps is the EPA taking to expedite hemp research protocols to update test guidance documents and determine what type of data may still be required?

Response: Current test guidelines do not need to be updated to address hemp. EPA test guidelines already outline the criteria for the types of tests needed for determining how people could be exposed to pesticide residues in hemp products. The EPA and IR-4 are working together to identify the information needed to support tolerance petitions for hemp for conventional pesticides. The EPA and IR-4 held a technical working group meeting in August 2019, and discussed how to apply these criteria to hemp. We also discussed alternate approaches, including the use of surrogate data from similar crops. The EPA and IR-4 plan to continue to meet to address these issues.

    c. Will you work with the state of Colorado in the registration process to identify and approve much needed tools to address pest issues that hemp growers are facing?

Response: The EPA will continue to collaborate with the states, including Colorado, on these issues. The EPA had a call with IR-4, the state of Colorado, and other states in July 2019, to discuss these issues, and additional discussions are anticipated.

U.S. FOOD & DRUG ADMINISTRATION

SEP 27 2019

The Honorable Pat Roberts
Chairman
Committee on Agriculture, Nutrition and Forestry
United States Senate
Washington, DC 20510

Dear Chairman Roberts:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the July 25, 2019 hearing before the Senate Committee on Agriculture, Nutriuon, and Forestry, entitled "Hemp Production and the 2018 Farm Bill." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

Karas Gross
Associate Commissioner for
Legislative Affairs

cc: The Honorable Debbie Stabenow, Ranking Member, Senate Committee on Agriculture, Nutrition, and Forestry

U.S. Food & Drug Administration
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Committee questions are restated below in bold, followed by our responses.

Ranking Member Debbie Stabenow

1) **Your written testimony talks about three new products derived from hemp seed, including hemp seed oil, that were recently added to FDA's Generally Recognized as Safe list of foods for human consumption. There is some confusion about the differences between hemp seed oil and CBD oil products in the marketplace. Does FDA have any plans to establish standards of identity for both hemp seed oil and CBD oil to address quality concerns in the marketplace?**

   The products at issue in the three generally recognized as safe (GRAS) notifications (dehulled hemp seeds, hemp seed oil, and hemp seed protein powder) contain only trace amounts of THC and CBD. Hemp seed oil is pressed from the seeds of the hemp plant, similar to other pressed oils like olive or flax seed oil. The composition of the hemp seed oil that is the subject of the GRAS notification is described in the GRAS notice. This includes specification levels for heavy metals, THC ($\leq$10 µg/g), microbial contaminants, aflatoxins, and fatty acid profile. In contrast, CBD oil is extracted from the stalks, stems, and flowers of the hemp plant, and contains varying amounts of CBD and other cannabinoids. Under current law, it is lawful to add hemp seed oil (for use in human food as described in the GRAS notice to food sold in interstate commerce, that is not the case for CBD oil.

   FDA's CBD Policy Working Group is carefully considering whether there is a safe level at which CBD can be added to food and other products. As part of that process, we are exploring many different regulatory pathways. On May 31, 2019, the Agency held a public hearing on CBD with an associated public docket open through July 16. Through the hearing and comments submitted to the docket, FDA was able to hear from a diverse array of stakeholders. However, questions related to gaps in safety data remain. A few examples include the effects of cumulative exposure, effects on pregnant or lactating women, and effects on children. As the CBD Policy Working Group examines the available data to determine the appropriate path forward, the Agency will update the public with its findings. The CBD Policy Working Group is working expeditiously to examine this issue while upholding the Agency's mission to protect the public health through the development and implementation of science-based policy within our statutory authorities.

Senator John Hoeven

1) **What progress has the FDA made in establishing a framework for ensuring that hemp-derived CBD foods, dietary supplements, cosmetics and other products are safe?**

   The regulatory issues pertaining to CBD are challenging, and FDA is actively taking steps to inform our decision-making. FDA held a public hearing on May 31, 2019, with presentations from over 100 speakers, representing a diverse array of stakeholders,

including patients, consumers, and their advocacy groups; health care providers; academia; manufacturers, retailers, and distributors; agricultural coalitions; and state and local government representatives. The public docket had received 4,492 comments when it closed on July 16. We are in the process of reviewing these comments now.

FDA has also formed a high-level internal working group to discuss findings and potential regulatory pathways across many product areas. The working group intends to report on findings in fall of 2019. Our work is science-based and data driven as we look to evaluate the safety first to fulfill our role in protecting the public health.

2) **As Chairman of the Senate Agriculture-FDA Appropriations Subcommittee, we will soon be working to draft our FY20 spending bill. Does the FDA need additional resources so that it can establish a CBD framework in a timely manner?**

The President's FY 2020 Budget Request does not include funding for research specific to the health effects of CBD products. Currently, FDA's knowledge about the health effects of CBD products, beyond that of Epidiolex, is limited. FDA appreciates your interest in the Agency's resource needs. FDA recognizes that given the reported size of the CBD market, that the Agency's current resources may need to be assessed if the Agency establishes a broader regulatory framework for CBD products. We look forward to working with you to complete FY2020 appropriations, as well as work on the FY2021 budget next year.

Senator Joni Ernst

1) **Ingredient refinement is a common practice in food production today, and is used to develop consistent, concentrated ingredients for foods. As you know, the Farm Bill sets out a 0.3% THC limit for plants. Can you clarify how your agency is interpreting this limit as it relates to ingredient refinement? Specifically, does this limit apply to only plants, or both plants and any product derived from hemp plants (e.g. CBD oils, tinctures, foods)? Further, is this an issue your agency is concerned with and discussing more broadly?**

The 2018 Farm Bill added a definition of "hemp" to the Controlled Substances Act (CSA). The CSA now defines hemp as cannabis plants and any parts of cannabis plants, including derivatives and extracts, with no more than 0.3 percent THC on a dry weight basis. The Farm Bill also removed hemp from the definition of marijuana in the CSA, which means hemp is no longer a controlled substance under the CSA. However, the Farm Bill explicitly preserved FDA's authority to regulate cannabis and cannabis-derived products within the agency's jurisdiction. A product's legal status under the Federal Food, Drug, and Cosmetic Act is not necessarily related to its status under the CSA.

Senator David Perdue

1) **When will the FDA issue guidance on hemp products as a pharmaceutical, a food or an ingredient?**

FDA is committed to sound, science-based policy and therefore, the agency treats hemp and hemp-derived ingredients as it would any other drug ingredient. FDA's Center for Drug Evaluation and Research (CDER) offers extensive guidance on the development of new drugs, and will apply the Federal Food, Drug, and Cosmetic Act provisions under section 505 for new drugs, and all implementing regulations and guidance, no differently for hemp and hemp-derived preparations or cannabinoid isolates as for other new drugs. The safety and efficacy of each new drug proposed for marketing in a new drug application (NDA) will be determined in the course of CDER's review of all data appropriately submitted or referenced in the NDA to support the application. FDA approval of an NDA will be given for those new drugs that are demonstrated to be safe and effective for their intended therapeutic use.

For hemp and hemp-derived ingredients intended for use in dietary supplements or conventional food products, FDA's internal CBD Policy Working Group is actively evaluating questions related to these products. In December 2018, FDA completed its evaluation of three generally recognized as safe (GRAS) notices for hemp seed-derived food ingredients to be used in human food. The Agency had no questions about the notifier's conclusion that the following ingredients are GRAS under their intended conditions of use: hulled hemp seed, hemp seed protein powder, and hemp seed oil. These ingredients can lawfully be added to human food.

Regarding CBD, current law prohibits the introduction into interstate commerce of food to which CBD has been added, and CBD products are also excluded from the statutory definition of a dietary supplement. This is because CBD has been the subject of substantial clinical investigations, and it is also the active ingredient in an approved drug (Epidiolex). FDA does, however, have the authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are currently analyzing the comments received on the docket associated with our May 31 public hearing as we consider the path forward to appropriate regulation of these products. There are real risks associated with CBD and critical questions remain about the safety of its widespread use in foods and dietary supplements, as well as other consumer products – including cosmetics. For example, during FDA's review of the marketing application for Epidiolex, safety concerns were identified. Specifically, at doses of 20 mg/kg/day in clinical trials, there was a potential for liver injury, evidenced by elevated transaminase levels. Liver damage is a potentially serious risk that can be managed when the product is taken under medical supervision in accordance with the FDA approved labeling for the product, but it is less clear how this risk might be managed if this substance is used far more widely, without medical supervision, and not in accordance with FDA-approved labeling. Other serious treatment-emergent adverse events reported in clinical studies of Epidiolex included somnolence and lethargy; and hypersensitivity reactions. Common adverse reactions included decreased appetite, diarrhea, and sleep disorders. Some of FDA's concerns include risks of lifetime exposure, the effects of CBD on pregnant or breastfeeding women, and risks associated with CBD use in children and pets. The

working group is looking at these important safety questions carefully in the regulatory context and intends to report on its findings this coming fall.

2) **Will "standards of identity" be established? Will FDA enforce its standard of identity? How?**

   a. **For 15 years, FDA has not enforced the standard of identity for milk very well. Do you hope to improve this enforcement practice in regards to hemp products?**

      FDA's high-level CBD Policy Working Group is considering several policy and regulatory questions related to CBD. FDA is working to enhance our safety surveillance efforts on products being marketed that contain CBD. In addition, as a part of our surveillance, lab testing for product purity and contamination is important and will need to be increased. There are also open questions relating to cumulative exposure, impacts to special populations (e.g., children, the elderly, and pregnant or lactating women), and interactions with other drugs or foods. Our first effort is to determine if it is safe to add CBD to dietary supplements and/or conventional food. If FDA were to reach a determination to allow CBD in one or both of these products, FDA would consider additional policy questions such as product labeling, as appropriate.

<u>Senator Charles E. Grassley</u>

1) **In your written testimony, you state, "FDA has issued numerous warning letters to firms selling unapproved CBD drug products with claims to treat or prevent serious diseases, and in fact, the Agency began doing this in 2015, prior to the passage of the 2018 Farm Bill." How effective are these warning letters in stopping businesses and individuals from making unsubstantiated claims about the efficacy of CBD?**

   FDA has issued warning letters to companies marketing products that made unsubstantiated therapeutic and disease claims that could deter vulnerable patient populations from seeking FDA-approved therapies. While we cannot discuss the presence or absence of ongoing enforcement actions, FDA monitors the compliance of firms that have received warning letters.

2) **The Farm Bill's removal of hemp from the Controlled Substances Act has changed the way that our country addresses the cannabis plant and its derivatives, particularly CBD. Effective enforcement on the use of hemp-derived CBD relies heavily on FDA, and DEA plays a role in ensuring that any derivatives of marijuana – as opposed to hemp – are still controlled by their agency. Has there been any other substance that has been treated the same way that CBD is being treated now?**

   The removal of hemp from the Controlled Substances Act created new challenges to the already complicated questions of how FDA-administered laws apply to hemp and hemp-

derived ingredients in FDA regulated products. This is further complicated because CBD is an ingredient in an FDA-approved drug product. Because the Farm Bill specifically preserved FDA's authorities over the products it regulates, the agency treats hemp and hemp-derived ingredients, including CBD, as it would the use of other substances in products we regulate.

Senator Deb Fischer

1) **What measures is the FDA considering to address accumulated dosage of THC in a hemp-based product (meaning the actual milligrams of THC in a given product)?**

   FDA has convened a high-level, internal working group with a science-based, public health focus, that is considering many questions regarding hemp and hemp-derived products. For our goal of protecting consumers, FDA's top priority is to understand the safety profile of cannabis-derived compounds, including THC, that could be present in FDA-regulated products made from or containing hemp or hemp derivatives. FDA is working quickly and efficiently to evaluate the available data.

2) **Will FDA address the accumulated dosage in labelling or other commercial communications about the products?**

   The first priority of the Agency is protecting the public health. The risk of cumulative and life time exposure to hemp derivatives remains unknown, and the internal FDA working group is considering this issue, including as it pertains to potential labeling issues.

3) **Should states expect that FDA will have the regulatory framework in place that can be enforced nationally with regard to truth in advertising, meaning production and testing in compliance with the hemp definition of the farm bill?**

   FDA is actively collaborating with states to provide clarity with respect to regulatory questions and to share data. Through the public hearing testimony and FDA's own laboratory analysis of products, we are learning about potential safety concerns such as product formulations that do not match labeled claims or the presence of contaminants in a product, such as pathogens or heavy metals. These issues remain of concern as FDA considers the regulatory path forward.

4) **What kind of restrictions with regard to labelling (or other commercial communications) does FDA deem to be appropriate and enforceable nationally, such as restrictions on products or advertising that would be attractive to children?**

   FDA has not yet made that determination. FDA's CBD Policy Working Group is considering questions of labeling as it works to understand relevant safety data. FDA remains committed to protecting consumer safety through truthful and non-misleading labels for all products over which we have authority. Our first effort is to determine if it is safe to add CBD to dietary supplements and/or conventional food. If FDA were to reach a determination to allow CBD in one or both of these products, FDA would consider additional policy questions such as product labeling, as appropriate.

5) **To what degree are FDA's efforts in truth in advertising intended to preempt state law? What is the role of the state?**

FDA is actively communicating with state officials to facilitate collaboration, and we will continue to work with states to ensure that any product being marketed complies with relevant regulatory requirements to protect the public health. Our greatest priority is ensuring that the products available to consumers and that are within FDA's purview are safe. We will continue to actively engage in a productive dialogue with our state regulatory partners on this important topic as we strengthen our collaborative efforts in this area.

6) **Is the FDA considering any restrictions on forms of hemp based products, particularly in light of the FDA's actions?**

In line with FDA's public health mission, FDA's internal working group is analyzing available data and addressing gaps in safety data relating to the safety of hemp-derived products that are regulated by FDA. FDA has issued warning letters on some products, such as those making egregious and unsubstantiated drug claims that could deter vulnerable patient populations from seeking medical care. FDA is working quickly to evaluate the safety of hemp-derived products.

Senator Patrick Leahy

1) **Regulatory uncertainty continues to undermine the market for hemp-derived products. During his testimony before the Senate Appropriations Committee last spring, former FDA Commissioner Gottlieb suggested that, because Food and Drug Administration rulemaking on some hemp-derived products, especially cannabidiol (CBD), could take years, Congress could consider legislation alternatives.**

    a. **If Congress were to consider a legislative pathway to regulate hemp-derived CBD, what specific guardrails would FDA recommend to protect the public interest and consumer safety, while also creating a stable marketplace for producers, processors, and retailers?**

FDA will review any legislative proposals concerning CBD-containing or other hemp products and provide technical assistance in this area. Our primary concern is to ensure that any legislative proposal preserve the Agency's ability to protect the health of consumers and patients using and consuming the products we regulate. Along those lines, it would be critical that any legislative intervention with respect to the marketing of CBD-containing or other hemp-derived products **not** preempt FDA review and approval of a product that would be marketed as drug, as defined in the Federal Food, Drug, and Cosmetic Act, nor would it undermine incentives into research and development of therapeutic products.

FDA is working quickly to gather the necessary safety data to inform the appropriate path forward in a way that protects patients and consumers. Recently, FDA held a public hearing to hear from stakeholders, including producers, processors, retailers, academia with research experience, physicians, patients, and consumers. The associated public docket closed on July 16, and FDA is in the process of reviewing the 4,409 comments received. The Agency's internal CBD Policy Working Group is discussing the findings and potential regulatory pathways which may be appropriate for some products, and intends to report on findings in fall of 2019.

FDA is working as quickly and efficiently as possible, but recognizes the considerable interest among consumers, industry, and Congress in determining whether CBD can be safely added to foods at certain levels. FDA understands the need for clarity and is making every effort to ensure our process is as efficient and transparent as possible, including how we would view legislative options that might lead to more efficient and appropriate pathways than might be available under current law.

b. What will be the regulatory and enforcement posture of the FDA as regards CBD pending its adoption new rules or legislative action?

FDA's mission is to protect the public health using science-based policy. Any regulatory and/or enforcement actions will be to promote the safety of patients and consumers. Over the past several years, FDA has issued warning letters to firms that market products containing CBD that make unsubstantiated claims, including treatment of Alzheimer's disease and cancer, which may deter these vulnerable patient populations from seeking approved treatments. FDA's CBD Policy Working Group is actively analyzing existing data to inform the appropriate regulatory path forward. FDA intends to report on findings in fall of 2019.

Senator Michael Bennet

1) **Colorado currently has an expanding industry that uses hemp and hemp-infused products as food ingredients. Some in Colorado would like to see hemp designated as a food crop so they can continue to grow their markets, across the US and internationally. They have informed us that such a designation would allow the EPA to begin the process of fully assessing pesticide risk and tolerances to protect public health.**

   a. How does the FDA intend to address this question on hemp as a food crop?

We note that the Agency does not recognize a formal designation of "food crop." However, the Federal Food, Drug, and Cosmetic Act does define the word "food," and there are a variety of laws and regulations that govern the production of food products.

Since the passage of the 2018 Farm Bill, to the extent that hemp and hemp-derived products fall within the definition of "food," FDA treats these products like any other food product we regulate. For example, manufactured food products such as roasted/salted hemp seeds or hemp seed oil for human consumption are generally subject to the preventive controls regulations under the Food Safety Modernization Act (FSMA). We are committed to making sure hemp producers and processors have the guidance or technical assistance they need from FDA.

In December of 2018, FDA issued responses to three GRAS notifications for hemp seed derived substances (dehulled hemp seeds, hemp seed protein powder, and hemp seed oil) for use in human food. FDA had no questions about the notifier's conclusion that there was sufficient publicly available data such that qualified experts would agree that their use, as defined in the GRAS Notices submitted to the Agency, is generally recognized as safe. These ingredients can lawfully be used in human food.

Regarding CBD, current law prohibits the introduction into interstate commerce of food to which CBD has been added, and CBD products are also excluded from the statutory definition of a dietary supplement. This is because CBD has been the subject of substantial clinical investigations, and it is also the active ingredient in an approved drug (Epidiolex). FDA does, however, have the authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are currently analyzing the comments received on the docket associated with our May 31 public hearing as we consider the path forward to appropriate regulation of these products.

FDA regularly engages in interagency discussions, to include EPA, and will continue to discuss hemp issues as they apply to the agencies' overlapping respective authorities.

FDA recognizes the interest of industry, consumers, and Congress in the development of appropriate hemp products. FDA is working as expediently as possible to set policy on this matter that includes a thorough analysis of the safety risks to the public.

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Hemp Production and the 2018 Farm Bill
July 25, 2019
Questions for the Record
Mr. Brian Furnish

Ranking Member Debbie Stabenow

1) You discussed issues regarding hemp production and the need for research to address these critical concerns. Can you expand further and discuss what some of the critical research needs are to enhance production of hemp and hemp processing?

We need money for research for genetics, pesticides, harvest technology, and processing and extraction technology for seed, fiber and cannabinoid products.

Many machines are being sold with no proven performance.

Also, most of the seed is being sold with no true documentation or actual germ information.

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Hemp Production and the 2018 Farm Bill
July 25, 2019
Questions for the Record
Mrs. Erica Stark

Ranking Member Debbie Stabenow

1) In your written testimony you mention that there is a need to "eliminate the unintended consequences of legal gray areas" caused by differences in hemp regulation in every State and Tribe. What are the top issues that USDA needs to provide clarity on in order for States and Tribes to be able to develop hemp production plans that provide consistency for the hemp industry to ensure quality products nation-wide?

Thank you for your insightful questions and the opportunity to elaborate on these important issues.

We believe that consistency in THC testing requirements is the most important issue to ensure that we don't face a situation where what tests legal in one state could test illegal in another. This would entail a clear definition of what types of testing protocols are permitted, standards in calibration and standards and in how the samples are taken. As indicated in our written testimony, we recommend that samples be a composite of the whole plant and not just the flower. There also needs to be a reasonable variance built into the calculations post-decarboxylation based on the type of testing performed (ie GC_FID or HPLC).

This would only apply to the field testing to ensure the farmer is compliant with their permit. Most harvested hemp will be sold to a processor or manufacturer who have the ability and responsibility to ensure finished products that reach consumers comply with the .3% THC requirement within the Farm Bill.

Hemp flower that is to be sold directly into the marketplace may need an additional testing requirement of the final product to ensure compliance.

Another very important issue is the USDA's role in coordinating a multi-agency approach to implementing the changes brought forth in the 2018 Farm Bill. The removal of hemp from the Controlled Substances Act (CSA) is a change that affects numerous agencies that are outside the direct jurisdiction of USDA. Specifically, there needs to be guidance issued regarding the challenges that still face the industry, such as in obtaining traditional banking services and also for legal transportation of hemp across state lines. The banking industry is looking for rules relating to hemp to come from Treasury and DOJ can give guidance to State Attorney Generals to avoid seeing farmers, retailers and consumers improperly arrested.

There should also be standards in what can be done with crops that slightly exceed THC limits. For an example, stalk (fiber) and seed have always been exempted from the Controlled Substances Act. Therefore, it seems logical that if a crop tests 'hot' (above the 0.3% THC) that any seed and fiber from those plants should still be allowed to be used and that only the flower of the crop be destroyed.

Finally, when the USDA looks to approve plans submitted by states or tribes, they should be mindful that any regulations states or tribes seek to impose that are more restrictive than federal guidelines will not affect the legality of the crop elsewhere.

2) **In your written testimony, you recommend that the USDA apply the statutory felony ban only to individuals seeking a permit to produce hemp in accordance with a State, Tribal or Federal plan. Why do you make this recommendation? Should USDA decide to implement this ban in a way that it applies to all forms of employment opportunities in the hemp production space and not just the permit holder, how could broad implementation of this ban harm agricultural business and economic opportunities for rural farmers and other workers?**

We believe that the intent of Congress in legalizing hemp as a commodity crop was to allow American farmers the opportunity to introduce another rotational crop into their plantings. The drug felon ban provision, if implemented to affect anyone working with this crop, would greatly restrict farmers from taking advantage of this new source of revenue. Frankly speaking, no other legal commodity crop is subject to a similar drug felon provision and therefore we see this provision as placing yet another undue burden on struggling farmers.

In addition, agricultural businesses, farmers and other workers seek to benefit from the economic opportunities that the newly legalized domestic hemp industry will bring to rural communities across the country. However, the hemp drug felony ban provision could severely harm these economic prospects if agricultural businesses and farmers can't hire enough employees to fill hemp production jobs. Jobs are already scarce in many rural communities, and farmers and agriculture business interests have a tough time as it is finding reliable workers to fill various roles involved in production. This includes seasonal farmworkers who are already hard to come by with the current H2A program. Any additional strain on the ability to hire workers only further affects farmers in a negative way.

The private sector would also be burdened by the considerable cost and human resources required to police workers involved in hemp production should USDA implement the hemp felony ban beyond licensees. Screening and tracking workers involved in hemp production operations such as cultivation, processing, packaging and transporting hemp products would be very costly to the agriculture industry and individual farmers. This would also be very burdensome for states to similarly conduct costly background checks and enforce the drug felony ban.

It is also simply unfair to shut out people from job opportunities in this fast growing industry on the basis of a prior conviction alone. In rural areas where job opportunities are already scarce, a prior conviction can make it extremely difficult to find employment. This includes people of color who, as Pew Charitable Trusts highlighted in a recent article, would likely be disproportionately harmed by a broad implementation of the hemp drug felony ban since people of color are disproportionately convicted of drug offenses. It is especially unfair to deny new job opportunities to people because they made a past mistake, especially in light of the recent steps taken by Congress and the Trump administration to ease barriers to employment for returning citizens. Applying the hemp drug felony ban to hemp production jobs would be a major setback for these efforts.

Multiple states have not had any restrictions on drug felons or any felon regarding growing hemp, processing or manufacturing since 2014 with no negative impacts. In fact, one of the jails in Colorado have collaborated with hemp farmers to allow inmates to work in hemp fields during work release. This is a great opportunity to learn a new skill, transition back into society and have a potential job upon release.

3) **In both your written and verbal testimony you talked about a lot of the various issues regarding hemp production. Can you expand further and discuss what some of the critical research needs are to enhance production of hemp and hemp processing?**

Due to the versatility and potential of this plant the need for research is only limited by our imaginations. However, we believe the top priorities are currently in the areas of equipment and medical research.

To reach the full potential of hemp as an industrial fiber crop there is a great need to develop specialized harvesting equipment and decortication facilities. Fiber hemp can grow upwards of 20' tall making it impractical or impossible to use a standard combine. Specialized harvesting equipment, as they use in Europe, will maximize value for the farmer by ensuring that all parts of the plant; stalk, seed, leaves and flower are all captured.

Decortication is the process of breaking down hemp into its two component fibers. The bast fiber which is on the outer part of the stalk and is considered the strongest natural fiber on earth and the hurd which is the inner woody core. Both fibers have a vast number of uses in manufacturing but the infrastructure to produce these raw materials is lacking in the US. Farmers will not grow hemp if they do not know where they can sell the crop and manufacturers will not buy raw hemp unless they know there is a supply change. These two major issues must be address in parallel.

Medical research is also a top priority. Research and clinical trials are needed for CBD both for humans and animals. Its also important to note that CBD, which is a whole plant extract (like an essential oil from lavender) is only one of many cannabinoids found in the hemp plant and

research into the other cannabinoids will be needed in addition to research around the entourage effect which is how all the cannabinoids work together.

There should be specific research into determining how the totality of the environmental benefits of hemp in, both cultivation and products, can be deployed to help meet sustainability and climate goals. Hemp is well known to be a hyperaccumulator and capable of sequestering large amounts of C02. As one example, building products made of hemp continue to sequester C02 resulting in carbon neutral or carbon negative structures. Hemp can be an important piece of the overall strategy to combat climate change while benefiting farmers and creating manufacturing jobs.

Research funds should be allocated to the Tribes and Territories that were excluded from participating in the 2014 Farm Bill hemp research trials as a way to help expedite their participation in this industry.

Another area of research that is vital is the development of better field tests for law enforcement to be able to differentiate hemp from marijuana. The standard NIK tests commonly used by law enforcement are not sensitive enough and falsely identify hemp as marijuana. While there are portable tests available, none are at a price point that is reasonable enough to replace NIK tests.

Other research needs include, but are not limited to, agronomy, genetics, pesticides, bioplastics and hi-tech applications for hemp fiber.

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Hemp Production and the 2018 Farm Bill
July 25, 2019
Questions for the Record
Chairman Darrell G. Seki, Sr.

Senator Amy Klobuchar

1) The Red Lake Nation has a long tradition of agricultural production, including crop production, fish harvesting, and wild rice cultivation. The production of hemp is a relatively new development and one that I supported in the 2018 Farm Bill.

    a. How do you foresee hemp production being incorporated into the Red Lake Nation's future agricultural production?

RESPONSE:

We believe Reservation hemp production and Reservation hemp processing fits with our Red Lake tradition of working with our land and water to create, prepare, and market products of value to surrounding markets. We have a rich history of doing this with wild game, timber, rice, and fish. We plan to use the same ingenuity to grow hemp and to develop value added hemp products. We have thousands of acres of arable, irrigable land and are well-positioned to provide a foot print for regional processing plants that are well-connected to markets. Our Tribe has a proven and experienced marketing and distribution system. Our governmental and regulatory framework is ready to attract the necessary outside capital and our labor force is likewise willing, able and available.

2) The Department of Agriculture has continued to delay the implementation of hemp regulations from the 2018 Farm Bill. As you noted in your testimony, this has placed Tribal agribusinesses at a competitive disadvantage because the 2014 Farm Bill only allowed Tribal hemp research pilots in partnership with a state government.

    a. What impact would further delays have on your tribal members who are attempting to prepare for the 2020 hemp growing season?

RESPONSE:

The impacts could be devastating. We cannot prepare an accurate and honest business plan in this time-sensitive competitive market if we, unlike our competitors that are regulated by the state, are unable to predict a starting point. And without a well-constructed plan, we are unable to attract outside investors who will go elsewhere with their capital to producers and processors who can provide a more certain timetable for returns on their investment. Tribes

like Red Lake continue to suffer the handicap of being treated as an after-thought, having been shut out of the hemp head start given states in the 2014 Farm Bill. When we are forced to start the race four laps behind the states, our work force and our economic development continues to struggle against unfair challenges. We need certainty now so that we are able to finalize our regulatory framework, attract necessary capital, and make arrangements for obtaining the necessary inputs for getting the hemp crop in the ground. Further delays by the Department of Agriculture in implementing hemp regulations from the 2018 Farm Bill makes it impossible for Tribes to move forward in this promising new enterprise.

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