HEMP IN THE MODERN WORLD: THE YEARSLONG WAIT FOR FDA ACTION

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH CARE AND FINANCIAL SERVICES

OF THE

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

JULY 27, 2023

Serial No. 118–57

Printed for the use of the Committee on Oversight and Accountability

Available on: *govinfo.gov*
oversight.house.gov or
docs.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

53–026 PDF WASHINGTON : 2023

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

JAMES COMER, Kentucky, Chairman

JIM JORDAN, Ohio
MIKE TURNER, Ohio
PAUL GOSAR, Arizona
VIRGINIA FOXX, North Carolina
GLENN GROTHMAN, Wisconsin
GARY PALMER, Alabama
CLAY HIGGINS, Louisiana
PETE SESSIONS, Texas
ANDY BIGGS, Arizona
NANCY MACE, South Carolina
JAKE LATURNER, Kansas
PAT FALLON, Texas
BYRON DONALDS, Florida
KELLY ARMSTRONG, North Dakota
SCOTT PERRY, Pennsylvania
WILLIAM TIMMONS, South Carolina
TIM BURCHETT, Tennessee
MARJORIE TAYLOR GREENE, Georgia
LISA MCCLAIN, Michigan
LAUREN BOEBERT, Colorado
RUSSELL FRY, South Carolina
ANNA PAULINA LUNA, Florida
CHUCK EDWARDS, North Carolina
NICK LANGWORTHY, New York
ERIC BURLISON, Missouri

JAMIE RASKIN, Maryland, *Ranking Minority Member*
ELEANOR HOLMES NORTON, District of Columbia
STEPHEN F. LYNCH, Massachusetts
GERALD E. CONNOLLY, Virginia
RAJA KRISHNAMOORTHI, Illinois
RO KHANNA, California
KWEISI MFUME, Maryland
ALEXANDRIA OCASIO-CORTEZ, New York
KATIE PORTER, California
CORI BUSH, Missouri
SHONTEL BROWN, Ohio
JIMMY GOMEZ, California
MELANIE STANSBURY, New Mexico
ROBERT GARCIA, California
MAXWELL FROST, Florida
SUMMER LEE, Pennsylvania
GREG CASAR, Texas
JASMINE CROCKETT, Texas
DAN GOLDMAN, New York
JARED MOSKOWITZ, Florida
Vacancy

MARK MARIN, Staff Director
JESSICA DONLON, Deputy Staff Director and General Counsel
RYAN GIACHETTI, Counsel
SARAH FEENEY, Professional Staff Member
BEN TARDIF, Professional Staff Member
MALLORY COGAR, Deputy Director of Operations and Chief Clerk
CONTACT NUMBER: 202-225-5074

JULIE TAGEN, Minority Staff Director
CONTACT NUMBER: 202-225-5051

SUBCOMMITTEE ON HEALTH CARE AND FINANCIAL SERVICES

LISA MCCLAIN, Michigan, Chairwoman

PAUL GOSAR, Arizona
VIRGINIA FOXX, North Carolina
GLENN GROTHMAN, Wisconsin
RUSSELL FRY, South Carolina
ANNA PAULINA LUNA, Florida
NICK LANGWORTHY, New York
ERIC BURLISON, Missouri
Vacancy

KATIE PORTER, California *Ranking Minority Member*
ALEXANDRIA OCASIO-CORTEZ, New York
JIMMY GOMEZ, California
GREG CASAR, Texas
SUMMER LEE, Pennsylvania
JASMINE CROCKETT, Texas
Vacancy

C O N T E N T S

WITNESSES

Written opening statements and statements for the witnesses are available on the U.S. House of Representatives Document Repository at: docs.house.gov.

INDEX OF DOCUMENTS

Documents are available at: docs.house.gov.

HEMP IN THE MODERN WORLD: THE YEARSLONG WAIT FOR FDA ACTION

Thursday, July 27, 2023

HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
SUBCOMMITTEE ON HEALTH CARE AND FINANCIAL SERVICES
Washington, D.C.

The Subcommittee met, pursuant to notice, at 2:21 p.m., in room 2247, Rayburn House Office Building, Hon. Lisa C. McClain [Chairwoman of the Subcommittee] presiding.

Present: Representatives McClain, Foxx, Grothman, Comer (ex officio), Porter, Lee, and Raskin (ex officio).

Mrs. MCCLAIN. All right. I want to welcome everyone to today's hearing.

We are here, yet again, to discuss the failures of the—oh, let me back up. Let me back up. Start over. Start over.

The Subcommittee on Healthcare and Financial Services will come to order.

Welcome, everyone.

Without objection, the Chair may declare a recess at any time.

I recognize myself for the purpose of making an opening statement. Here we go.

I want to welcome everyone today. We are here, yet again, to discuss the failures of the Food and Drug Administration. Earlier this year, the Subcommittee learned how failures at the FDA led to the infant formula crisis. Now, we are learning of the FDA's failure to regulate hemp products.

In both cases, the FDA's action or, quite frankly, lack thereof, have hurt families and children. The growth and sales of hemp and hemp-derived products, including CBD, was legalized in the 2018 Farm Bill.

CBD was also removed from Schedule I status, which are drugs that have no currently accepted medical use and a high potential for abuse. It makes sense to remove CBD from Schedule I status. We know that CBD can have a medical use, because the FDA approved a prescription CBD drug that is used to treat children with severe forms of epilepsy. We also know that pure CBD does not have a high potential for abuse and cannot cause a high because it is not intoxicating. However, if you buy a CBD consumer product off the shelf today, in many cases, there are no way for the average consumer to verify its purity or even the amount of CBD in it, or rely on the FDA's enforcement of regulations.

In fact, one study tested almost 3,000 CBD products, showed that only one-quarter of the brands tested their CBD products for purity and that only 16 percent of those products tested contained exclusively what was stated on their label. Sixteen percent. And that is because the FDA has not regulated CBD as a dietary supplement or food additive in the 5-years since hemp was legalized.

It is also common for CBD products to contain contaminants, like heavy metals, mold, and THC, which is the intoxicating chemical in the cannabis plant. The widespread usage of CBD products that contain other unknown contaminants has led to children accidentally ingesting and overdosing on THC. This could be fixed if the FDA regulated CBD as a dietary supplement. That would mean that the FDA would have the enforcement authority to enforce labeling requirements and keep Americans safe and healthy.

But instead of regulating hemp-derived products under its currently—currently existing authority, the FDA announced earlier this year that it needs a new regulatory framework for hemp and CBD. Translation: Give us more authority, give us more money, give us more staff, and only then will we actually do our duties under the law.

This announcement has led to confusion and uncertainty in the market, which has suppressed the ability for good-faith manufacturers to sell CBD products. It only benefits bad actors who capitalize on the confusion and the flood of the market with potentially unsafe products.

The FDA must do better and use their already existing authority to regulate hemp-derived products. You know, actually do the job they were signed up to do.

I now recognize the Ranking Member of the Subcommittee, Ranking Member Porter, for her opening statement.

Ms. PORTER. Thank you very much, Chairwoman.

I want to focus on doing the job that they are supposed to do as well. But I want to focus on a different body, not the FDA. I want to talk about Congress doing the job that it is supposed to do.

Hemp-derived products may provide numerous health benefits, such as easing anxiety, insomnia, chronic pain, and addiction. That is why today, we have Members on both sides of the aisle who are interested in determining how we should regulate these products.

Right now, as the Chairwoman said, you can buy CBD and other hemp-derived products in grocery stores, or you can order them online to be shipped anywhere. While this framework provides a great deal of accessibility, it also creates challenges.

Because hemp-derived products are not federally regulated, they may include, not just CBD, but THC, an intoxicant. These products can be sold in packaging that makes them look like traditional snack foods. That can be confusing to adults and children alike, who may not want or intend to consume products with intoxicating levels of THC.

This is a real problem. In fact, just a few weeks ago, the FDA and the Federal Trade Commission issued warning letters to six companies for illegally selling products containing THC. We should all be able to agree that the Federal Government needs to regulate hemp-derived products in a way that protects our constituents while also making safe products available to them.

In fact, the FDA convened an internal working group to explore how the agency might go about regulating hemp-derived products. After its review, the FDA working group came back, and they said, we need a new regulatory pathway for hemp-derived products. They even added that they would like to work with Congress—nobody wants to work with us—they would like to work with Congress to get that pathway set up through legislation.

Today, Republicans have convened this hearing because they believe, apparently, that the FDA does not need any more authority from Congress to properly regulate hemp-derived products. The problem is that some of the same lawmakers who want to do oversight of the FDA for being cautious about its existing powers would turn around and blast the agency if they ever felt like it went too far beyond its legal authority.

Look, we cannot have it both ways here. The FDA knows Congress will appropriately hold it accountable if the agency exceeds its authority. That is our job. So, the FDA is not going to take the risk of going too far. Why ask them to take that risk when we could just work together across the aisle on some commonsense legislation?

Given the bipartisan interest, Members of Congress should have no problem rolling up our sleeves—hell, I do not even have any sleeves—and getting to work to establish the regulatory pathway that the FDA says it needs. Let us not jump to blaming the FDA until Congress has done everything it can to set it up for success.

At this point, we should certainly evaluate how the FDA does. In the meantime, the better institution to exhort to do its job is us, Congress. We are the better oversight subject at this point.

Thank you, and I yield back.

Mrs. MCCLAIN. Thank you, Ms. Porter.

The Chair now recognizes Chairman Comer for an opening statement.

Mr. COMER. Well, I want to thank Chairwoman McClain for having this very important hearing today on this very important topic, and I want to thank our great witnesses who are here today.

Five years ago, Congress passed the 2018 Farm Bill. That bill removed hemp and hemp-derived products, including CBD, from Schedule I status under the Controlled Substances Act. Since that time, farmers, manufacturers, researchers, and distributors have looked for various ways to grow the industry and provide hemp and CBD products to the American people.

The U.S. Department of Agriculture's February 2022 National Hemp Report shows that over 54,000 acres of U.S. land is utilized for hemp farming. Clearly, hemp has so much potential for our American economy, from growers and manufacturers to businesses of all sizes and consumers of many backgrounds. And since 2018, scientific research and careful study has continued to shed light on both the efficiency and safety of these products, especially CBD.

FDA continues to imply that adequate scientific data is not available to inform their decision-making around CBD and hemp-derived products. But there is ample available data studying CBD and hemp-derived compounds. FDA is simply not being transparent with the industry stakeholders or Congress in what scientific studies it relies on, and often moves the goalpost for researchers at-

tempting to satisfy the FDA's requirements through rigorous studies.

So, even though we have more and more data available to regulators to make appropriate decisions about CBD in the marketplace, the FDA has taken no meaningful action to provide clear guidance and certainty in the market, refusing to regulate CBD products under existing lawful pathways. Without FDA regulations, the good-faith producers of these products are left with no path forward, and consumers are left in the dark. It is well past time for FDA to do its job and act.

More than just a major obstacle to the economic prosperity of our great farmers and producers of these products, the FDA's inaction has also led to concerns for consumers. With no regulations, shelves have been flooded with products that make various claims about content and dosage that may or may not be accurate, while others may be mislabeled and actually contain intoxicating variants of the cannabis plant, like delta–8 or delta–9 THC.

Consumers are often unaware that the CBD product that they are ingesting is not only going to assist them with joint pain and other relief, but could be adulterated with other compounds. The American people need to know what is in their products, and the FDA has the power to enforce reasonable regulations by regulating CBD as a dietary supplement or food additive—and I repeat that—regulate it as a dietary supplement or food additive. But still they have not acted.

I am also concerned about the availability of potentially dangerous products making their way into the hands of children. Hemp-derived products like CBD and others intended for human consumption should be clearly labeled with an accurate accounting of their contents and available to responsible adults who are aware of any side effects and risks associated with those products.

I have said this before at Oversight hearings, but I take hemp-derived CBD—hemp-derived CBD from labs in my congressional district in Kentucky that I have seen and have confidence in. I think we all agree that it is beneficial for the industry and consumers alike when our shelves are stocked with products that contain what they say contain, while limiting the ability of irresponsible and bad-faith actors to mislead consumers.

If CBD were regulated as a dietary supplement, the FDA would have enforcement power to make this a reality. The hemp industry would prosper. Consumers would have choice in the market and ability to rely on accurate labeling. It would be a win for our economy, a win for industry, and a win for the American consumer. But instead of doing its job here, the FDA has refused to act and use this as an opportunity for a power grab, asking Congress for even more authorities and more money. Let me be clear. Further bloating the Federal bureaucracy is not the answer.

I look forward to hearing from the witnesses today to obtain an accurate understanding of the issues here. I hope there is bipartisan support on this issue, and I look forward to ways we can work across the aisle to bring about positive changes for the hemp industry, the Americans who rely on that industry for their livelihood, as well as American consumers demanding hemp products.

Thank you, Madam Chair, and I yield back.

Mrs. MCCLAIN. Thank you, Mr. Chairman.

The Chair now recognizes Ranking Member Raskin for an opening statement.

Mr. RASKIN. Well, thank you kindly, Chairwoman McClain, and Chairman Comer also, for being here for this important hearing.

While the hearing itself is focused on hemp, I do think it is part of a sweeping rethinking of cannabis policy that is going on across the country. And earlier today, I am proud to say that Congresswoman Mace and I introduced our bipartisan Cannabis Users Restoration of Eligibility Act, or the so-called CURE Act, or at least we hope people will call it the CURE Act.

Our bill would remove prior marijuana use as an obstacle to people getting hired in the Federal Government or passing the Federal security clearance process, and so it would allow for people who have been denied security clearance on the sole basis that they had once used marijuana, either legally as part of a medical marijuana or recreational marijuana state, or unlawfully in college or whatever, that these people would be able to get their security clearance reviewed again, and that no longer could be used to nullify their opportunity to be hired in the Federal Government.

This change is imperative, and it is long overdue. I learned of the problem because of a constituent who is a distinguished scientist and doctor who was about to get hired to a sub-Cabinet-level post in the Biden Administration, but who failed the security clearance because he accurately and faithfully reported on his security clearance form that he had used medical marijuana because of a chronic back condition, and then he was immediately disqualified. Even though they had already told him they were going to offer him the job, he was told he could no longer get the job because he had told the truth about having used medical marijuana to treat a medical condition.

And then, when we began to look into this, there are, well, hundreds of thousands, if not millions, of people who are disqualified from even being even able to apply for positions they are qualified to hold. And thousands of people that we know of who have actually gone through the process and then suddenly run into the professional guillotine of a marijuana question on the security clearance form.

So—but I want to thank Ms. Mace for her collaboration and cooperation on this bill. We look forward to moving it through this Committee with the help, I hope, of Chairman Comer, who I know has asked some good questions about it. But I am hoping that we will be able to arrive at a good, commonsense bill that all Americans would be able to get behind.

Now, turning back to the Federal rules related to hemp and its derivatives, it is important here again that we take a commonsense approach to these regulations. The FDA released a statement earlier this year explaining that current regulatory frameworks for foods and supplements are not appropriate for cannabidiol, or CBD, one of the biggest hemp derivatives. The FDA explained that the regulatory frameworks may not be sufficient for managing risk in conducting appropriate oversight for CBD products.

And I agree with my colleagues that we need reasonable regulation of the hemp and hemp-derivative marketplace to protect con-

sumers and to ensure that good actors in the hemp industry can grow their businesses and we can have a legitimate and flourishing market in hemp, but we need to make sure that the regulations make sense.

A vast world of hemp derivatives is flourishing beyond just CBD. Among them are newly developed synthetic cannabinoids, including delta–8 THC, which can have intoxicating effects when consumed. Without regulation, companies can synthesize these intoxicants from legal hemp and evade regulatory scrutiny and Federal marijuana laws, sending products to market without proper testing, labeling, or other safety precautions.

Hemp-derivative products can come in all sorts of different forms. They cannot be easily or always categorized simply as food or supplements. These products can be oils, tinctures, vape pens and cigarettes, and even cosmetics and skin care. The FDA realistically cannot regulate the entire world of hemp and its derivatives without additional research authority and resources.

So, I hope we can work with our colleagues to figure out the proper path forward, and with the assistance of today's expert witnesses, on regulating hemp and its derivatives so that we can protect the American people and provide a more effective framework for the regulation of a potentially strong industry.

I thank you, Madam Chair, and I yield back to you.

Mrs. MCCLAIN. Thank you, Mr. Raskin.

I am pleased to introduce our witness panel today.

Jonathan Miller is a longtime advocate for the hemp industry in the United States. He currently serves as the general counsel for the U.S. Hemp Roundtable, which advocates for the broader hemp industry, including agriculture, oil, seed, fiber, and extracts like CBD. Welcome.

Dr. Rayetta Henderson is a toxicologist and senior managing scientist at ToxStrategies. She is the lead author of several peer-reviewed publications relating to the safety assessment and toxicology testing of CBD as a dietary ingredient.

Richard Badaracco—did I say that right? Look at me—is the incoming president of the Kentucky Narcotic Officers Association, who brings four decades of experience as a professional law enforcement officer. Among other law enforcement roles, he brings special expertise as a retired Assistant Special Agent In Charge at the U.S. Drug Enforcement Administration. Thank you, sir, for your service.

And, finally, Dr. Gillian Schauer is an Executive Director of the Cannabis Regulators Association, where she leads a nonpartisan association agency involved in cannabis and hemp regulation across 45 states and U.S. territories. Welcome.

Pursuant to Committee Rule 9, the witnesses will please stand and raise their right hands.

Thank you.

Do you solemnly swear or affirm that the testimony that you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

Let the record show that the witnesses all answered in the affirmative.

We appreciate all of you being here today and look forward to your testimony.

Let me remind the witnesses that we have read your written statements, and they will appear in full in the hearing record. Please limit your oral statements to 5 minutes. As a reminder, please press the button on the microphone in front of you so that it is on, and the Members can hear you. When you begin to speak, the light in front of you will turn green. After 4 minutes, the light will turn yellow. When the red light comes on, your 5 minutes has expired, and we would ask you to please wrap up.

I now recognize Mr. Miller to please begin his opening statement.

STATEMENT OF JONATHAN S. MILLER
GENERAL COUNSEL
U.S. HEMP ROUNDTABLE

Mr. MILLER. Madam Chairwoman, Ranking Member Porter, I am grateful for the opportunity to testify before your Committee today.

Chairman Comer, I am grateful for your presence today, but, more importantly, for your decade-long leadership on behalf of Kentucky and U.S. hemp farmers. You and I started on this journey in 2012 and worked across the aisle to secure hemp's legalization in the Bluegrass state.

Indeed, hemp's policy success has always been a bipartisan hallmark. Unfortunately, the U.S. hemp industry has been struggling considerably in the last few years, and this turmoil is due, in large part, to decisions made by FDA.

When Congress passed the 2018 Farm Bill, it explicitly legalized the sale of hemp and its derivatives, such as CBD. Farmers across the Nation relied on this and invested considerable resources to grow and market commercial hemp crops, particularly for the product for which there was immediate processing, infrastructure, and consumer demand: CBD and cannabinoids.

But just a few hours after the Farm Bill was signed into law, FDA asserted its opinion that it was illegal to market CBD as a dietary supplement or to use as a food additive. Beyond warning letters that mostly targeted illegal disease claims, the agency has not engaged in meaningful enforcement. This position, coupled with lack of action, has cast a cloud over the industry.

FDA has swung back and forth with contradictory positions. First, the agency affirmed its ability to regulate CBD under current law. We agreed. But then, in the intervening 4 years, FDA stalled, even ignoring congressional appropriations report directives to take expedited action.

Finally, this January, the agency concluded that it could not regulate CBD under existing regulatory pathways. It stated a concern over the substance's safety. But in so doing, the FDA relied on a narrow set of research focused on super-high-dosage CBD isolate formulations, while refusing to acknowledge a range of studies that demonstrate the safety of various CBD formulations at much, much lower dosage levels, such as those typically found in products sold at retail. A summary of these studies appears in my written testimony.

Lack of a Federal framework has led to the proliferation of unregulated products, some of which raise significant quality and

safety concerns. Surplus hemp CBD biomass is being chemically converted into impairing products, such as delta–8 THC, which are being sold unregulated, sometimes to minors.

These products serve as a lifeline to U.S. farmers, and when manufactured properly, can be of considerable value to adult consumers. We oppose their ban or criminalization, but they need to be strictly regulated for safety and kept out of the hands of children.

Meanwhile, Federal regulatory uncertainty severely impacted the hemp and CBD market, with reduced manufacturing demand resulting in a more than 90 percent commodity price decline, crushing farming opportunities.

Please see this chart behind me. In all but one category, prices have collapsed due to FDA inaction. The one exception in green, that line represents the price of hemp flour, which recovered when it started being widely used for delta–8 THC.

It is clearly time for Congress to act. We support legislation that has been introduced by a bipartisan coalition. H.R. 1628 would provide a regulatory pathway for CBD as a food and beverage additive. H.R. 1629 would ensure that hemp ingredients could be lawfully marketed as dietary supplements. In the Senate, S. 2451 and its companion House bill, H.R. 4849, would provide both regulatory paths.

All of these would require compliance with the entire existing comprehensive regulatory frameworks for dietary supplements and food, which help ensure products are safe, properly labeled, and produced under good manufacturing practices.

While we disagree with FDA's opinion that a new regulatory regime is needed, especially given the length of time this would require, we are certainly open to stricter regulation of CBD and other cannabinoid products on top of the existing frameworks.

In the absence of FDA action, the hemp industry has established the U.S. Hemp Authority, a self-regulatory organization to promote high standards and best practices. States have stepped in, but a patchwork of inconsistent law has emerged.

Without a Federal regulatory pathway for requiring such standards, economic opportunities for U.S. hemp farmers will be diminished, and consumers will not have access to safe, quality products. Legislation is necessary to protect consumers, help stabilize hemp markets, open up a promising economic opportunity for U.S. agriculture, and honor the commitment made to growers in the 2018 Farm Bill.

Madam Chairwoman, the hemp industry may be unique in that we are coming to Congress to ask: Please regulate us.

We appreciate your consideration.

Mrs. MCCLAIN. Thank you, Mr. Miller.

The Chair now recognizes Dr. Henderson.

STATEMENT OF RAYETTA G. HENDERSON, PH.D.
SENIOR MANAGING SCIENTIST
TOXSTRATEGIES, LLC

Ms. HENDERSON. Chairwoman McClain, Ranking Member Porter, Chairman Comer, Ranking Member Raskin, and Members of the

Subcommittee, thank you for inviting me to participate in today's hearing. I appreciate the opportunity to talk about our research and its utility in an overall evaluation of CBD to support its safe use as a dietary ingredient.

I am a toxicologist and senior managing scientist at ToxStrategies, a scientific consulting firm that provides support for clients in the public and private sectors. I have experience in the safety assessment of ingredients that are often used in food, supplements, and/or feed. And since the 2018 Farm Bill, I have been actively involved in the safety assessment of CBD and other hemp-derived products.

I am here today to present our recently published preclinical safety studies that provide key information needed to conduct robust science-based assessments to evaluate the safety of CBD as a dietary ingredient. These studies, in combination with other available data, provide a sufficient basis from which to determine safe levels of CBD for oral consumer use.

To ensure consumer protection, dietary ingredients must meet the relevant prescribed safety standards for their intended use, such as those established for new dietary ingredients. We have conducted a safety testing program to specifically address gaps identified for a CBD product that would be expected to be filled as part of regulatory compliance. The need for these studies was determined based on standard practices typically employed in the safety evaluation of dietary ingredients.

Before I present the outcome of these studies, it is important to provide some background on how they are designed and used to support safety. A fundamental concept in any safety assessment is that the finding of a potential adverse effect does not automatically mean there is a risk of that effect occurring. Preclinical toxicology studies are intentionally designed to be conducted at high enough exposure levels to identify potential adverse effects. This is an important distinction because exposure levels associated with human consumption may be very different from exposure levels tested in toxicology studies.

Substances considered to be beneficial and even necessary for health can be toxic if consumed in large enough amounts. Understanding the levels at which these effects might occur provides the information necessary to determine levels of consumption that are unlikely to be associated with such effects.

When sufficient data are available for an ingredient, a risk assessment can be performed based on information from safety studies and exposure levels and consumers to evaluate whether a sufficiently protective margin of safety exists and determine a safe level of intake for consumers.

Our program included six preclinical toxicity studies on a hemp-derived CBD isolate. All studies were performed according to the highest standards available and involved a collaboration and oversight of scientists from multiple disciplines and research organizations. In addition, three manuscripts summarizing these studies have undergone an independent peer-review process and are now publicly available in scientific journals. A copy of each is provided as an appendix to my written statement.

First, CBD did not cause DNA or chromosomal damage in our testing program. This is critical, as a genotoxic finding would have precluded its use as a dietary ingredient. Next, our studies demonstrated that CBD was well-tolerated following repeated consumption in animal models up to the highest dose tested of 140 milligrams per kilogram body weight for 90 days.

In our reproductive study, exposure up to 100 milligrams per kilogram body weight a day did not cause adverse effects on fertility or reproduction in female animals, nor did it cause any developmental effects in offspring. For context, when converted to milligrams a day based on body weight, this value would be 100fold higher than a dietary supplement product containing 70 milligrams of CBD.

Finally, no adverse effects on male reproductive parameters were observed up to the highest dose tested of 300 milligrams per kilogram body weight a day.

Together, this suite of studies provides the baseline data that are typically required to evaluate use of a dietary ingredient.

Providing the science to do safety and risk assessment for dietary ingredients is expressly in line with the objective of protecting the health and well-being of the American consumer. We have conducted core safety studies that add to an already extensive body of science for CBD, which includes human clinical trials and studies in animal models.

Based on my experience performing similar evaluations, the data available are sufficient for conducting a safety assessment of hemp-derived CBD isolate. The process would follow the same principles that we as risk assessors apply when evaluating any ingredient for dietary use.

Recommendations for safe use, such as exposure levels, will depend on a number of factors, including the data available for review by the assessors and the population of interest for the product. Recommendations for safe use could be refined as necessary as new data continue to become available.

I thank the Subcommittee and its Members for your interest, and look forward to answering any questions you may have.

Mrs. MCCLAIN. Thank you, Dr. Henderson.

The Chair now recognizes Mr. Badaracco.

STATEMENT OF RICHARD A. BADARACCO
PRESIDENT-ELECT
KENTUCKY NARCOTIC OFFICERS ASSOCIATION
(RETIRED) ASSISTANT SPECIAL AGENT IN CHARGE
U.S. DRUG ENFORCEMENT ADMINISTRATION

Mr. BADARACCO. Chairman Comer, Chairwoman McClain, Ranking Member Porter, and esteemed Members of the Subcommittee, I am grateful for the opportunity to testify before your Committee today.

My testimony today focuses on the absence of a Federal regulatory structure to govern the marketing of CBD and other hemp-derived products. Mr. Miller testified earlier that the collapse of hemp and CBD led many farmers and businesses to chemically convert CBD biomass into intoxicating compounds, most prominently, delta–8 THC.

The passage of the Agricultural Improvement Act of 2018 and the deregulation of hemp did not specifically address delta–8 THC, but effectively legalized the sale of hemp-derived delta–8 THC products with no oversight. Its popularity has grown dramatically since 2020, gaining the attention of consumers and market stakeholders alike throughout the country.

Hemp and marijuana are primarily the same plant and often are not visually distinguishable. Each contain many cannabinoids. The two well-known compounds naturally produced in the cannabis plant are tetrahydrocannabinol, THC, both 8 and 9, and cannabidiol, CBD.

Mostly, the distinction between hemp and marijuana is the concentration of delta–9 THC in the two plants. Hemp, by definition, must contain no more than 0.3 delta–9 THC. Marijuana plants usually contain anywhere from 5 to 30 percent delta–9 THC. It is this substance that produces the intoxicating effects of the marijuana plant.

CBD is a much more prevalent compound in the hemp plant, so the standard method of creating delta–8 THC involves chemically extracting CBD from hemp and converting it into delta–8 THC. Delta–8 THC has psychoactive and intoxicating effects like delta–9, having about half of the intoxicating effects of delta–9.

In many states, including Kentucky, most delta–8 THC products are sold throughout unregulated market sources, like convenience stores, grocery stores, smoke/vape shops, gas stations, and can even be ordered online. These products are not reliably tested and have been found to contain many impurities.

In addressing these issues, Congress and regulators may choose to work with the U.S. Hemp Authority, the hemp industry's self-regulating organization. In the absence of FDA regulations, the Hemp Authority encourages manufacturers to participate in the program to use best practices and high standards in preparing their products. The standards are based largely on FDA's regulatory regime concerning dietary supplements in food and beverage additives and is enforced by third-party auditors.

However, self-regulation is not sufficient. Federal regulation is necessary to ensure that all products on the marketplace maintain the highest safety standards. These products and their abuse have become a concern for law enforcement in many instances.

However, Congress, law enforcement, and state legislators can, right now address some of the complex issues surrounding these substances, such as enact legislation regulating the manufacturing, sale, and distribution of products containing a hemp-derived cannabinoid, including licensing resale—retailers.

Enact legislation enabling testing requirements of all products containing hemp-derived cannabinoids and create rules specifying pass-fail action levels for safety and toxicity.

Establish child safety packaging and labeling requirements along with restrictions to advertising which may appeal to minors.

Regulate the hemp industry so products contain only the legal limit of 0.3 percent or less of a concentration of THC.

Mandatory reporting to a government entity when ingestion of these substances led to an adverse reaction. Law enforcement believes these events are underreported.

Seek state or Federal funding for forensic lab infrastructure that could assist and help with the development of improved hemp and marijuana differential methods.

And training for law enforcement officers concerning these substances and navigating the possible implications of arresting and prosecuting individuals under the influence.

In closing, I want to thank the Committee for examining this important topic, and I look forward to your questions.

Mrs. MCCLAIN. Thank you, Mr. Badaracco.

The Chair now recognizes Dr. Schauer for her opening statement.

STATEMENT OF GILLIAN SCHAUER, PH.D., MPH
EXECUTIVE DIRECTOR
CANNABIS REGULATORS ASSOCIATION

Ms. SCHAUER. Thank you, Chairman McClain, Ranking Member Porter, Chairman Comer, and Members of the Subcommittee. Thank you for inviting me to testify today.

My name is Gillian Schauer. I am the Executive Director of the Cannabis Regulators Association, referred to as CANNRA. CANNRA is a nonpartisan association of government agencies implementing cannabis and hemp regulation across 45 states and U.S. territories.

Prior to serving as the first Executive Director of CANNRA, I spent more than a decade working with Federal, state, and municipal agencies on cannabis-related policy, research, and public health. I have a Ph.D. in behavioral science and a master's in public health.

Thank you for holding this hearing. This is the No. 1 issue facing my members, cannabis and hemp regulators. Because of a broad definition of hemp in the 2018 Farm Bill, we have seen an explosion of hemp-derived products that are intoxicating, that are not regulated to be safe for consumers, and that can appeal to and be accessed by youth. Red states, blue states, every state is grappling with this issue.

Intoxicating hemp-derived cannabinoids, including delta–8, HHC, THC-O-acetate, H4CBD, are being made chemically using CBD as a source material. Many of these compounds have not been studied for safety. People consuming them are literally the test case for their safety. And yet they are widely available across all states in gas stations, grocery stores, and online.

Farm bill-compliant cannabinoid hemp products can also contain far more delta–9 THC than is legal in state-regulated marijuana markets, and yet still be under the 0.3 percent delta–9 THC threshold. They can contain high levels of THCA, which readily converts to delta–9 THC when heated in products. And products marketed as full-spectrum or whole-plant CBD that contain all of the compounds found in the hemp plant can also have enough delta–9 THC to be intoxicating.

Hemp and marijuana come from the same plant and have the same compounds. Whether delta–9 THC comes from what we call hemp or marijuana, it works the same in the body, yet the Federal legality of it differs based on the source.

The Farm Bill did not create a Federal regulatory structure to adequately protect consumers. Cannabinoid hemp products are sold to anyone, anywhere, without any standards or Federal regulations. These products, whether intoxicating or not, have no required testing for contaminants, pesticides, heavy metals. They are not regulated federally for ingredients or additives, particularly those that could be harmful when smoked or vaped. They have no required packaging and labeling to tell consumers what is in the product and whether they are intoxicating. There are no Federal restrictions on products that mimic commercial food and candy, and kids can access intoxicating hemp products because there are no Federal age restrictions.

This is in stark contrast to state-regulated marijuana markets, which are highly regulated for consumer safety and youth prevention. s have seen a range of public health and safety issues directly linked to intoxicating cannabinoid products, including accidental ingestion by young kids resulting in hospitalization, overconsumption by teenagers resulting in hospitalization, and unexpected impairment by adults who thought they were purchasing something nonintoxicating.

With no Federal regulation in place, state legislatures are enacting policies state by state. Policy differs, but, increasingly, states are bringing intoxicating hemp products under the purview of the marijuana regulator, where the same cannabinoids, but derived from marijuana, are being regulated. Without Federal minimum standards, we are creating a patchwork of regulation that creates consumer safety and market challenges and leaves regulatory gaps that cannot be covered by states alone, including in online markets and through interstate commerce.

As an association of state regulators, CANNRA is not encouraging the recriminalization of cannabinoid hemp products but, rather, comprehensive regulation that protects consumers and public health across a range of available products.

We have an opportunity to learn from the approaches that states have taken to set thoughtful and comprehensive Federal regulatory policy. A Federal regulatory agency with a focus on public health and safety, like FDA, needs to be authorized and funded with a specific timeframe in which to implement a regulatory framework for these products.

And that framework cannot just focus on CBD. It must contend with the breadth of hemp-derived cannabinoids we see on the market today, both intoxicating and non, and it must account for those products we do not yet know about. It must consider the many ways cannabinoid hemp products are consumed: as foods, as beverages, vaped products, smoked products. It must also require contaminant testing and compliance and enforcement. These essential components of a regulatory framework for cannabinoid hemp extend beyond traditional food and dietary supplement pathways.

These issues are far more nuanced and detailed than what I have been able to cover with you in these opening remarks. My written testimony provides additional information.

I would encourage all of you to reach out to CANNRA, to connect with your state cannabis or hemp regulator, to hear firsthand from

them what this issue looks like on the ground in your state, in your jurisdiction.

Thank you for your time and attention, and thank you for including a regulatory perspective on this hearing about regulation. I welcome your questions today and your continued engagement moving forward.

Mrs. MCCLAIN. Thank you—thank you, Dr. Schauer.

The Chair now recognizes Chairman Comer for questions, 5 minutes.

Mr. COMER. Thank you, Madam Chair.

Mr. Miller, hemp products, including CBD, were removed from Schedule I status in the 2018 Farm Bill. Is that correct?

Mr. MILLER. Yes.

Mr. COMER. Since the 2018 Farm Bill, have private companies attempted to enter the market with hemp and CBD products for the American people?

Mr. MILLER. Absolutely.

Mr. COMER. Do you have any data on the size of the CBD market?

Mr. MILLER. There is—there is considerable data in my written testimony that—that——

Mr. COMER. OK.

Mr. MILLER. [continuing]. We have shared with the Committee.

Mr. COMER. The FDA has not regulated hemp-derived products, including CBD, in the 5 years since the 2018 Farm Bill was passed. Has the FDA's lack of action impacted the hemp industry?

Mr. MILLER. Yes. No. As I mentioned earlier, the lack of action has cast a shadow over the industry. There have been—it has kept a lot of big box stores from carrying products that they otherwise would. It has kept a lot of big food and beverage companies from adding CBD to their mixes. And as a result, there was a decrease in demand when the supply went way up. And as you have seen, economics 101, by the chart I shared earlier——

Mr. COMER. Uh-huh.

Mr. MILLER [continuing]. The prices collapsed——

Mr. COMER. Yes.

Mr. MILLER [continuing]. And the farmers are bearing the burden.

Mr. COMER. That is right. It has affected farmers too.

Mr. MILLER. The farmers, worst of all.

Mr. COMER. In a bad way.

Mr. MILLER. Yes.

Mr. COMER. So, Dr. Henderson, you are the lead toxicologist at three published scientific papers analyzing data from studies of CBD isolate. Is that correct?

Ms. HENDERSON. Yes, that is correct.

Mr. COMER. Your studies were designed to determine the levels of CBD at which you would observe adverse effects?

Ms. HENDERSON. That is correct. Yes.

Mr. COMER. In addition to your research, are you also aware of other scientific studies on CBD that would be available to FDA regulators?

Ms. HENDERSON. Yes, I am. Data on CBD specifically are plentiful. CBD has been evaluated as a drug, as we know—Epidiolex—

and so FDA has access to the clinical and nonclinical data packages submitted as part of that review.

It is also my understanding that FDA has commissioned and has been conducting their own targeted safety studies on CBD. There are other human clinical trials outside of Epidiolex, with other CBD formulations, across a wide range of populations. And in addition to our studies, there are other studies that have been conducted by stakeholders that are not published yet. And then there are other preclinical safety related studies that are published.

So, there are a lot of data that we typically do not have access to when reviewing an ingredient as a dietary supplement.

Mr. COMER. All right. So, Mr. Miller, given the availability of scientific data related to CBD, would you agree that the FDA is not doing its job here by saying there is not enough data to proceed?

Mr. MILLER. Correct. They—there is enough data to pursue a regulatory pathway for dietary supplements and food and beverage additives.

Mr. COMER. So, has the FDA at least been transparent with stakeholders as to what it needs to move forward with regulating CBD? And, if not, how so?

Mr. MILLER. Well, as I mentioned in my testimony, we do not think a new regulatory pathway is needed, but we would be happy to entertain or—so even support additional regulatory safeguards above what is currently under law. But the FDA has not specified those in a way that has allowed Members of Congress to draft legislation to accommodate that.

Mr. COMER. All right. Mr. Badaracco, I am very concerned with—that without FDA regulations, products mislabeled as CBD that are adulterated with other substances will continue to be available and potentially present a danger to the public and even children.

Can you describe some of what you are hearing in the law enforcement community about the dangers consumers may face?

Mr. BADARACCO. Well, I have—when I knew that I was testifying at this hearing, I had caused a solicitation email out to the members of KNOA, which is 400 members within the state of Kentucky, to give firsthand or anecdotal reports of these intoxicants being ingested by middle school children or high school children and what the adverse—what the adverse—what the adverse, if I will, results were.

Mr. COMER. Right, right.

Mr. BADARACCO. And it—I am continuing to get reports from across the state——

Mr. COMER. Right.

Mr. BADARACCO [continuing]. From—I know in far eastern Kentucky, there is a police department, there has been so many of these instances——

Mr. COMER. Uh-huh.

Mr. BADARACCO [continuing]. That that is their No. 1 priority——

Mr. COMER. Right.

Mr. BADARACCO [continuing]. With these substances.

Mr. COMER. Right.

Mr. BADARACCO. I have got two physicians from two hospital ERs. I have not talked to them yet, but they want to talk to me——

Mr. COMER. OK.

Mr. MILLER [continuing]. As well as far as what they are seeing.

Mr. COMER. Yes. So, it is a huge problem. We see that everywhere. We have seen that in other products that claim to contain CBD, and there is no regulatory body to regulate that. And very seldom do I, as a typical Republican, advocate for regulations, but what you have in the hemp industry, you have a lot of credible actors that are doing the right thing, and then there are a lot of bad actors.

And when I say it needs to be regulated like a nutraceutical or the vitamins or things like that, you go in, and the bottle of supplements—let us use as an example—it says how many milligrams of this and what is in the supplement. The FDA, to make sure that what the label advertises is what actual—what the actual product is that the consumer gets.

And that is what we are asking for here. Right now, there is no one to determine whether or not someone selling CBD is being factual when they advertise what is on the bottle, and that is a threat, not just to the industry, but to consumers as well.

So, hopefully, the FDA will do that.

Madam Chair, thank you, and I yield back.

Ms. PORTER. Madam Chair, I would like to enter into the record a letter from the American Trade Association for Cannabis and Hemp and a report titled, "Toward Normalized Cannabinoid Regulation."

Mrs. MCCLAIN. Without objection.

Mrs. MCCLAIN. The Chair now recognizes Ms. Lee for 5 minutes.

Ms. LEE. Thank you, Madam Chairwoman. I literally was about to get up and go to vote, so I appreciate being called on.

So, yes, we are here today because the Food and Drug Administration has committed to using science and data as a basis for making policy decisions to protect public health and safety. FDA has publicly and repeatedly stated that it had a roster of important questions about hemp-derived products that needed answers before it could regulate these products.

They have questions about how much hemp-derived product an individual could safely consume in a day, whether this amount varies depending on the form taken, potential negative interactions with other drugs or substances, effects on special populations like children or the elderly, and the risk of long-term exposure.

To be clear, I am glad we have extended hemp and CBD into our marketplace. However, anecdotal evidence and marketing claims are not the same as rigorous scientific research.

Dr. Schauer, what is the problem with using online calculators or trusting product manufacturers regarding an appropriate dose of CBD?

Ms. SCHAUER. Well, I think state hemp and cannabis regulators would tell you that we need academic data, we need nonpartisan data sources, and we need pathways that account for what we are seeing in the field. So, we are not just seeing dietary supplements in the field. We are seeing inhalables and combustible products as well. We need data on those products. Those products do not fit neatly into a regulatory pathway that FDA currently has and need to be studied.

These novel cannabinoids that are coming out as well, being converted from CBD, we need data to understand those. And, increasingly, very few products are just CBD. The products contain CBD and many other cannabinoids. We need to understand how those cannabinoids interact, what their effects are on humans. And we need not to be using humans as the test case for that. We really do need science to create thoughtful regulation.

Ms. LEE. So, would regulating industry through the existing food and dietary supplemental regulatory pathway address these concerns with the safety of CBD products? Yes or no?

Ms. SCHAUER. I do not believe that it will. If I can take a second, there are three main reasons, I think, for that. One is we have inhalable and combusted products that do not fit into a food or dietary supplement pathway.

Two, dietary supplements usually follow GMP practices. Every state is trying to use testing. We really need to know what contaminants are in the products, and that is not a traditional part of the dietary supplement pathway.

And then, finally, we need specific warnings and labeling based on the route of administration, which, again, is not just food or dietary supplement; it includes other pathways.

Ms. LEE. So, the FDA believes it needs additional scientific studies and new authorities to balance consumer access with appropriate safeguards and oversight. This Subcommittee should understand the need for careful oversight, and we should work with the FDA to achieve it.

In addition to protecting public health, we also need to ensure we encourage diversity and inclusion in this growing industry. I have worked hard in this Congress to promote diversity, both in and out of committee hearings. In my role on Science, Space, and Technology Committee, I will be sending a letter to the Chair addressing the need for more diverse witnesses.

Mr. Miller, can you tell us about the purpose of the U.S. Hemp Roundtable's Minority Empowerment Committee?

Mr. MILLER. Yes. As you are all too aware, cannabis has a very sad history when it comes to disparate treatment of people of color, and there has been structural racism that has pervaded Federal farm programs. And so that is why our organization, and I think the industry at large, has really engaged in an effort to promote diversity and equity in our ranks.

Ms. LEE. Thank you. Effective oversight and a dedication to science and evidence are the best way to move forward with hemp and CBD. However, I also want to be sure that we are deliberate in our approach to regulation and do not follow the path of overcriminalization. I am encouraged by the potential benefits of these products and look forward to continuing to learn and work on this issue.

With that, thank you so much, and I yield back.

Mrs. MCCLAIN. Thank you.

Pursuant to the previous order, the Chair declares the Committee in recess, subject to the call of the Chair.

We will plan to reconvene rather quickly right after votes. We just need to go vote, and we will come right back. Thank you.

So, the Committee stands in recess.

[Recess.]

Mrs. MCCLAIN. The Subcommittee on Healthcare and Financial Services will come to order, and we will reconvene.

The Chair now recognizes Mr. Grothman for 5 minutes.

Mr. GROTHMAN. Mr. Miller, if CBD is regulated as a food supplement or additive by the FDA, what would the economic consequences be?

Mr. MILLER. There would be enormous economic consequences. I laid this out in my written testimony, but there are independent studies. The Brightfield Group is one of those economic groups that claim that that difference could be a $5 billion a year difference if these avenues are—these regulatory pathways are made clear.

Mr. GROTHMAN. OK. Other countries like U.K., Australia, have regulated CBD. How is our—and they found it safe. How is our market different than theirs?

Mr. MILLER. It is not at all different. I think that we can look at Australia and Great Britain and Canada for good examples of how CBD could be regulated.

Mr. GROTHMAN. OK. What do you think we should do with CBD in this year's farm bill?

Mr. MILLER. I would love to see the legislation like 1628, 1629 attached to this year's farm bill. I understand that there are jurisdictional issues with the House Agriculture Committee, but I am hopeful that those can be resolved. And perhaps, if it has to be added in conference committee, we would be very supportive.

Mr. GROTHMAN. OK. What percentage of hemp farming is dedicated to CBD and other extracts?

Mr. MILLER. It used to be about 90 percent. That was the last study I have seen. That was a couple years ago. I do think it has declined a bit. There has been a growth in the fiber side, but it certainly is still an overwhelming part of the hemp industry.

Mr. GROTHMAN. OK. So, we do not know. It has probably dropped, though?

Mr. MILLER. Yes.

Mr. GROTHMAN. OK. What does action look like from Congress so that we do not interfere with the FDA's authority?

Mr. MILLER. Pass H.R. 1628, 1629. Congressman, you have been a strong supporter of both of those bills in the last Congress as well. We really appreciate that. But if we are able to affirmatively direct FDA to regulate CBD as a dietary supplement and food beverage additive, even if we are going to add additional regulatory oversight on top of that, we are open to that as well.

Mr. GROTHMAN. OK. Mr. Badaracco, in your estimate, is it legal to ship delta–8 THC products derived from CBD across state lines?

Mr. BADARACCO. It really depends on the state, I think, and it is kind of a mixed bag, if you will, between——

Mr. GROTHMAN. There is not a norm you can cite?

Mr. BADARACCO. I am sorry?

Mr. GROTHMAN. There is not a norm that you can cite?

Mr. BADARACCO. No. No. I mean, you have states that decriminalized marijuana. You have states that have criminalized delta–8 products. You have states that have medicinal only, states that have recreational and medicinal. So, it is really a mixed bag across the country.

Mr. GROTHMAN. OK. Can it be ordered on the internet?

Mr. BADARACCO. Yes.

Mr. GROTHMAN. OK. Why do you think some companies feel that they can do this?

Mr. BADARACCO. You know, it is without regulation—I mean, there is two ways, and they are using the 2018 hemp bill to do this. You know, I think it was an unintended consequence, because they can extract—CBD and hemp is infinitesimal. I mean, it is less—1 percent or even less. But there is plentiful CBD in hemp, so they will extract the CBD, chemically convert it into delta–8 THC, and then use that to make a variety of retail products, whether that be hemp flowers and they treat it with delta–8 for smoking, capsules, ingestibles which is candy, brownies, other ingestibles.

Mr. GROTHMAN. Does anybody have the idea of the size of this so-called problem or problem?

Mr. BADARACCO. I can only speak anecdotally from the response I am getting from the memberships from the Kentucky Narcotic Officers Association. I am getting more and more firsthand, as well as anecdotal reports of these substances being consumed by middle school and high school kids and having adverse reaction. I am also——

Mr. GROTHMAN. You think they are ordering it on the internet?

Mr. BADARACCO. I am sorry?

Mr. GROTHMAN. You think they are ordering it on the internet?

Mr. BADARACCO. We do not know. We do not—we really do not know. There are ongoing investigations concerning that, but at this point, I do not know.

Mr. GROTHMAN. Mr. Miller, are there any hard numbers on this you know?

Mr. MILLER. No. It has been gathered on a state-by-state basis, but it is clear that kids have been getting it. Vape stores, convenience stores, those are other places where you will find that kind of commerce.

Mr. GROTHMAN. OK. Thank you.

Mrs. MCCLAIN. Thank you, Mr. Grothman.

The Chair now recognizes the gentlelady from North Carolina, Dr. Foxx.

Ms. FOXX. Thank you, Madam Chairwoman.

And I will follow up on Mr. Grothman's comments. Mr. Badaracco, what are the dangers of problems associated with consuming CBD products that may contain widely varying levels of intoxicants?

Mr. BADARACCO. I mean, with children having to go to the emergency room—which there is reports that I referenced to that we are starting to get now—it can add to agitation, increased heart rate, nauseous, unconsciousness, things of that nature. There was a report just yesterday from Covington, Kentucky, of a 10-year-old, I think was the age of the individual, who bought a gummy bear which turned out to be a THC delta–8 gummy bear treated, and it had 10 dosages in it. And the child consumed it and, of course, went to the ER and was experiencing many of those symptoms that I had just described. And I am finding this across the state.

Ms. FOXX. I was going to follow up about children, so thank you for covering that in your answer.

Why doesn't the Drug Enforcement Agency go after intoxicating CBD products that are synthesized from legally grown hemp?

Mr. BADARACCO. Well, I think it is—you are seeing kind of a mixed bag from the court system. I know the Ninth Circuit said that delta–8 is the derivative of hemp, so therefore it is illegal. A Kentucky court has also expressed that opinion as well, legalizing delta–8 in the state of Kentucky. But it is—other than that, there is really no direction or regulatory framework to use, because under 2018—the Farm Bill under 2018 where it is a derivative of hemp, it is being treated as legal.

Ms. FOXX. So, can the average person tell with any confidence if a CBD product contains intoxicants?

Mr. BADARACCO. Not really, no. Not right now. Not without having a specific labeling of what exactly is in the substances. Part of the—how should I say? You know, part of the chemical process, you know, CBD is in large quantities from the hemp plant, and it is extracted chemically to make delta–8 THC. And they use syrup—many, many manufacturers will use solvents to make that conversion and acids to convert it as well.

Ms. FOXX. Thank you.

Mr. Miller, we know the FDA has not been regulating hemp-derived products, but has the FDA engaged in any meaningful enforcement?

Mr. MILLER. No. The only enforcement actions they have taken so far are sending warning letters. Most of those warning letters have been to companies that have been making outrageous medical claims, like this CBD is going to cure cancer or it is going to cure COVID. But to date, they have not been seizing anything off the shelves or taken any other more direct enforcement action.

Ms. FOXX. Mr. Miller, do you believe that delta–8 THC and other compounds derived from CBD that can be intoxicants are legal to produce and sell under Federal law?

Mr. MILLER. You know, it is still an open question, but as Rich mentioned earlier, the Ninth Circuit has weighed in and says that they are legal. A number of state courts have said the same thing. However, in certain states, we have seen them be declared illegal. New York is one of those, for example. So, it is really a mixed bag and really a reason why FDA—we need to have a Federal approach. And as we argue, let us not ban them, let us not criminalize them, but let us strictly regulate them and keep these intoxicating compounds out of the hands of children.

Ms. FOXX. So, mention was made already of the 2018 Farm Bill. With the passage of that bill, did Congress intend to allow for the sale of intoxicants?

Mr. MILLER. You know, when we were lobbying up on the Hill for the 2018 Farm Bill, in 2014, for that matter, we said hemp is not marijuana. Hemp is not intoxicating. And so, I do not believe that that was the intent of Congress. But the language got written as it was, and this loophole was found. And frankly, as I mentioned earlier, it has really been a lifesaver for many farmers who have struggled because of CBD lack of regulation. We just need to get a hold of it. We need to regulate it. We need to get it out of the hands of kids.

Ms. FOXX. So, do you believe intoxicants should be sold under the farm bill?

Mr. MILLER. I would like to see new legislation that would put intoxicating cannabinoids under a stricter regulatory regime, whether that be at FDA or, potentially, the TTB is another possibility. But we look to Congress to try to make sure that they are regulated in a way that will help keep them away from kids.

Ms. FOXX. Thank you. And thank you, Madam Chair.

Mrs. MCCLAIN. Thank you.

I recognize myself for 5 minutes.

Thank you all again for being here. I really appreciate it.

I want to understand a little bit about regulation. Am I assuming, Mr. Miller, without regulation from the FDA right now, is there any way for the average consumer to verify the ingredients?

Mr. MILLER. As both Rich and I mentioned in our testimony, there is a self-regulating organization called the U.S. Hemp Authority that provides a certificate for manufacturers who go through an intensive process of good manufacturing practices, truth in labeling, and they put on the label——

Mrs. MCCLAIN. So, as consumers, we should look for that, so that would be——

Mr. MILLER. Yes, I would look for the U.S. Hemp Authority label. Some states have also stepped into the breach and have come up with good regulatory structure.

Mrs. MCCLAIN. If there is a consequence, meaning I have a CBD product and I say it is X and it is less than X or, unfortunately, more than X, whatever it may be, is there any consequence to my action if I falsify what is in the ingredients?

Mr. MILLER. In some states, there is some regulatory ability to do that, but the vast majority of products, there is no enforcement.

Mrs. MCCLAIN. Not real enforcement, so to speak?

Mr. MILLER. No.

Mrs. MCCLAIN. OK. I am curious how this has affected the private sector's ability to participate in marketing a product that was legalized in the 2018 Farm Bill.

Mr. MILLER. I mean, it has devastated our industry, and it has imposed tremendous burdens because of this lack of regulatory authority.

Mrs. MCCLAIN. Hence, you showed us that slide at the very beginning of the opening.

Mr. MILLER. Right.

Mrs. MCCLAIN. The only one I think you said that was profitable was the flower?

Mr. MILLER. Yes. The flower that is converted into delta–8 THC, which we mentioned——

Mrs. MCCLAIN. And that is very dangerous, right?

Mr. MILLER. It can be dangerous. Certainly, if it is manufactured improperly and if it is sold to children.

Mrs. MCCLAIN. And there is no regulation on that as of current?

Mr. MILLER. No. No, regulation at all.

Mrs. MCCLAIN. OK. Has the FDA been receptive to efforts from private sectors to have their products regulated?

Mr. MILLER. No. The FDA meets with us—the industry about once a year. They are always listening sessions, so we do the talking and they do the listening.

Mrs. MCCLAIN. So, just to be clear, this is private industry petitioning for more regulation?

Mr. MILLER. Yes.

Mrs. MCCLAIN. I mean, that is like cats and dogs living together.

Mr. MILLER. I know. We are begging. We are begging.

Mrs. MCCLAIN. OK. Can you explain why regulations in this instance would not help industry? If we did not regulate it, would it help industry?

Mr. MILLER. No, no. Regulation will help industry because it would help stabilize the markets. These big box stores and big food companies would start carrying their products, the prices would go up, and it would give consumers a lot more confidence that these products are safe. Right now, they are taking a risk in buying them. So, regulation would be really good for business, which——

Mrs. MCCLAIN. OK. So, it is good for business. It helps protect children. It was instituted in the 2018 Farm Bill, yet the FDA has slow-walked, maybe, not even at all, done any sort of regulation on this?

Mr. MILLER. Yes. They—oh, go ahead.

Mrs. MCCLAIN. Correct?

Mr. MILLER. Correct.

Mrs. MCCLAIN. I just find that ironic that we give this agency money, authority, and they cannot do their job. I would love to come into work and say, you know what, if you just paid me a little bit more, I will go to a few more hearings, I will take a few more votes. It just does not work like that, right? I am sure the average American would love to do that.

Do the job you were signed up to do. I mean, I am almost on the opposite. I think we should start rescinding dollars until people actually start doing the job they signed up to do, and stop with the excuses. It drives me crazy.

I often wonder, Mr. Miller, I am just curious, it is my understanding, and I could be wrong, that the FDA has not returned to its pre-pandemic telework policy. Is that correct?

Mr. MILLER. I am unaware of their policies.

Mrs. MCCLAIN. Anybody have any data on that?

The data I show is they have not returned back to work a hundred percent.

Do you believe that the failure to work in person may be contributing to this?

Mr. MILLER. Yes, I would not comment because this has been a running problem since before the pandemic hit.

Mrs. MCCLAIN. Yes. Perhaps if we just went back to work, we would have more hours in the day to do the job that we signed up to do.

What are the concrete steps that the FDA can immediately do to engage—to take this more seriously? If you could have a wish list, what could the FDA do right now?

Mr. MILLER. Well, the first thing is they could immediately start regulating these products as dietary supplements and food and beverage additives.

Mrs. MCCLAIN. And they have the authority to do that?

Mr. MILLER. We believe they have the authority to do that.

Mrs. MCCLAIN. I do too.

Mr. MILLER. Now, they would like to have an additional set of regulations on top of those, and we are not opposed to that. And so, the next best thing they can do is to define, very specifically, what that regulatory structure would look like, so to aid Congress in developing a regulatory regime.

Mrs. MCCLAIN. Very good. Thank you, again. And I thank each of you for being here today. I appreciate your insightful testimony and expertise. Unfortunately, the government bureaucracy appears to have gotten in the way of the American hemp industry and consumer safety, the actual opposite of what they were supposed to do.

To be clear, the industry wants regulation to inject certainty into the market so good-faith businesses can prosper and deliver high demand products to consumers. And we want this opportunity to happen right here in the United s to benefit growers and everyone else up and down the supply chain, all the way to the end of consumers who consume the hemp product. It is interesting to note that, even though the FDA has not approved CBD products as dietary supplements or food additives 5 years after the passage of the 2018 Farm Bill.

Mr. Miller, as he indicated in his testimony, the FDA also has not engaged really in any meaningful enforcement actions either. Again, wouldn't it be nice to just pick and choose what you get to do every day? I would love that, just love it.

The FDA has not always been transparent or consistent in their decision-making with the hemp industry either, and that is unfortunate. And although FDA claims to have the available safety data, it is limited. The fact is, is that there is data available to regulators to actually make informed decisions about labeling requirements, dosages, and other measures necessary to actually ensure public safety.

There is rigorous scientific process that goes into the toxicology testing and research that scientists like Dr. Henderson and others have conducted. On top of that, the research is peer-reviewed before it is published. FDA has research data available to them to make appropriate decisions under their existing authorities.

We have also heard from law enforcement professionals with years of experience, like Mr. Badaracco, about the difficulties consumers face in an unregulated market. Lack of FDA action has left a market where dangers lurk for consumers who may receive products altered with unlabeled substances or with wildly inconsistent dosages.

And finally, Dr. Schauer enlightened us as to how it is likely just the first step for the FDA. CBD is just one of many derivatives of the cannabis plant, and the public needs the FDA not to just start doing its job with respect to CBD, but continue to be engaged in this emerging market for the benefit of industry and consumers alike.

The pathway already exists. Congress spoke in 2018. The FDA just needs to do the job that the American taxpayer is paying them for. And if they cannot do their job, maybe we should stop funding

them or funding them at reduced levels. Again, the pathway already exists.

Once again, I truly want to thank you all for being here today.

And with that, without objection, all Members will have 5 legislative days within which to submit materials, to submit additional written questions for the witnesses which will be forwarded to the witnesses for their responses.

If there is no further business, without objection, the Subcommittee stands adjourned. And again, thank you, and have a nice recess.

[Whereupon, at 3:50 p.m., the Subcommittee was adjourned.]