OVERSIGHT OF THE U.S. FOOD AND DRUG ADMINISTRATION

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY U.S. HOUSE OF REPRESENTATIVES

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OVERSIGHT OF THE U.S. FOOD AND DRUG ADMINISTRATION

Thursday, April 11, 2024

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
Washington, D.C.

The Committee met, pursuant to notice, at 1:07 p.m., in room 2154, Rayburn House Office Building, Hon. James Comer (Chairman of the Committee) presiding.

Present: Representatives Comer, Gosar, Foxx, Grothman, Cloud, Palmer, Higgins, Sessions, Biggs, Mace, LaTurner, Fallon, Donalds, Perry, Timmons, Burchett, McClain, Fry, Luna, Langworthy, Burlison, Waltz, Raskin, Norton, Lynch, Connolly, Krishnamoorthi, Khanna, Mfume, Porter, Bush, Brown, Stansbury, Garcia, Frost, Lee, Crockett, Moskowitz, Tlaib, and Pressley.

Chairman COMER. The Committee on Oversight and Accountability will come to order. I want to welcome everyone here today.

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

Alright. I will recognize myself now for an opening statement.

Again, welcome to the Committee on Oversight. We want to thank Commissioner Califf for his participation in today's oversight hearing of the U.S. Food and Drug Administration. There might not be a Federal agency that is more integral to Americans' day-to-day lives than the FDA. FDA is charged with regulatory oversight of the food and drug industries, industries that ensure Americans have food on the table by innovating safer and more stable crops, industries that provide Americans new medications to treat diseases, industries that create cutting-edge medical devices that can keep your heart pumping or replace a knee. These industries are vital to keep Americans safe, healthy, and happy. These industries provide millions of jobs and nearly $3 trillion in economic value.

Unfortunately, the FDA under President Biden is suffering from dysfunction and is failing to do bare minimum to carry out its core mission, which is to make certain our Nation's food and drug products are safe and effective. Further, the FDA appears consistently unprepared for certain crises. That is why our Committee has conducted several investigations into areas of concern at the FDA. These investigations have identified a pattern of issues within the FDA.

At the beginning of Congress, Subcommittee Chairwoman McClain launched an investigation into the infant formula crisis.

Her Subcommittee revealed how the FDA attempted to hide behind the COVID–19 pandemic as an excuse for neglecting facility inspections and justifying poor performance. The FDA's telework policies and lax approach to oversight left it unprepared to address the shortages when Abbott's facility in Sturgis, Michigan was shut down. Additionally, the Biden White House and the FDA took 3 months to act to increase production of infant formula. The result of these failures? Barren shelves, leaving millions of young families unable to access the formula needed to feed their babies.

We have also investigated the FDA's failure to prepare for and adequately respond to drug shortages for essential medications used to treat infection, heart disease, and cancer, just to name a few examples. FDA and Democratic policies, such as the Inflation Reduction Act, have dramatically diminished the profitability of manufacturing generic medications. This has resulted in fewer manufacturers and a greater risk of shortage. The FDA must improve coordination with manufacturers and Federal agencies, including DEA, DOJ, and DOD, to increase production. The FDA has failed to incentivize domestic manufacturing of pharmaceuticals, resulting in significant offshoring of these facilities. We conducted oversight of the FDA's failure to return to pre-pandemic levels of inspections of those manufacturing facilities for prescription drugs abroad. Inspections of foreign manufacturing facilities were 79 percent lower in 2022 than 2019. Last year alone, this failure resulted in two separate recalls of eye drops manufactured in India that caused an outbreak of dangerous drug-resistant bacteria, killing four people.

Through our investigation of tobacco products regulations, we learned the FDA is failing to consistently and effectively regulate tobacco products. According to the Reagan-Udall Foundation, the FDA has been reactive and overwhelmed in its tobacco products regulation. The FDA has delayed review of applications for products that can reduce harm for many Americans. Further, the FDA's failure to regulate has allowed unsafe and illicit products to proliferate. In fact, the United States Court of Appeals for the Fifth Circuit slammed the FDA for sending manufacturers of flavored e-cigarette products on a wild goose chase. Meanwhile, the FDA is also failing to prevent illicit-flavored tobacco products from China entering the country and harming Americans. The FDA is not implementing enforcement actions to address illicit-flavored tobacco products in stores across the country.

Additionally, the Committee examined the FDA's refusal to regulate hemp-derived products, such as CBD. Instead of using its existing authority, the FDA is requesting new authorities and money that it does not need. This is the FDA putting its own bureaucratic priorities over the American people who can benefit from these products. The FDA's refusal to regulate hemp products is creating a significant confusion in the market and resulting in products with intoxicants that can be dangerous to Americans who use these products. It has also halted businesses trying, in good faith, to enter the market while bad actors continue to thrive. Finally, we found that the FDA ignored decades of research regarding the ineffectiveness of an over-the-counter decongestant causing Americans

to waste their hard-earned money on a medication that is simply ineffective.

These examples are just scratching the surface of the dysfunction and failures that are ongoing within the FDA. Today, I am hopeful we can take a deep dive to better understand how the FDA is responding and taking action to ensure a safe food and drug supply. I now yield to Ranking Member Raskin for his opening statement.

Mr. RASKIN. Thank you very much, Mr. Chairman, and thank you to Commissioner, Dr. Califf, for being with us here today.

The FDA regulates everything from bottled water to infant formula, meat, poultry, and egg products, prescription and non-prescription drugs, vaccines, medical devices, microwaves, personal care products, and tobacco. During the Biden-Harris administration, the FDA has made critical progress to ensure that we have access to safer food and to effective drugs.

For example, last fall, FDA acted quickly to investigate reports of lead appearing in children's cinnamon applesauce packets for their school lunch. The cinnamon was adulterated with lead, which was added by the manufacturer in order to increase the weight of the product to make it more profitable in the process. However, the applesauce contamination issue could have been completely prevented if end-product inspections for food were required. The FDA asked Congress to amend the Food, Drug, and Cosmetic Act as part of the Fiscal Year 2024 budget request to require that industry conduct testing of final products exactly for such contaminants and provide FDA immediate access to those results. This would greatly help to ensure the safety of all of our food products for kids and for everyone else, but the FDA needs these additional authorities to make that happen. And, Mr. Chairman, I was very pleased to hear your opening comments, and I hope you would join me in supporting giving the FDA additional regulatory authority, precisely to address the kinds of problems that both you and I have identified. The FDA itself has proposed multiple solutions that would address the problems we are talking about today. The Democrats support greater and more refined regulatory authority to make our food and drugs safer and we hope our colleagues will join us.

In the wake of infant formula and prescription drug shortages, FDA also advanced legislative proposals earlier this year to strengthen notification requirements and data sharing. Right now, they do not have any authority to tell drug manufacturers to produce more drugs. One proposal they have offered would require manufacturers to notify the FDA—dealing with this first problem of the applesauce—would require manufacturers to notify FDA about pathogens that are discovered in certain critical foods. In the case of infant formula, this authority would help FDA prevent contaminated infant formula from reaching any more consumers and babies. A second proposal they have suggested would expand FDA's authority to gather data from industry about potential drug shortages and supply chain disruptions.

FDA has improved access to contraception and protections for medication abortion access. In 2021, FDA advanced the accessibility of medication abortion by removing the in-person dispensing requirement for mifepristone and allowing it to be distributed by mail through retail pharmacies. In July 2023, FDA approved the

first over-the-counter birth control pill, Opill. As a result, consumers' access to contraception has improved at a critical time when many states are enacting increasingly draconian and oppressive abortion restrictions.

FDA has also made advancements to combat a range of life-threatening diseases. In March of last year, FDA approved the first OTC opioid overdose reversal medication, naloxone nasal spray, a critical step toward reducing opioid overdose deaths in our districts. FDA also recently approved new genome editing technologies to treat sickle cell anemia, a disease that has ravaged a lot of communities, primarily African-Americans. This advancement is a crucial step toward treating sickle cell anemia and represents a breakthrough in gene therapy. FDA also secured additional supply chains in the wake of cancer drug shortages.

It is crucial that FDA continue to carry out its mission and create meaningful regulations based on sound science and not conspiracy theories or ideological programs. Public attacks on FDA without any corresponding legislative solutions simply undermine its ability to effectively protect public health.

Anti-abortion activists brought a case against FDA over its updated guidance on mifepristone, the first of a two-pill medication abortion. The activists claim that FDA did not properly collect data on drug risks and complications. However, this claim is contrary to the FDA's review of "extensive research showing that mifepristone is safe, including to take it home." FDA followed its standard procedure in reaching that conclusion, and according to FDA, it must act reasonably based on the information available rather than act based on perfect data which seldom exists. If the objective of anti-abortion activists is to undermine FDA's authority, the consequences will be devastating to public health. An FDA that bases its decisions on political science rather than actual science is not in the best interest of consumers.

Congress must ensure that FDA is empowered to rely on the facts rather than bend to the will of people pushing an ideological agenda. Thank you, Mr. Chairman, and I yield back.

Chairman COMER. The gentleman yields back. Now pursuant to Committee Rule 9(g), the witness will please stand and raise his right hand.

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

Dr. CALIFF. I do.

Chairman COMER. Let the record show the witness answered in the affirmative.

We appreciate you being here today and look forward to your testimony. Now, let me remind the witness, who I am pretty sure you are an old pro at this by now, we have read your written statement, and it will appear in full in the hearing record. Please limit your oral statements to 5 minutes. As a reminder, press the button on the microphone in front of you, so that it is on and that 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 that you please wrap up.

I now recognize Commissioner Califf to please begin his opening statement. Dr. Califf?

STATEMENT OF DR. ROBERT CALIFF, M.D., MACC
COMMISSIONER OF FOOD AND DRUGS
U.S. FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. CALIFF. Thank you, Chair Comer, Ranking Member Raskin, and members of the Committee. Thanks for the opportunity to testify about the Food and Drug Administration's work to protect and promote public health.

In the United States, the safety of medical, food, and cosmetic products depends on the actions of both industry and the FDA. Industry bears the responsibility of creating a supply of medical, food, and cosmetic products that are safe and protect and promote public health. FDA guides an overseas industry to help ensure that Americans can have a confidence about the medical, food, and cosmetic products they are using and that they are duly warned about the risks of tobacco products. From that lens, I would like to focus on the Agency's work in four main areas today: first, addressing vulnerabilities in the supply chain; second, reversing the decline in our national life expectancy; third, accelerating effective treatment for thousands of rare genetic diseases; and fourth, undertaking the most significant reorganization in FDA history with a focus on human foods and improving oversight of all of our regulated industries.

As we saw during the pandemic and continue to see, we have a significant global supply chain vulnerability, including lack of redundancy and resiliency and over-reliance on foreign sources for critical products, particularly medicines and devices. Preventing and mitigating supply chain issues in the industries we regulate have been a primary focus. In 2023 alone, we worked with manufacturers to prevent over 230 threatened drug shortages. During the infant formula shortage, FDA's use of temporary enforcement discretion enabled safe products to enter the U.S. market, which increased supply and doubled the number of firms producing infant formula for the U.S. from 2021 to 2022.

FDA's continued oversight will be critical until supply chains are more resilient, particularly for infant formula. We will continue to promote competition in manufacturing quality and implement modernized systems to respond to shortages faster. It is why we have requested additional authorities that would provide more visibility into the supply chain.

The trends in life expectancy and chronic disease in the U.S. are concerning. And while we are leading the world in the creation of new drugs and devices, our major causes of death and disability are driven by fundamentals: tobacco use, poor nutrition, and lack of adherence to inexpensive generic medications. Given the burden of tobacco-related diseases, it is encouraging that over the past year, we have seen a reduction in cigarette smoking in the U.S. and a significant decrease in overall tobacco product use among high school students, primarily driven by a decline in e-cigarette use. Despite these important wins, driven by a combination of education and enforcement actions, our work is not finished. We re-

main committed to reducing the health burden of tobacco product use in the U.S.

Food safety and improved nutrition are essential to combat the epidemic of chronic disease and premature death. A healthier food supply, coupled with improvements in key nutrition information, will help consumers make informed health choices. This includes proposed actions to display simplified, at-a-glance, front-of-package nutrition information, to establish voluntary sodium targets, update the definition of the term "healthy" in advertising, and to create a nutrition center of excellence.

Thanks to Congress' investment in the Human Genome Project decades ago, many of the approximately 10,000 rare diseases which impact at least 30 million Americans can now be treated with new gene editing and gene therapy technologies. We are preparing to navigate a large number of these exciting therapies that will require new clinical trial methods, deep scientific reviewer expertise, and development of reliable long-term follow up systems involving electronic health records for real-world evidence.

Last, the Agency has made significant progress in its proposed reorganization. The proposal aims to unify human foods functions into the new Human Foods Program under the direction of the deputy commissioner for human foods, and to solidify the Office of Regulatory Affairs' role as a front line of FDA's field-based operations. This will enhance our outbreak response and fully realize the preventive vision of the FDA Food Safety Modernization Act. These proposed changes will strengthen the Agency, making it more efficient, nimble, and ready for the future with the ever-changing and complex industry we regulate.

In conclusion, the essential work of the Agency continues in thousands of work streams that Americans and the world count on every day, thanks to the dedication and perseverance of FDA staff. We look forward to continuing to work with Congress on the Agency's mission and thank you for the opportunity to testify.

Chairman COMER. Thank you very much, Commissioner. We will now begin the questioning phase. The Chair recognizes Representative Gosar from Arizona for 5 minutes.

Mr. GOSAR. I thank the Chairman. Now obviously, the FDA made a mistake in granting the Emergency Use Authorization and license of COVID–19 vaccines. It has been confirmed that the vaccines do not stop transmission. Moreover, 1,635,048 injuries due to COVID–19 vaccines have been reported to the Health and Human Services through the Vaccine Adverse Event Reporting System, including 37,382 deaths. Considering that under 10,300 deaths have been reported due to all other vaccines combined, the harm due to COVID–19 vaccines is absolutely staggering, and not to mention that there is no accountability.

Legally, it is impossible to sue COVID–19 vaccine manufacturers for the injuries caused by their products. Just last month, the Federal court forced the FDA to retract tweets and statements for its years-long smear campaign against ivermectin as an effective treatment for COVID–19. Now, let us enter Ozempic. J.P. Morgan predicts the market of Ozempic and similar drugs will exceed $100 billion by 2030. Concerningly, there is a plethora of Federal lawsuits, 18 in all so far, alleging serious side effects from this class of

drugs, also known as glucagon-like peptide–1 receptor agonists, or GLP–1 RAs. Gastroparesis, or simply stomach paralysis, and several severe indigestion, obstruction, and vomiting have been cited in the lawsuits. One woman claimed to have lost teeth from excessive and frequent vomiting. One law firm is investigating the claims of additional 10,000 people potentially harmed by this class of drugs. The plaintiffs predict 20,000 total people will be suing manufacturers of the GLP–1 RAs in the future. The European Medicine Agency is investigating Ozempic for suicidal ideation, according to Forbes. Also, according to Forbes, studies indicate that Ozempic and other GLP–1 RAs, like Rybelsus and Wegovy, may cause gallbladder disease.

Furthermore, a recent study linked Ozempic to thyroid cancer. Ozempic is basically a synthetic hormone that tells your brain that it is full, therefore deactivating digestion, as well as causing the pancreas to increase insulin levels in order to lower blood sugar. Many Ozempic patients face blockages and obstructions. That makes sense as the body is being fooled into stopping that digestive pathway. Does purposely paralyzing the stomach strike you as a healing type of a remedy? It does not to me.

It seems that the goal of Big Pharma is to get people hooked for life on their products, whether it be an annual flu or COVID–19 vaccines, perpetual statins to lower cholesterol, beta blockers for high blood pressure, expensive never-ending cancer treatments, yet all this intervention does not seem to yield much fruit. Chronic disease is skyrocketing. Fifty percent of American adults have a chronic disease. Forty percent have two or more. Are Ozempic and related drugs the next big thing Big Pharma is going to push on millions of people no matter what the harms are or lack of effectiveness?

As the head of the FDA, you should like to take this opportunity to express your regret. As head of the FDA, would you like to take an opportunity to express your regret in failing to curtail the chronic disease epidemic in America?

Dr. CALIFF. I would like to respond. You raised so many issues and I have got a minute and 20 seconds, so I will just start with the vaccine, which I think may be the most important one to talk about. So, here is the progression as I see it. First of all, I am pretty simple. I am from South Carolina, and I am a cardiologist. I am used to looking at life and death and seeing what the differences are. The question with any medical intervention, knowing that all interventions have risks and benefits, and the question is always do the benefits outweigh the risk. I will remind you, the initial vaccine trial that led to the EUA did show a dramatic reduction in the rate of infection in the two groups. The virus then mutated, but the good news is now we have a progression of overwhelming evidence in every country, including the United States.

Mr. GOSAR. So, would you——

Dr. CALIFF. If you are up-to-date on your vaccine——

Mr. GOSAR. I understand this, but——

Dr. CALIFF [continuing]. You are less likely to be dead. You are less likely to be admitted to the intensive care unit. If you live in a county with a higher vaccine rate, the mortality rate is lower. If you live in a country with a higher vaccine rate, the mortality rate

is lower. So, when you compare the two, yes, vaccines have side effects. The risk of being dead is lower if you are vaccinated.

Mr. GOSAR. OK. This is my last question because I am running out of time. Do you not agree that the vaccine should have put into the fund or face liability issues because the people were used as guinea pigs? Do you believe in peer-reviewed science because there is another part that did not get really reviewed very well?

Dr. CALIFF. Well, I will remind you again, we always have to do studies or clinical trials to figure out the risks and the benefits. That is a normal part. In most of my career, I personally participate in clinical trials when I have the chance, so that we can have the data and the knowledge to make wise decisions, for example, and get vaccinated, so we are less likely to be dead.

Mr. GOSAR. I get that, but why did you have to retract everything you said about ivermectin? Because your office came out against ivermectin. Now, I agree that there are some problems in the manufacturing of that dosage, but if in doubt, leave it out.

Dr. CALIFF. Well, we didn't retract everything we had to say about ivermectin, and, in fact, you know, possibly we had an attack against ivermectin. Drugs are not——

Mr. GOSAR. I hope the courts are watching this right now because they ordered you to.

Dr. CALIFF. If you look at the randomized trials of ivermectin, and there are many of them now, there is no benefit of ivermectin in the treatment of COVID. That is a statement, just a fact, and any drug for which there is no benefit in their risk, people have to make their own decisions about what to do. What we are not doing is telling doctors what they have to do. Doctors have the right to prescribe off label.

Chairman COMER. The gentleman's time has expired. The Chair now recognizes the Ranking Member for 5 minutes.

Mr. RASKIN. Mr. Chairman, thank you. I am going to follow up on this because this exchange to me was extremely illuminating because what we have here is the commissioner, who is the head of the Food and Drug Administration, and then we get a drive-by spray of propaganda, disinformation, and ideological attacks. So, let me try to sort some of this out, and maybe it will help to illuminate why we have a Food and Drug Administration rather than leaving it to politicians in state legislatures or in Congress to make decisions based on ideological whim.

But let us start with ivermectin, which I believe is an animal deworming agent that some people were advocating for use to treat COVID–19. Has this been approved as a form of treatment or a cure for COVID–19?

Dr. CALIFF. No, it has not. If I may, I should also point out it also has benefit for humans with worms, which is a huge problem in Asia. So, it actually won a Nobel Prize because it is an amazing drug both for animals and humans who have worms. And there was a good reason to think it may work in the case of COVID, and that is why, thankfully, the community, including the NIH, did a number of randomized clinical trials. There is just no benefit, and you know that is true of most things that we try. There is nothing wrong with thinking it might work. It just didn't.

Mr. RASKIN. Well, what about hydroxychloroquine, which was another thing that was advocated?

Dr. CALIFF. Basically, the same story. There was really exciting preliminary work in the laboratory that said hydroxychloroquine may have activity against COVID, so the randomized trials were done. Unfortunately, no benefit. Again, nothing wrong with thinking it may work and trying it out in a randomized trial, but then we have the data now, so that leads you to the conclusion. So, we have not been able to grant occasion for those.

Mr. RASKIN. Yes. I mean, I am aware of a lot of political attacks and criticism against the FDA, but I can never figure out the coherence of it. Sometimes, they seem to be saying get out of the way and just let anybody advocate whatever they want and use whatever they want without any testing and without the various protocols you go through. And then other times they attack you because you do not have enough authority to do the things that we would want you to do in order to make kids' cinnamon applesauce clean, for example. So, let us take that one, which has caught my eye since we certainly ate a lot of cinnamon applesauce in our house when our kids were little.

Let us see. Your FDA-regulated products are manufactured or handled at something like 275,000 or 280,000 different registered facilities across the land. So, what keeps you from inspecting every private manufacturing facility that produces things like cinnamon applesauce or peanut butter?

Dr. CALIFF. Well, if I may, I will try this very quickly. I think the best way to think about FDA, in general, is that we are referees. You all in Congress actually write the rulebook, much like in any sport. It is the leadership that writes the rulebook. We enact what is in the rulebook. And in the case of food establishments, like most sports, the first line of defense are the players in the game, which is the industry that produces the products, and by and large they do a great job, but sometimes they do not. And as referees, we have to be really wise about where we step in because we do not have an unlimited budget.

So, what keeps us from inspecting all 275,000? You do not have to be a brilliant mathematician to know how many people you would have to have. But what we can do, for example, in food for children is to have the manufacturers be required to do the testing, which is the way the drug system works. The manufacturers of drugs have to test every batch. And in the case of cinnamon applesauce, if there had been mandatory testing when it got imported into the U.S. from Ecuador, the stores that were selling it probably would have picked it up at that point.

Mr. RASKIN. And those kids ended up with lead poisoning, right?

Dr. CALIFF. Right. Lead poisoning is a very serious problem, as you know, and it causes chronic issues.

Mr. RASKIN. So, you advocated mandatory testing. You would like us to give you that regulatory authority?

Dr. CALIFF. Yes.

Mr. RASKIN. And I do hope that is something that our colleagues on the Republican side of the aisle would join us in. In the case of infant formula shortages, last Congress, we passed a bipartisan bill to help address those shortages, but nearly 200 House Repub-

licans voted against a second bill to give FDA resources to strengthen its oversight and inspection of facilities to prevent shortages like that from happening. So, we cannot have it both ways. If we want an effective, strong regulator, we have got to give them the authority and the resources to get the job done. Thank you very much, Mr. Chairman. I yield back.

Chairman COMER. The gentleman yields back. The Chair now recognizes Mr. Grothman from Wisconsin for 5 minutes.

Mr. GROTHMAN. Thank you much. I do not know if this is why you came over here, but we are going to give you another vitamin, another COVID-related topic. Throughout the COVID epidemic, I spoke multiple times on the floor with regard to the value of vitamin D. Now, the adequate level of vitamin D varies depending upon how you talk to, you know, 20 nanograms, 30 nanograms, 50 nanograms, but whatever the study you look at, the number of lives saved if everybody had adequate levels of vitamin D is tremendous, OK? It is a relatively cheap vitamin, but for whatever reason it was not pushed by the medical establishment and resulted, in my opinion, in the deaths of hundreds of thousands of people. I mean, even the most moderate studies, I would say, would say that you were less than half as likely to die of COVID if you had adequate levels of vitamin D, and if you get up to around 50 nanograms, you have a very, very small population dying.

Oh, by the way, another thing bothers me. If you went in for a medical checkup during that time, they would not even test you for vitamin D, which is not all that expensive because you get blood tests for other things you are doing. Could you comment on the lack of emphasis of the benefits of vitamin D, given that the evidence appears overwhelmingly helpful and very cheap, the lack of emphasis from the public health establishment on having vitamin D?

Dr. CALIFF. Well, as I have already said, you know, as FDA, this is really not in our domain. The vitamin D is available on the market. We do not regulate the practice of medicine. That is determined by the medical profession, and other agencies may have more to say about that. But I would point out one key thing about vitamin D, just very basic in my role as a person who has done clinical trials all my life. There are many diseases for which if you measure vitamin D levels, the higher the vitamin D level, the lower the risk of the disease. But it turns out when randomized trials have been done, where you take equal people and give some vitamin D and others placebo, for most diseases, it turns out there is no difference, and that is because people with higher levels of vitamin D are different in many other ways. They tend to be healthier and spend more time in the sunshine and all sorts of other things that are different. And the randomized trials so far, and COVID, to the best of my knowledge have not been positive, but, again, I want to make the point. This is not something FDA regulates. It is a dietary supplement, basically a vitamin. It is on the market, it is freely available in your local store, and that is between the doctor and the patient.

Mr. GROTHMAN. I would like to submit a couple of columns here, and I will yield the remainder of my time to the Chairman.

Chairman COMER. Without objection, so ordered.

Chairman COMER. He yields me time. So Commissioner, I want to ask this question about tobacco. With tobacco and FDA's Center for Tobacco Products, I think it is safe to say the current regulatory process at the CTP is not at all what Congress envisioned when it passed the Tobacco Control Act 15 years ago. From the Reagan-Udall Foundation report you commissioned and recent court rulings, I have to conclude that those seeking to play by the rules do not even know what the rules are because FDA will not tell them or FDA will not put information out, or they will put information out and then change it.

So now, after 15 years, FDA has granted only 45 authorizations out of some 26 million applications and only five authorizations for modified risk tobacco product. And while FDA rejects applications based on science and data from manufacturers who have spent untold millions to comply with what they think the rules are, American store shelves are overflowing with products from China, and your Agency does not seem to be doing anything about it. So, Commissioner, given what I just described, I have to wonder, do you even want a functional regulatory process for these products, or is it the objective to target the U.S. tobacco industry even if it means allowing a flood of Chinese products containing God knows what into this country?

Dr. CALIFF. Mr. Chairman, you know, you are from Kentucky. I grew up in South Carolina, lived in North Carolina, and I was a cardiologist at a major medical center. I saw many, many people die from the ravages of tobacco. So, the basics here, first of all, the major cause of remediable death in the United States still today is tobacco-related illness. Four hundred and sixty thousand people will die from tobacco-related illness this year. So, we are very much intent on doing the very best job we can, starting with combustible tobacco, and the good news is, as I said in my opening statement, we have a decline in that. Well, it was not even present when the initial law was passed that you referred to, the presence of vaping or e-cigarettes. No one anticipated there would be 26 million-plus applications of vaping products. That is a bit overwhelming. The good news here, we are 99 percent done, including almost completely done now with the major manufacturers.

And so, the onus that Congress did give us is what is called a public health standard. When it comes to vaping products, does the benefit of helping adults reduce use of combustible tobacco, the major killer, outweigh the risk of teenagers and children getting addicted to nicotine, which is a brutal, fierce addiction that is almost impossible to shake once you have it. And so far, only 31 products, last I counted, have produced the evidence to meet that public health standard. All the others you refer to simply didn't produce the evidence.

Now, if I could say a word about enforcement. I know that was the other issue. It bothers me as much it does you to see what is on our shelves, but I do want you to know that we really picked up our enforcement: over 600 warning letters to manufacturers, hundreds of civil money penalties now, and we have also now begun to do injunctions to stop. But every one of these cases is in an environment where every step we make ends up in court in complicated lawsuits and have to cause us to go back and take that

into account, so it is a battle every day. We are engaged in it, and, yes, we do want to regulate it. The closer we can get to zero combustible tobacco, the better. The role of vaping is still something we are working on.

Chairman COMER. And we will get back to that. My time has expired. I will have another round of questioning with that specifically because these products on the shelves that are getting the bad headlines are Chinese products that are not even regulated by the FDA. FDA regulates the American companies, but the Chinese companies are the ones that are the bad actors, so we will get back.

My time has expired. I now recognize Ms. Norton from Washington, DC. We will get back on that. Ms. Norton?

Ms. NORTON. Thank you, Mr. Chairman. Dr. Califf, across the Nation and right here in the District of Columbia that I represent, drug shortages are negatively affecting patients and their families. Drug shortages can lead to daily challenges for patients, affecting every element of their lives as well as health outcomes. For example, because of shortages of ADHD medication, we have heard reports of previously capable students barely able to pass grades. Adults are forced to contact every local pharmacy to track down a medication that may be the difference between being productive and focused in the workplace or losing their livelihoods. Drug shortages have occurred for decades. And in the wake of recent shortages, the Department of Health and Human Services and the Food and Drug Administration developed new proposals to prevent and mitigate shortages. Earlier this month, HHS released a white paper with potential policy solutions to address shortages. Mr. Califf, what policies can the FDA execute to mitigate drug shortages?

Dr. CALIFF. Thank you so much for the question, and I will try to go quickly here because we have spent so much time on this. This has been going on for decades, and most of what the FDA can do is to mitigate impending shortages when we know one is about to happen. But the way we do that right now is we have spotty pieces of information about what is going on out there from the manufacturers, and we spend a lot of time on the phone finding manufacturer B to make up for what manufacturer A cannot do. So, we have given you a comprehensive list of the information we need.

Remember that most of the starting material now for our drugs is coming from China, the key petrochemicals that lead to drugs. India is a major player in the generic drug industry, and so the supply chains are complicated, and we only have bits and pieces of information. We need more of it. But you referred to several other kinds of drug shortages, and it may be worth just quickly going through this. I do not want to take all your time, but I think the most common shortages by orders of magnitude are inexpensive generic drugs.

Well, believe it or not, the price is not supporting the cost of manufacturing and distribution and quality, and the white paper you referred to has a lot of detail about this in it that I would refer you to. Our supply chain pricing has hit a point where the price is below what keeps the manufacturers in the game. So, when we do an inspection and find a problem and a supply line shuts down,

that company may very well go out of business. Now, that is very different than the shortage of Ozempic that you referred to and has been discussed. There, the manufacturer is making a huge amount of money with every dose. It is just that the demand is so much higher than they anticipated. That will take care of itself over time.

We also referred to Adderall, which is the stimulants for ADHD, very important because these drugs are highly effective for this problem, and it is bad for students that have ADHD to not be treated. Unfortunately, the very same chemicals are showing up increasingly in overdose deaths. The over 100,000 overdose deaths we have are typically a mixture of fentanyl plus something else, often a stimulant. The supply of these drugs is determined by the DEA, not by the FDA because it is a scheduled addictive substance, so it is a much more complicated issue.

The generic one is the one that we hope that we have now solutions in this white paper that have to do with fixing the economics of that industry. Remember that it is not just Americans. The 8 billion people in the world need a reliable source of generic drugs. For the world, these drugs are really important to treat the chronic diseases that were referred to. And right now, in most low-income countries, we just heard from a foundation that 80 percent of antibiotics in one country were actually fake drugs. So, we have to have an industry that produces high quality at a low cost with a supply chain which is completely known, and we need the data, so that we can actually help intervene when there is an impending shortage like a supply line goes down or a company goes out of business. So, we have asked for that, and I hope we can get it.

Ms. NORTON. My time has expired.

Chairman COMER. Thank you. The Chair now recognizes Ms. Mace from South Carolina for 5 minutes.

Ms. MACE. Thank you, Mr. Chairman. Commissioner Califf, thank you for being here today, and thank you for your work on scheduling reform and your recommendation that cannabis should be moved to Schedule III. Well, I and many cannabis advocates believe this does not go far enough. This is a long-overdue start. So, my first question today, I understand this issue now rests with the DEA, and I am curious if you have an update on the timing of their decision.

Dr. CALIFF. Now, we are both from South Carolina, we know, you know I cannot. I do not even know. But if I did, I could not tell you anyway. So, that timing of a regulatory decision is something that would be up to the DEA, not up to me.

Ms. MACE. We think it will happen this year or have any idea?

Dr. CALIFF. I know that there is no reason for DEA to delay. I think they just have to take into account all the regulations that are in play.

Ms. MACE. OK. Thank you. If the DEA concurs with the FDA's recommendation, can you help me understand if the FDA will take on additional responsibilities or if your role will change as it relates to cannabis?

Dr. CALIFF. This is a very complicated topic, but I will just say that cannabis, you know, remember, there are over 30 different forms of cannabis now, different chemicals that are made, and it falls in this area where state regulation has been dominant. This

is an area where I believe we would be better off if we had guidance from Congress about how to proceed. Medical marijuana is one thing where there is a medical purpose, and it is proven through traditional medical pathways, but when it is used for recreational purposes, there is no medical benefit in that case, so it does not fall under our typical regulation.

But what is in play with this and several other things that I think we will probably talk with the Chairman about here shortly, like CBD, the question is how do we reduce harm that is done when it is used inappropriately or at a dose which is dangerous, or when it is packaged in a way to market it specifically to children. We are seeing some of this stuff packaged in gummy bears that is easily mistaken for children's candy, but we are going to need help and a regulatory pathway, remembering that almost everything we do, there is a health benefit. Like, you create a new drug or a new device or a food for a health benefit. This is an area of harm reduction when it is used recreationally.

Ms. MACE. Right. Well, and also, I mean, it reduces the morbidity and the addiction to opioids prescribed by doctors, too. I mean, there is just a huge amount of benefit. I have seen it benefit in my own life, and welcome to my world. I am a mom of teenage kids. I have seen packaging of things. I see what kids are bringing to school. Even in a state that prohibits cannabis, kids are doing it all over the place, and I have a bill called the States Reform Act. There is a balance between Federal regulation and also regulation amongst the states. One of the things you mentioned was about packaging. Myself, like my colleagues, we are concerned about the safeguards for our youth. And one of the things in the States Reform Act is it addresses the packaging that should not be marketed like it is candy, or candy bar, or chips, or whatever kind of candy is your favorite.

In South Carolina, I understand these products, so I am concerned about safeguards for youths in intoxicating hemp-derived products. So, in South Carolina, these products are not age-gated or appropriately tested, and many of the packages do resemble candy or snacks, and that sort of thing. For my family, it is an ongoing conversation about what looks cool and looks like it might be fun and exciting really is not, especially on a young brain.

Dr. CALIFF. Without revealing too much about my age, I am a child of the 1960's. So, it would be nice if in my lifetime, we came up with a regulatory scheme where I think America, you know, whatever your belief is about use of the product, where the safety issues that you have referred to are written into law, so that we have a scheme whereby we can regulate it. As I said, we are referees. You write the rules. We need the right rulebook in order to play the referee role.

Ms. MACE. I would encourage you and I would love for you to review the States Reform Act, a bill that I wrote last session, that takes into account, you know, the regulatory side and the Federal side, but also states being in the driver's seat. Again, one of the impositions in the bill is addressing and ensuring that we do not market to kids, things are not packaged to children, and that sort of thing.

And then I only have 20 seconds left. While I firmly support the right of Americans to make choices about what to put in their body, we can all agree it is a desirable outcome for less people to smoke cigarettes, the negative health effects of which are well-known. Any comment on alternative non-nicotine products today while you are here, in 5 seconds or less?

Dr. CALIFF. So, yes, there are several categories. Medications is one category where I hope we will see more in the pipeline. It is not robust. When it comes to chemicals that are synthesized that also activate nicotine receptors, they also cause addiction to nicotine, and the inventiveness of entrepreneurs in this area is profound right now because chemistry has gotten so much better. So, there are some things I am very concerned about in non-tobacco nicotine and even compounds that are one component removed from nicotine, which may even be more potent in terms of addiction.

Ms. MACE. Thank you, and I yield back, Mr. Chairman.

Chairman COMER. The gentlelady yields back. The Chair now recognizes Mr. Lynch from Massachusetts.

Mr. LYNCH. Thank you, Mr. Chairman. Dr. Califf, welcome. Thank you for your good work.

Dr. Califf, in March 2024, the FDA issued a proposed rule regarding electrical stimulation devices that are intended to reduce or stop self-injurious or aggressive behavior in some patients. The proposed rule, if finalized, would remove ESDs, these electric stimulation devices, from the market, and the devices will no longer be considered legally marketed. I have tried to read as much as I can on these. As an attorney, I try to refrain from making medical decisions on my own, especially for my constituents. I do know that the Geneva Convention regards these devices as torture. But I also have a group of families in my district, who have children and loved ones who are undergoing these treatments, and they claim that those treatments help.

Now, as a result of this rule, these treatments will go away, and my constituents have asked me to ask you and the FDA to meet with them to talk about the consequences of the FDA's rule. And so, as a Member of Congress, on behalf of my constituents, I am asking you and all your staff to provide an opportunity for those families to meet with you and to discuss their concerns.

Dr. CALIFF. Well, thank you for bringing this up. I know it is part of your duty to do so. This is a very tough issue. And I have worked in psychiatric wards during my career, and I think most people cannot appreciate the anguish of families who have loved ones who are in a situation that might call for this or other serious mental health problems, but anyone who has been through it, I think, has a special feeling about it. As I think you know, there is a proposed rule that we have now put out there. There is a docket, and we do encourage everyone to submit their comments and views to that docket. I will definitely take this back to our staff. I know that our staff has met with these families before, but this has been going on for a while, so we will go back and reconsider.

Mr. LYNCH. It has. It has. It has, and it is heartbreaking. Let me ask you. So, shifting to something completely different. Last year, the FDA made nearly 200 additions to its public list of AI-and ma-

chine-learning-enabled medical devices currently marketed in the United States, and there has been some wonderful success. You know, Dana-Farber Cancer Center is near and dear to my heart, Mass General Brigham, that cancer center as well. Wonderful, wonderful progress in diagnosing breast cancer from mammograms. Clearly there are enormous potential benefits here, but there is also some concern around privacy and also the lack of explainability of some of these algorithms that are being used on the diagnosis or the predictive end.

What are we doing to mitigate the negative aspects of the use of AI? And I know it is coming at us hot and heavy in so many areas, but I would like to hear what the FDA is doing about guarding against the dangers that might be present by this widespread adoption of AI.

Dr. CALIFF. Thanks for the question. I will have to contain myself here because you may know that I worked at Alphabet, or Google, during the 5 years between my two FDA stints, and very heavily into this. And I think it is going to be a huge benefit but also with a huge risk on the other side if it is not regulated. And also, we have many mutual friends. I will be at Mass General next week as visiting professor and learning from the people in the Harvard system, you know, a lot about this stuff. Well, this is one of the topics.

The thing I would emphasize is that I do not think it is explainability that is really the issue. And I think an easy way to think about this, think about yourself before you had a map in your car that you could talk to when you used to drive the car, and you get into an argument about which way to go and then you would have to pull out the map and look at it. Well, now you just talk to your car, and what is going on with the car is AI continuously, in real time, taking into account everything that is happening on the roads. The template of what is there and your personal preference is that it learns as you go along. And I think if AI works, we will take it for granted because there are many things we do in medicine. If you ask me how does aspirin work, we know a lot about aspirin, but exactly how it works for each disease, we are not so sure, but we know it does work for particular things.

So, what we are really focused on is creating a community in our health systems and the industry that, like I have already said, we are referees. The first line is self-regulation by the industries. And what is really important here, I think where AI is going, generative AI, it learns as it goes. The more information it has, either the better it gets or the worse it gets. You do not know which one, and if you just put it in place and do not tend to it and monitor it, it can go wrong in really bad ways. I saw that at Alphabet. It was something we were really worried about.

And so, we have got to reformat our health system so that, as time goes on, you are constantly looking at what the algorithm is doing. Are its predictions accurate? That is really the key thing that we have to do, and right now, we are not configured to do that. So, we are working very much with a community of health systems and the industry to come up with a scheme of what is called assurance labs, and this would be you sell your AI thing to somebody, it goes out there, there has got to be a monitoring that

says it is either working or it is not, in practice. And it also looks for this bias that we are all concerned about, that if you put the wrong information in, you end up with a prediction which is preferential to one type of person compared to another. That has got to be looked at. So, I will stop there, and I can go on a while on this.

Mr. LYNCH. Yes. Yes. Well, thank you for your answer, Doctor. Mr. Chairman, thanks for your indulgence. I yield back.

Chairman COMER. The Chair recognizes Mr. Sessions from Texas for 5 minutes.

Mr. SESSIONS. Mr. Chairman, thank you very much. Commissioner, thank you for taking time with us. As you have noted, a cardiologist also spending time in mental health stress units, I think that part of what I am going to talk with you about would come directly to observations that you may strongly identify with.

In August of last year Assistant Secretary for Health Levine sent Drug Enforcement Agency director, Anne Milgram, a recommendation from the FDA to downgrade marijuana, also THC, from Schedule I, to Schedule III under the Controlled Substances Act. This recommendation made the claim that marijuana meets the criteria for control under Section III. In reviewing the FDA's recommendation, I believe that the FDA did not base its assessment in scientific fact or realities of how marijuana has been abused and used in our country today. The FDA's assessment relied on, I think, cherry-picked data, for example, concluding in the report that since the potential for abuse of marijuana is less than heroin, marijuana should be downgraded.

This completely ignores the realities of a drug that is causing enormous consequences of children and adults in our country, high schools, middle schools, and communities. Just last week, *Bloomberg* editorial board published an article emphasizing the sharp rise in marijuana THC related traffic fatalities. One analysis, which is consistent with the HITDA report out of Colorado, a 10-percent increase in vehicular deaths, in California, the increase was 14 percent, in Oregon 22 percent. During 50 percent of the deaths on a highway, the driver had THC in their blood, and those are only the marijuana-related traffic deaths that we know about. We know that there are other problems.

In your Agency's analysis, you scrap the long-held five-factor test for determining a drug's medical necessity to simply two factors. Two factors that relied on the fact that marijuana, as was reported, currently is accepted for medical use because it is prescribed by healthcare practitioners through medical marijuana programs. So, what I would ask you is, why did the FDA create a new, less rigorous two-factor test to determine this when you know the reams of data and evidence suggests it is not only addictive, but it is a contributory to not only death, but long-term stress of people who use this and confirmed by the medical community?

Dr. CALIFF. Well, sir, I appreciate the question. I think you have already demonstrated, between you and the other representative, that there is not agreement in Congress about what should be done with this. And again, we would very much appreciate if Congress did come to a conclusion for the country. It would make our job better.

Mr. SESSIONS. Well, I think Congress has not spoken——

Dr. CALIFF. Right.

Mr. Sessions—because we believe it is a dangerous product. We receive calls from thousands of parents every year about their children. We see drug-related not only instances in schools, but principals, teachers, people report the real problem, and the problem gets even worse as gummies are introduced into the system.

Dr. CALIFF. I certainly appreciate those concerns.

Mr. SESSIONS. So, I think Congress has spoken.

Dr. CALIFF. Let me remind you that a Schedule III does not put marijuana on the market in the United States. It is still highly controlled.

Mr. SESSIONS. No, it does not, but you do know exactly what it does do, and you have, through the FDA, suggested that it is not a dangerous product like heroin. Well, neither were cigarettes like heroin.

Dr. CALIFF. Well, with all due respect, I think it is differentiable from heroin and cigarettes.

Mr. SESSIONS. I think it is, too, that it is a dangerous product.

Dr. CALIFF. Cigarettes directly cause death. I appreciate that you feel that way, and your colleague just gave exactly the opposite point of view.

Mr. SESSIONS. No, she talked about the public opinion, not the medical opinion. You are a medical doctor——

Dr. CALIFF. Yes——

Mr. SESSIONS [continuing]. A cardiologist, and you are here to answer. And I thought you did do a fair job to answer that you do see where, when not used properly, it is a dangerous product, and it is a dangerous product. And I thank you very much, and I appreciate you being here today.

Dr. CALIFF. All right. Thank you.

Mr. SESSIONS. Mr. Chairman. I yield back my time.

Chairman COMER. The gentleman yields back. The Chair recognizes Mr. Krishnamoorthi from Illinois for 5 minutes.

Mr. KRISHNAMOORTHI. Thank you, Mr. Chair. Dr. Califf, in February 2021 I was Chair of this House Oversight's Subcommittee, Economic and Consumer Policy Subcommittee. We studied the presence of toxic heavy metals in baby food at that time. And in March 2021, we issued a report with regard to the presence of lead, arsenic, cadmium, and mercury in astonishing levels in baby food products. For example, we found that baby food had, on average, 177 times the permissible amount of lead in drinking water. In response to public pressure coming off that report, FDA issued an action plan called Closer to Zero. This was the first time FDA would be regulating toxic heavy metals in baby food, which is obviously a good thing.

When my Subcommittee issued its report in March 2021, FDA said that it would issue its initial draft guidance regarding permissible lead limits and baby food within 1 year, so roughly April 2022. Instead, it missed that deadline and issued its draft guidance in 2023. But let me talk to you about some of the other toxic heavy metals in baby food that are covered by the Closer to Zero Program. I want to throw up here a screenshot of your website from today.

[Chart]

Mr. KRISHNAMOORTHI. And specifically, I want to talk about when you say final guidance will be issued with regard to permissible limit of other toxic heavy metals. So, in terms of when, for instance, arsenic in baby food would be examined and you would be issuing final guidance on permissible levels, your website says, and this is my red circle, "no update." That is what it says, right?

Dr. CALIFF. I cannot see it, but I will take your word for it. I cannot see it from this distance.

Mr. KRISHNAMOORTHI. Let me talk to you about cadmium levels. Again, screenshot from your website today. You say that we should expect final cadmium levels at some undetermined point, and, again, your website says, "no update." You do not disagree with that, right?

Dr. CALIFF. I am not up to date on the exact, but I will assume that you are telling the truth here.

Mr. KRISHNAMOORTHI. Thank you. Mercury, a dangerous toxic heavy metal in baby food, again, we go to your website, and with regard to when we should expect to hear from you with regard to permissible levels of mercury in baby food, you say "no update," right?

Dr. CALIFF. You say it, it must be so.

Mr. KRISHNAMOORTHI. Dr. Califf, this is unacceptable, completely unacceptable. It has been 3 years since we issued that report. The public, the parents are outraged about the amount of toxic heavy metals that are present in baby food. And quite frankly, sir, I respectfully say that your Closer to Zero Program at this point is closer to zero update, and that is very, very disturbing.

[Chart]

Mr. KRISHNAMOORTHI. I want to turn my attention to another topic, which is the youth vaping epidemic, and you and I have spoken about this before as well. Your own 2023 survey indicates that 10 percent of middle and high schoolers are vaping today, 90 percent of them prefer flavored vapes, and the vast majority, sir, the vast majority of those flavored vapes are illicit vapes coming from China. Here is one of those illicit vapes right here. It is a Strawberry Mango EBCREATE vape, and it is illegal, but you can buy it today because you folks have not cleared the shelves of these illicit products. On December 7, 2023, a dozen of us wrote to you asking for a comprehensive approach to dealing with these illicit Chinese vapes, and you didn't respond to me at that time, did you?

Dr. CALIFF. I would have to go back and look, but we have had much correspondence about this issue, so I am not sure of that particular one.

Mr. KRISHNAMOORTHI. I know you are too busy to respond to us. Of course, it has been 5 months, sir. After that, we wrote you February 1, 2024, again, same issue. We want to know how you are going to deal with these illicit vapes coming from China. You didn't respond to that one either, right?

Dr. CALIFF. I would have to go back and look.

Mr. KRISHNAMOORTHI. Sir, what bothers me about your answers, is this. The reason why you did not respond to us with your approach to clearing the shelves of these illicit vapes from China is perhaps because you do not have an answer. It is because you do

not have an approach. And mark my words, the illicit vapes coming from China flooding our market, these kid-friendly flavors such as the ones here or the ones I hold in my hand, is the next chapter in this youth vaping epidemic, and it is time you take this seriously. Thank you. I yield back.

Chairman COMER. The gentleman yields back. The Chair now recognizes Dr. Foxx from North Carolina for 5 minutes.

Ms. FOXX. Thank you, Mr. Chairman. Commissioner Califf, the Center for Tobacco Product, or CTP, must make timely decisions on whether products, especially tobacco harm reduction products, can be allowed for sale or not. However, stakeholder groups with pending premarket tobacco product applications, or PMTAs, have been waiting for several years for a decision, which far exceeds the 180-day review period written into law. Can you tell me in 25 words or less why has the CTP failed to comply with the statutory review period, despite the fact that the CTP staff has more than doubled in the last decade?

Dr. CALIFF. You said less than 25 words. It has 26-plus million applications. We are now 99 percent done, and soon we will be within that timeframe.

Ms. FOXX. But you know among those applications are very frivolous applications, and there are, like, a couple of dozen in there that are coming from legitimate places, and you all should have focused your attention on those. It is hard to believe that an Agency that has doubled its staff over a decade to over 1,200, receives over $700 million per year in funding, is still not meeting the deadline for these PMTAs, the serious ones, again, it is my understanding relatively few serious from legitimate companies. What steps are needed to bring more accountability to the CTP?

Dr. CALIFF. I would remind you that the vaping industry right now pays no user fees, so all the money and people that are hired are hired off of the combustible product industry. There we have tremendous gains. So, in terms of the transparency, now the applications, people can track it. The information is published, and you are seeing continuous improvement in our efficiency.

Ms. FOXX. So, what performance metrics does the CTP have to ensure they are being good stewards of the tobacco user fees?

Dr. CALIFF. It is the numbers of applications, the time it takes to review them. The outcomes of the reviews are discussed by numerous watchdog groups that are looking at everything that we do.

Ms. FOXX. Had the CTP done its job over the last decade, there should have been tobacco harm reduction products approved through the appropriate process. There is clearly a demand for these products. It is being filled by illicit-flavored disposable e-cigarettes, now make up more than 70 percent of the e-cigarettes or ends market, as my colleague is talking about, most of which are from China. What is the FDA doing to rectify this problem of illicit products in the market?

Dr. CALIFF. If I may, "tobacco harm reduction product" is an industry term. I would say we are all in favor of reducing harm from tobacco, and as I went over with an earlier question, we have an increasing number of warning letters, civil money penalties and injunctions now, and seizures now at places of import. It is a very

large number of products. There is no question about it, it is a big job, and we have a lot more work to do.

Ms. FOXX. Commissioner, you have recognized the critical need for the public to have access to accurate medical and scientific information to help inform the decisions they make about their health. How does the FDA justify the decision to spend millions on ad campaigns and scare tactics, such as brain worms or metal dragons that are not based on verifiable facts? And when will the FDA focus on the facts about what can make cigarettes deadly as Congress intended in the Tobacco Control Act instead of relying on misunderstandings and outdated narratives?

Dr. CALIFF. I am not sure I follow that question. I would just say we have seen dramatic progress and reduction in combustible pack tobacco use, significant reduction in the number of people dying, although it is still 460,000. I will just note that in my time at Alphabet, I learned a lot about advertising. I think our statements are based in fact, and they include a component to reach into the culture of people that need to receive the information. Simply stating a fact, when you are talking to a teenager, it is not necessarily the best way to reach that teenager. You need to have the mind prepared to absorb the information.

Mr. FOXX. So, brain worms and metal dragons——

Dr. CALIFF. I do not know about brain worm and metal dragons, but I will take your word that something alluding to that must exist somewhere in there.

Ms. FOXX. Thank you, Mr. Chairman. I yield back.

Chairman COMER. The gentlelady yields back. The Chair recognizes Mr. Khanna from California for 5 minutes.

Mr. KHANNA. Thank you, Mr. Chairman. Commissioner Califf, thank you for your service. So many Americans are frustrated that even with insurance, they are having to pay thousands of dollars for drugs for cancer, for multiple sclerosis, for getting inhalers, hundreds of dollars. I want you to help explain to the American people why this is happening and to start by giving two sentences on what the FDA's "Orange Book" is.

Dr. CALIFF. Well, the "Orange Book" is a listing of patents that are relevant to drugs that are marketed.

Mr. KHANNA. Correct. And if something is listed on the "Orange Book," is it correct that for 30 months, a generic manufacturer cannot produce that?

Dr. CALIFF. With some caveats, but, essentially, that is a fair statement.

Mr. KHANNA. So, let us take a couple of examples. You have a multiple sclerosis drug, Copaxone, produced by Teva. It costs patients between $3,000 and $50,000, and it is currently listed on this "Orange Book." Now Teva, the company producing it, is going to come again to have it listed with no real changes to the drug, cosmetic changes. If they list it again, then no generic-manufactured drugs can be produced, correct, for 30 months?

Dr. CALIFF. It is a little more complicated than that. I mean, you left out one step before that, which is that you have to have a patent, which says it is a significant new thing.

Mr. KHANNA. Sure, but——

Dr. CALIFF. Our role in the "Orange Book" is ministerial; that is, we list——

Mr. KHANNA. But you have discretion on whether to list it or not, correct?

Dr. CALIFF. Not much discretion.

Mr. KHANNA. But technically, you have that discretion?

Dr. CALIFF. Not really. We have to list them, and——

Mr. KHANNA. What would happen if you did not list them?

Dr. CALIFF. We would get sued.

Mr. KHANNA. But what is happening is you have these companies that are getting you to list this and not have generic competition. And so then, as a result of it, the American people are paying $50,000 for drugs on multiple sclerosis, or in the case some—revumenib for leukemia

—they are paying $17,000 because you are listing something in the FDA that is not allowing generic competition. Now, you can say the blame is with the Patent Office, but if those were not listed at the FDA, you would have generic alternatives. Is that not correct?

Dr. CALIFF. You know, my grandfather was a Baptist minister, we are all sinners, so we will take our share of blame here. It is a point of emphasis between us and the Patent Office now to try to get rid of frivolous patents, which is what you are referring to, frivolous patents just to extend the time period in which a company——

Mr. KHANNA. Would you say that in the case of Copaxone where Teva is asking for more patents and multiple sclerosis patients are paying $3,000 to $50,000, that that could be frivolous, or with revumenib, which is where they have 27 patents to treat leukemia, there could be some of those being frivolous?

Dr. CALIFF. As FDA commissioner, that decision really is an FTC decision. I have personal opinions about parts of this——

Mr. KHANNA. What is your personal opinion on those two?

Dr. CALIFF. There are too many efforts made to extend patents, but I will not comment on this specific one.

Mr. KHANNA. But what about for AstraZeneca and the inhalers with Symbicort?

Dr. CALIFF. I cannot refer to a specific one. I will note that my mom got some extra life expectancy due to revumenib, so, and I am very familiar with what happened with the cost.

Mr. KHANNA. And so, my question I guess is, what can we do in Congress because this is what is frustrating people. And I am not blaming you, sir, but I am saying that you have got a system where you are listing these drugs—maybe you are saying your hands are tied—it is not bringing those costs down. From the American people's perspective, how do we solve this? And if you could give me 10 seconds because I have one more question, but do you have a 10-second recommendation?

Dr. CALIFF. Maybe the analogy is worn out. Again, we are the referees, so it may be something where our staff will meet together with yours and the Patent Office and see if there is anything that can be done to tighten up the laws here.

Mr. KHANNA. The last question I want to ask, and it is not a "gotcha" or anything because I know when you were in the FDA, then afterwards, you got consulting fees from Merck, AstraZeneca,

Biogen. I take you at your word that there were ethics reviews, and then you said that there were no ethical conflicts, but one of the things I proposed is Members of Congress should not become lobbyists. Would you commit today, that after your service as FDA chair, you will not take any money as consulting fees from Big Pharma going forward?

Dr. CALIFF. I have a written record on this for 2 years. Beyond that point, you know, we will have to see. I will be——

Mr. KHANNA. But why not just make that commitment, so that the American people have confidence that you will not take? You can make plenty of money at Google or somewhere else. Why not just say I am not going to take Big Pharma money?

Dr. CALIFF. I am not looking to make money. I am looking to contribute to the development of effective——

Mr. KHANNA. And why not say you will not take it after regulating it? Just make that commitment today.

Dr. CALIFF. I certainly have made a commitment for a period of time, but I cannot speak for the rest of my life.

Mr. KHANNA. I think you should.

Dr. CALIFF. I appreciate your opinion.

Chairman COMER. The gentleman's time has expired. The Chair recognizes Mr. Fallon from Texas for 5 minutes.

Mr. FALLON. Thank you, Mr. Chairman. I think we have some bipartisan agreement. Representative Khanna, I would love to coauthor any bills you have for preventing Members of Congress from becoming lobbyists. I think it is good government, so thank you for that.

Thank you, Mr. Chairman, and I am here today, Commissioner, not so much as a Member of Congress, but as a parent, and I just wanted to visit with you on a few things. Particularly, you know, I have two teenage boys, 17 and 14, and I see the teenage vaping, you know, skyrocketing, and I think that is an entry to some really nefarious habits moving forward. And I am particularly concerned about the use of illegal and unregulated Chinese vapes. I know it was touched on before and the FDA's role in contributing to this, I think, you know, proliferation that we see across the country.

So, the Tobacco Control Act of 2009 created pre-market review process allowing for new tobacco products to enter the market. Yet, as myself and nearly 60 of my colleagues pointed out in a letter we sent to the President last month, a letter led by my good friend, Congressman Richard Hudson, despite the FDA's receiving over 26 million smoke-free applications since this law, the FDA has authorized fewer than 50 product applications, with less than 10 being commercially available. During this time, however, they have authorized thousands of combustible cigarette product applications, but as of January 2024, there were only 23 authorized e-cigarette products and all by three manufacturers.

The FDA's inability to produce, or to process rather, the PMTAs in a timely manner has resulted in the proliferation of illegal Chinese vapes flooding the market all over the country to meet the consumer demand, often in flavors that, I am sure you hopefully agree, are horrific insomuch as they appeal to kids. Peach, mango, watermelon, which is a flavor currently offered by EBCREATE, a wildly popular brand formerly known as Elf Bar, this is a Chinese

company whose vapes are illegally here yet easily purchased at local stores. In fact, a local smoke shop over in Virginia, this picture was taken 2 days ago.

[Chart.]

Mr. FALLON. And you can see in the yellow up there, those are all displayed. They are illegal Chinese vapes along the wall, and we are not speaking about hypotheticals or back-alley deals. This is flagrant noncompliance, and this was just randomly discovered. By the inaction of the FDA, what we essentially see is almost a prohibition on legal products with unregulated and illegal products rushing in to meet the demand. Then by further weak action on enforcement, U.S. stores have seemingly no concerns about openly selling the products all over the place. So, Commissioner, by law, how long does the FDA have to review PMTAs and take action on?

Dr. CALIFF. I believe it is 180 days as legal.

Mr. FALLON. You are correct, and how long on average is it actually taking?

Dr. CALIFF. It is hard to calculate an actual number. There are 26-point-something million applications, so, and some still outstanding. So, you know, we are obviously not meeting 180-day timeline, although it is getting better as we are plowing through, and 99 percent complete, which still leaves hundreds of thousands to go.

Mr. FALLON. The industry stakeholders have told us that they are claiming it is 3 years. Is that feasible?

Dr. CALIFF. You know, remember the history, and when I was commissioner in 2016 was right when vaping was starting and then went immediately to millions of products. There were some laws in between. And it is the case that there was such a flood of products, it could be if you went back, you know, 3 or 4 years ago, you would say OK, 3 years until now, but you look at applications coming in now, it is much shorter than that.

Mr. FALLON. Because the FDA's website shows that they approved PMTs for 2023 took roughly 2-and-a-half to 3 years for each one.

Dr. CALIFF. There was a bolus effect that had to be dealt with. As one of your representatives already pointed out, millions were taken care of by getting rid of the ones that did not have useful data in them.

Mr. FALLON. I think that it would behoove you all to have a regulatory framework in place, and warning letters are one thing. How many seizures have we had at retail shops across country?

Dr. CALIFF. We have only had a few seizures. We have had 32,100 civil money penalties, and those are ramping up considerably as we go. As I think you know, seizures require a whole different order of magnitude of legal work both before and——

Mr. FALLON. So, we only have a few seconds left. These are all over the place. So, what do you think that the FDA can do to, you know, mitigate this?

Dr. CALIFF. Well, given the fact that there is a vape shop in almost every neighborhood, it would take a lot more people to do what you are saying of clearing the shelves. So, we have an action plan. It is going to get better and better. As I have already said, if user fees were paid by the vaping industry—that will be about

$100 million—we could hire a lot of people and spend a lot more time out there in the shops.

Mr. FALLON. And I am not trying to suggest that every illegal Chinese vape is going to be taken from the shelves, but you know as well as I that you can set examples and make examples, and then word gets out that if you have these products, you are going to heavily fine and they are going to seize them as well. Thank you, Mr. Chair. I yield back.

Chairman COMER. The gentleman yields back. The Chair now recognizes Mr. Mfume from Maryland.

Mr. MFUME. Thank you very much. Mr. Chairman, I want to thank you and Ranking Member Raskin for convening this hearing. And before I go into my observations, Dr. Califf, let me go back to something that the Ranking Member said earlier that I do not want to get lost in all of this. And that is that maybe what we ought to be doing in addition to this is trying to find a way to create more regulatory pathways, giving the FDA the ability to do many of the things that you said you could not do here today.

Dr. Califf, I am deeply concerned about the over-prescribing of ADH medications, particularly Ritalin and Concerta, as it relates to kids in poor neighborhoods as a means of dealing with their "hyperactivity in school," and that so many studies have shown that whether they are poor Black, poor White, poor Latino, this over-prescription seems to take place. And I am not a conspiracy theorist. I just do not think Humpty Dumpty fell. I think he was pushed. And so, moving under that premise, I think that unless we do have greater regulations over the over-prescribing of these medications, it will continue.

Now, let me just flip that around to the other side. I am also deeply concerned about children who are unable to focus on things and are given these medications and where all the protocols have been followed, and I am concerned about that because, in many instances, those drugs, unfortunately, have been part of the shortages. I am concerned about cancer patients who are forced to delay treatment, as you know because many of the required medications are out of stock.

So, those are just a couple of things that I am hearing from my constituents in Baltimore on a regular basis. I know that supply chains were disrupted during COVID, and that there had been intermittent and sometimes not intermittent drug shortages occurring throughout the U.S., but I would be less than honest if I did not just tell you from my perch some of the things that I hear. And I recognize you do not carry your magic wand in your back pocket. The only thing you can do is to help guide us, listen to us, and suggest to us ways that we can help you.

The FDA serves as an important regulator, to say the least, and it is well-positioned to assess potential supply chain disruptions. Can you tell us and this Committee and the people around the country who may be watching these proceedings, how is FDA working now currently with manufacturers to mitigate the ongoing drug shortages? And have those manufacturers, in your opinion, been transparent with the FDA about potential shortages and the real root causes of those shortages?

Dr. CALIFF. Thank you for that. First of all, just a comment you made about the under-prescribing and the over-prescribing. I think it exemplifies a major problem that we have in the intersection of the responsibilities of the FDA and the practice of medicine. There is no doubt that people that need these drugs are not getting them and people that do not need them are getting them, and that equilibrium, of course, is not set by the FDA. I am also a physician. It is a clinical quality issue that we need to work on, and we are trying to help as best we can with that.

But your main question about the manufacturers, we work every day with the manufacturers. They are required to give us certain information, but, frankly, they have resisted giving us some of the crucial information that we really need. When there is an impending shortage, we are finding that they are very cooperative to work together to try to fix it. But it would be better if we had all the data we needed to put together predictive algorithms that would allow us to intervene preemptively much, much earlier and prevent the shortage. So, we have a list that you all have a copy of that list the areas where the correct information would make a difference.

But, I also want to point out that while there is a shortage of the stimulants for ADHD, the biggest shortages are occurring in inexpensive generic drugs where the less expensive the drug, the more likelihood of shortage because of the way the market is not succeeding in rewarding high-quality manufacturing. And that is a point I think we really need to address over the next few years.

Mr. MFUME. And any guess on your part as to what factors affect non-generic drug shortages?

Dr. CALIFF. For non-generic drug shortages, there are really only two major types. Because a non-generic drug, as we have already discussed, in general, the manufacturer is making a handsome profit once the product is on the market.

Mr. MFUME. That is my point.

Dr. CALIFF. So, they are pretty good at figuring out how to make it.

Mr. MFUME. Yes.

Dr. CALIFF. The exception, as I said, is Ozempic or the weight loss drugs where the demand is just so high they have not been able to keep up.

Mr. MFUME. Yes. Thank you very much. Mr. Chairman, I yield back.

Chairman COMER. The Chair now recognizes Mr. Biggs from Arizona for 5 minutes.

Mr. BIGGS. Thank you, Mr. Chairman, and thank you, Commissioner Califf for being here today.

The University of Arizona has been engaged in research that would advance pain and addiction research to help combat the opioid crisis. They are looking for ways to expedite known drug candidates through the Phase 2 and Phase 3 trials to take non-addictive pain relief medications to the market. U of A has informed me that they have found if they can repurpose clinically available medications that are proven to be non-addictive and have also shown to be effective for treating different types of chronic pain. They think they are ready to go forward in these trials. But they

also report that there is a need to repurpose some of the medications specific to sex differences because pain is differentiated based on sex, and that would have an impact on how they develop this drug.

So, the question is, during the COVID era, FDA was able to expedite clinical trials. U of A tells me that they are struggling to obtain approval for Phase 2 and Phase 3 clinical trials on something that could alleviate chronic pain and help reduce the risk of opioid addiction that we see so rampant in the society today. So, I guess my question is, could this be a statutory problem, a regulatory problem, a resource problem? What might we be looking at? And I realize I am giving you a very specific example but hoping that you can give us some information.

Dr. CALIFF. Well, you know, the way it works at FDA on the drug side is there are user fees that are paid, and we have statutory or agreed-upon, passed by Congress every 5 years, for the user fees timelines. We are meeting those timelines which are agreed to between the industry, the FDA, and then put into law by your passing the law.

I am not aware of the particular circumstance you are giving. There is a thing that we say at FDA: "In God we trust. All others must bring data." So, I would have to know the specific data coming from University of Arizona to know if there may be some issue that is causing a back and forth that would not fall within the usual timeline, but when that happens, it is very much noted that that is the case, so.

Mr. BIGGS. We would love the opportunity to present you with additional information, whatever we need to——

Dr. CALIFF. Sure.

Mr. BIGGS [continuing]. Find out what may be the hitch in the get-along, if we could.

Dr. CALIFF. That will be fine.

Mr. BIGGS. With that, I will yield to the Chairman.

Chairman COMER. Thank you for yielding. Commissioner, it is FDA's responsibility to ensure the safety and efficacy of all drugs marketed and sold in United States regardless of where the drugs are manufactured. Yet the number of inspections conducted annually has been declining since 2013. At the same time, Chinese and Indian manufacturers have received the most FDA warning letters by far. These violations include contaminated medicines, non-sterile manufacturing, and falsified data. So, how is the FDA working to keep foreign manufacturers accountable?

Dr. CALIFF. I really appreciate that question. As I have already established, we are doing a major reorganization because I agree with you that we need to pick up the pace of the inspections that we are doing, but, again, as I have already said, the first line of defense is the manufacturers themselves. And so, here is where modernization of our data systems is important because the more we can keep up with what is going on, not just in U.S. facilities, but all around the world, the better we are able to target our inspections and to have the frequency that is needed to keep the manufacturer in shape.

One of the big areas that we are working on now is India, where we have completely redone our inspectional system, and I have per-

sonally gone to India to meet with the Indian Government to work on the relationship, so that the inspections can proceed, and I believe they are acting in good faith in India right now, as one example. So, think of it as a layer of data and information that should be constantly coming in now that all manufacturing is digitized. And on the human side where the inspector actually shows up, the investigator in the facility, those are being increased, and it has been a major point of emphasis in our reorganization.

Chairman COMER. There are not a lot of bipartisan agreement on controversial issues in this Congress, but one thing I think there is overwhelming bipartisan agreement on is the fact that we need to have more domestic manufacturing of our pharmaceuticals. In your medical opinion as commissioner of FDA, what can we do in Congress to encourage an environment where all of our essential, or much more at the very least, of our essential pharmaceutical production is manufactured in the United States?

Dr. CALIFF. As one of your colleagues pointed out through the Socratic method of asking the question, I do not think it is a big issue for innovator drugs because that industry does not experience much in the way of shortage. But for this generic area, it is an area where we do need to reshore significant——

Chairman COMER. But, it is a national security issue as well.

Dr. CALIFF. Absolutely.

Chairman COMER. Right.

Dr. CALIFF. And when the raw material is coming from China, it is an issue that we need to take seriously. So, as you know, FDA does not deal with the prices and the market per se. I would refer you to the HHS white paper that just came out with a large input from us. And basically, we need to create an economic market situation where the price is fair, so that the manufacturer can produce a product, but also invest in the technology of manufacturing and can be done using American labor, which is more expensive than labor in other countries. I would also say, I am not talking about 100 percent reshoring. I do not think we need that, but we need enough of a footprint in the U.S. and in nearby countries that we are assured that if something goes wrong anywhere in the world, we keep this up. Ninety-five percent of our prescriptions are now generic.

Chairman COMER. And we will touch on that later. My time has expired. The Chair now recognizes Ms. Bush from Missouri for 5 minutes.

Ms. BUSH. Thank you, Mr. Chairman. St. Louis and I are here today, Dr. Califf, to first thank you for the work that the FDA has done to eliminate cumbersome restrictions on mifepristone, one of two drugs used for medication abortion. As Ranking Member Raskin mentioned at the top of the hearing, mifepristone is subject to a risk evaluation and mitigation strategy, also known as REMS. During the peak of COVID–19, the FDA suspended enforcement of a REMS requirement that mifepristone be dispensed in person. Due to the success of this trial run, we know that in January 2023, the FDA permanently updated the strategy to remove the in-person dispensing requirement. This has proven that the in-person dispensing requirement was never actually medically necessary.

I have a bill called the Protecting Access to Medication Abortion Act, which would assure that mifepristone, one, does not have an in-person dispensing requirement; two, allows patients to access prescriptions for mifepristone via telehealth; and three, authorizes all pharmacies certified to dispense mifepristone to patients to do so via mail. So, thank you to the FDA for your commitment to your evidence-based care that serves patients and not politicians.

Next, I want to turn to sickle cell, a disease that affects approximately 100,000 people across our country, the majority of whom are Black people, and about 2,000 people across my district. In fact, according to the CDC, 1 out of every 365 Black children in the United States are born with sickle cell disease. It cuts at least 20 years from life expectancy. And so, as a nurse, I have treated people with sickle cell disease. Patients experience totalizing pain, and it is debilitating. This illness completely takes over your life and it is heart wrenching, and we do not speak enough about it.

So last year, the FDA issued a groundbreaking approval of the first gene therapy to treat sickle cell disease, and so this new technology is the first-time genetic editing has been used to treat any disease. As a result, patients who face excruciating pain and even death from sickle cell disease will now be able to better manage this life-threatening condition for many who may have been unable to hold steady employment, spend time with friends and family, or otherwise participate in everyday life because of this illness. This is truly life altering and is life sustaining. This technology would be impossible without the diligent and the science-driven work of the FDA.

So, Dr. Califf, what did the FDA consider when determining the new sickle cell treatment, determining that it is safe and effective?

Dr. CALIFF. As I believe you probably know, there are actually two treatments approved, one using gene editing per se and another using a viral vector, and in both cases, human clinical trials were done. Taking sickle cell patients, as you well know being a nurse, people with sickle cell disease, even though the genetic issue is essentially the same area of the human genome, the manifestation of the disease is quite different.

So, what was done in these trials were to take people who are having the worst outcomes—that is, many attacks, painful crises—and then doing the gene effort, and then following them after and showing that those crises abated almost completely. It was quite a remarkable result but in a small group of patients. And so, there is a lot yet to learn, but it was important to give access to that treatment to those who would benefit.

Ms. BUSH. OK. OK. Is there potential for this new treatment to be used to treat other genetic diseases?

Dr. CALIFF. It is very exciting, and I alluded to it in my opening comments. You know, I was around for the Human Genome Project, and people for decades said, "where is the beef", you know. We put all this money into $3.2 billion base pairs and knowing what they are. Now we are here because thanks to the science, we can go in with molecular scissors and snip out the gene that is causing the problem and put in a new one, or snip out the gene that is causing the problem if we do not need to put in a new one. There are 10,000 rare diseases with no treatment right now.

You are talking about parents of children who have terrible outcomes. And so, this is such a revolution in terms of therapeutics, that we are making major changes within the FDA, but it has got to go further than that because you are aware that the cost of these treatments is quite high. So, I think there is going to be a lot for you in Congress to work with the administration on here to figure out, you know, if you are a parent of a child with a rare disease, now there is hope that within a few years, we could have an effective treatment. But if we have hundreds to thousands of effective treatments, the environment in which this is done has got to look different than it does right now. I hope that was helpful.

Ms. BUSH. Yes. Yes. And, Chairman, can I? OK. Thank you. One last question. How can we ensure that people who require these genetic therapies are not priced out because like you started to allude to?

Dr. CALIFF. Well, I can take these out and say, you know, as FDA commissioner on a hearing about FDA, it is definitely not in our remit. But I can assure you there are many discussions going on across HHS where, as you know, for example, in sickle cell disease, the majority of patients are on Medicaid——

Ms. BUSH. Right.

Dr. CALIFF [continuing]. Because their medical costs are so high and the difficulty with jobs in a case where you are sick a lot, that we got to come up with new pricing schemes. And I am an academic, a health policy person, but I should not opine on that here at this hearing, but I would be glad to talk with you separately.

Ms. BUSH. OK. I will reach out. Thank you. Thank you, Mr. Chairman. I yield back.

Chairman COMER. The Chair now recognizes Mr. Higgins for Louisiana for 5 minutes.

Mr. HIGGINS. Thank you, Mr. Chairman. Mr. Califf, thank you for being here. Your authority is vast and your responsibility is great, and you are a gentleman of distinguished stature, so I appreciate you being here today. You have to give serious answers to hard questions, and I do indeed have some hard questions to submit to you, and, Bob, we are submitting the more interesting questions in writing for the record after the hearing.

Mr. HIGGINS. For legislative purpose, I have a specific line of questioning regarding imported seafood, so it is what I am going to be discussing with you. Just as a matter of background, according to my research and investigations, about 60 to 65 percent of seafood consumed in America is imported. And generally speaking, given the limited resources that you have at your avail, you are able to supervise the inspection of about one-tenth of 1 percent of imported seafood. Is that generally correct, sir?

Dr. CALIFF. Well, we settle it all differently. First, and by our account, it is more than 65 percent of seafood, if you are asking me.

Mr. HIGGINS. This is the Republican side, so I am being conservative.

Dr. CALIFF. OK. But much as I described on the drug side just a few minutes ago, it starts with a digital inspection. That is, we have information about these facilities from——

Mr. HIGGINS. And then the shipper and the owner and the input.

Dr. CALIFF. And as it comes in, we use artificial intelligence now to look at the characteristics of the shipment to pick out, so it is not just the small number you referred to out of overall. It is the high-risk part of the import that we are also looking at.

Mr. HIGGINS. Yes, and I appreciate that level of expertise and, of course, the dynamics of illegal imports or would include inspections beyond the biological and chemical realm. But according to a September 2017 GAO report titled, "Imported Seafood Safety: The FDA and USDA Could Strengthen the Efforts to Prevent Unsafe Drug Residues in Imported Seafood," a whistleblower has come forward indicating that a company called Choice Canning, an Indian shrimp exporter, has knowingly shipped antibiotic contaminated shrimp to the United States. Despite this, FDA data shows that only 21 shrimp samples from this company have been tested since 2003.

Just to put this in perspective, again, respectfully, sir, you have a massive job to do and limited resources. I respect that and I want to help. This company that I am referencing, the Choice Canning Company, which is a known violator, imported 24 million pounds of shrimp to the United States last year alone. So basically, imported seafood is coming into our country, and the billions and billions of pounds, very little of it is being actually inspected at the laboratory level for biological and chemical contaminants. And the reason we are not getting sick is because we cook the seafood, basically. That is the reality. So, I would like to ask you, if you had legislation from this body that gave you teeth in your enforcement, like the authority and mechanisms to destroy shipments that had been found to be contaminated, would that power be helpful for FDA enforcement of imported seafood that violates American standards for biological and chemical contaminants?

Dr. CALIFF. You ask the question in a specific way that I am reluctant to say just yes.

Mr. HIGGINS. Yes, you can say just yes.

Dr. CALIFF. What I would say is in the general direction you are going, I would say, in general, including this arena, the industries have, by and large, followed our ability to do what you described. It is not just true in the area that you mentioned, but, in general, I believe we would exercise our authorities responsibly and could more quickly take care. I mean, there is stuff which sits there for a long time given all the things we have to do in order to stop while it is coming in.

Mr. HIGGINS. Roger that. Thank you, sir. I am going to close by saying that my intention is to legislatively empower the FDA to have very aggressive responses to shipments of contaminated seafood that enter our country. Mr. Chairman, I yield.

Dr. CALIFF. Let me thank you for that. And I am a South Carolinian, and I think our shrimp is better than yours, but in any case, there is nothing I would like better than to see a resurgence of the seafood industry in the United States.

Mr. HIGGINS. Well, I have learned from a young man not to argue with a gentleman in a bow tie, so I will let you have that, sir.

Chairman COMER. The Chair now recognizes Ms. Stansbury from New Mexico for 5 minutes.

Ms. STANSBURY. Thank you, Mr. Chairman, and thank you, Dr. Califf, for being here today. It is wonderful to have you. I want to thank your staff for being here today as well, and I am grateful for the opportunity to highlight the importance of science and science-based decisionmaking in this hearing and all that you are doing to protect the American people to ensure that we have access to medicines that work, that we have food that does not harm us; and to ensure that every American can get lifesaving care, and also for your work and the Administration's support of our work this last Congress to pass once-in-a-generation legislation to expand access to healthcare, to invest in science and innovation, and, of course, to expand access to prescription drugs for our seniors.

The FDA is truly on the front lines of that battle every single day, and we are really grateful for the work that you do. And I will say on a personal note, I have a family member who was formerly an FDA employee, and you represent the best of the best that our country has to offer. And nowhere is this more important than in the realm of reproductive care where we have to continue to follow the science and ensure reproductive freedom, especially in the face of unprecedented attacks.

You know, as we have seen, Republicans in this body, in fact, in this room and across the country, have been working to ban abortion, first through Donald Trump's Supreme Court, which overturned Roe vs. Wade last summer, and then chipping away state by state to implement abortion bans, including where in Arizona, just this week, the Court has upheld a Civil War-era abortion ban. That is right. For folks that do not know this, this ban was put in place in 1864 before an end to slavery had been ratified by this body, before women could vote, and before Arizona was even a state. Let us be clear. No judge, no politician, no person should be able to tell any woman in America or anywhere in the world what she can do with her own body. And nowhere is this more important right now than in the U.S. Supreme Court, which we are all watching very carefully in the wake of their hearing of oral arguments in a case in which the FDA has been involved since the last couple of years over Mifepristone.

So, Dr. Califf, I want to ask you a question, if you could talk to us a little bit, not only about the implications of the decision by the Supreme Court, which we are expecting this summer, for women to access reproductive care through medicated abortion, but also what are the wider implications for FDA's ability to use science to approve medicines?

Dr. CALIFF. Well, thank you for the question. I have to note that since this case is under consideration by the Supreme Court, I am very limited in what I can say. I will say that we stand by our decisions. They are still in play today, and I will add that, you know, we do have concerns if judges start second guessing FDA decisions, about what that means for the broader area of having a rational system of availability of medications and devices for the American public.

Ms. STANSBURY. Right. So, the FDA approved Mifepristone to be used as a totally appropriate medicated way of addressing issues around reproductive care, and the broader implications are that if judges start legislating from the bench on this kind of medicine, it

could be anything. It could be cancer treatments. It could be any kind of medication or intervention in your health, and I think the American people need to understand the implications of this case, the potential impacts for public health and the ability for it to impact every American's opportunity to access life-saving care.

So, we appreciate your work. And I am personally thankful to be from a state, from New Mexico, that has worked to protect reproductive care. But, if the Supreme Court does overturn FDA's decision to approve that medication this summer, we could see a ban on medicated abortion across the United States, including in places like New Mexico, where it is protected. So that is why this body has to urgently take action, it is why we have to defend the science, it is why we have to sit here and defend our agencies who are making sure that American women and all people have access to the care that they need. And it is why we have to do everything we can to defend our institutions because the lives of our communities literally depend on it. Thank you.

Dr. CALIFF. Just a quick comment, if I may. Everywhere I go in the world, our system of drug development and decisionmaking is the envy of the rest of the world. They all want to be like us in that regard. As I have already commented, our use of generic drugs in public health is falling a little short now with our drop in life expectancy. But the system that you described is one that it is very important that we preserve in general, in addition to the topic you are specifically talking about.

Chairman COMER. The Chair now recognizes Mr. Perry from Pennsylvania.

Mr. PERRY. Thank you, Mr. Chairman. Thank you, Dr. Califf. I want to talk to you about the World Health Organization. And the——

Dr. CALIFF. I am sorry. My name is called all kinds of things. It is Califf.

Mr. PERRY. Califf, sorry. I am sorry. Sorry.

Dr. CALIFF. I have gotten a lot of different pronunciations here, but I am used to that.

Mr. PERRY. That wasn't an incorrect pronunciation. That was just plain damn wrong.

Dr. CALIFF. OK.

Mr. PERRY. I want to talk to you about this treaty, I think 185, maybe, plus nations, including places like Yemen, Iran, Iraq, Afghanistan, Cuba, Haiti, and some terms in that, we have not seen it. We have not seen the 30-plus amendments, so we are kind of shooting in the dark here. And I do not know that you know any more than any of the rest of it about it, you know, than we do, but there was another draft just last month that created a multilateral system for sharing pathogens with pandemic potential. I already listed some of the countries involved. It also commits each party, which would include us if we were signatories, to promote timely access to credible and evidence-based information on pandemics, and the aim there, I guess, is to combat misinformation and disinformation, I guess, as you see it or as they see it.

So, my question is, with the potential threat to U.S. sovereignty for decisionmaking on whether a pandemic even exists and the prescribed remedies, including lockdowns and maybe even medicating,

would you commit before the Committee today to pledge not to adopt policies included or pursuant to the treaty until such time and if such time as that treaty would be ratified by the U.S. Senate?

Dr. CALIFF. I am not sure how to answer that question given the complexity of what you said, but it is hard for me to imagine that we would do something at FDA that is not a government policy. Now, you refer to the Senate in particular. I am just not familiar enough.

Mr. PERRY. Well, if the Senate does not ratify it, it would not be a treaty that we would be signatories to, or at least not legally. And I just want some or to know if there is any intention on the FDA's part to institute any of the provisions within the treaty without the proper ratification from the U.S. Senate.

Dr. CALIFF. I do not think that particular issue would fall within our purview, so, and I do not know enough about it to make a commitment. But I will comment that——

Mr. PERRY. Sure.

Dr. CALIFF [continuing]. You know, if we just look at the avian flu situation we are in now, the knowledge of the molecular structure of whatever the pathogen is turns out to be really, really critical to come up with countermeasures to treat it, and so I hope we can work out a way. And then also, even for food safety, we talked about the imported food that we get the genetic composition of the pathogen turns out to be really important. So, I sure get what you are saying. We got to do this carefully, whatever we do, but I hope there will be a way that, for example, we do not get exposed to a new pandemic where we know nothing about the organism until it is too late.

Mr. PERRY. I think most people in America want to maintain their medical sovereignty, the individual medical sovereignty that we all enjoy. Regarding censorship, the CDC was involved in media companies taking down social media posts regarding misinformation and disinformation, again, terms that I think are loosely defined. But the FDA has been involved in this process in the past, having awarded several grants in the range of hundreds of thousands of dollars to places like the University of Maryland College Park, Texas Woman's University, regarding, again, misinformation and disinformation. Commissioner Califf, has the FDA coerced social media companies to take down users' social media posts regarding the pandemic or any other topic due to what they describe as myths or disinformation?

Dr. CALIFF. Not to my knowledge.

Mr. PERRY. Not at all to your——

Dr. CALIFF. Not to my knowledge.

Mr. PERRY. So, would you consider you are paying—If the FDA is granting-organizations, like the University of Maryland or Texas Women's University, to mitigate the spread of misinformation or disinformation, that is, essentially, subcontracting out that duty. You are saying the FDA has not done it, particularly, but have they done it indirectly through their surrogates or their subcontractors via the grant program?

Dr. CALIFF. I am not aware of the particular contract you are talking about, but let us remember that throughout the entire his-

tory of the FDA, the FDA considers data and information, makes a decision about a product, puts together the risks and benefits into a judgment as to whether it should go on the market. It is put in the label. The label is then transmitted to clinicians all over the country, who then work with their patients to make decisions about what to do. The sovereignty that you refer to is typically a patient-doctor relationship based on that information. Places like University of Maryland has a major, first-rate medical center. They are intermediaries in this process of relaying useful information. Now, if someone is saying something that is flat out wrong, you know, how that is dealt with by University of Maryland, that is their business.

Mr. PERRY. But, it also has the imprimatur of your approval, and when they are found out to have been wrong in the past for coercing social media companies to take down so-called posts that then were later found to be incorrectly done, where is the remedy, and is there an apology from the FDA? Is there an admonishment from the FDA to these universities that have been fast on the trigger and coerced and changed the narrative or changed behavior based on things that are not true?

Dr. CALIFF. Far be it from me to apologize for a university. I am a longtime university person before coming to FDA, but I think what the university does is the university's business.

Mr. PERRY. Well, understand it also is a reflection on the FDA. Mr. Chairman, I yield.

Chairman COMER. The gentleman yields back. The Chair now recognizes Representative Brown from Ohio.

Ms. BROWN. Thank you, Chairman, and thank you, Commissioner Califf, for coming before us today.

On March 15, 2023, Congresswoman Pressley and I wrote to you urging an investigation into the link between chemical hair straighteners and uterine cancer. I would personally like to express my gratitude to the Food and Drug Administration for your rapid response and dedication to addressing this matter. I am pleased the FDA has already taken immediate steps with the proposed rule to limit the use of harmful chemicals found in many hair straightening products. As you know, Black women experience scrutiny and discrimination regarding our hair, which has led to widespread use of these products. Black hair should not restrict our ability to learn in school or advance in the workplace, nor should our haircare products come with health risk. As the FDA finalizes this rule, I look forward to working together to ensure our consumer products remain safe for everyone.

Furthermore, I know you are hard at work to protect Americans in other ways, too. The Biden-Harris Administration and Democrats continue to fight to protect and preserve women's reproductive rights. The FDA's recent landmark approval of over-the-counter birth control moves us one step closer to reproductive freedom, even amid brutal, backward, and barbaric abortion bans like Arizona's and other attacks in reproductive health, including my own state of Ohio. Women must have the right to control when, if, and how to start a family. Increased access to safe and reliable contraception provides space for that decision to be made while putting control back in the hands of women. So, Commissioner Califf,

what have been the impacts so far of over-the-counter birth control hitting shelves across America?

Dr. CALIFF. Well, we are in the early phase of it, obviously, and there is always a lot to work out when something goes commercially because of pricing and all. But the availability, I think, as more manufacturers come on the market, given the precedent, we should see much more widescale availability so that people can use the products as indicated.

Ms. BROWN. OK. Thank you. And finally, one last issue I would like to touch on concerns a disease impacting far too many in the Black and Brown community. Roughly one in 8—1 in 8—Black Americans live with diabetes, while in my district of Cuyahoga County, the Black diabetes rate is over 25 percent, over 1 in 4. Certain FDA-approved weight loss drugs aid in obesity management for adults with weight-related conditions, like type 2 diabetes. For many, these drugs are lifechanging and lifesaving. Unfortunately though, these medications are often too unaffordable and inaccessible for those who need them most, especially uninsured individuals. So, Commissioner Califf, how is the FDA working to ensure these new, highly effective treatments are reaching populations who need them most?

Dr. CALIFF. Well, first of all, I appreciate your description of the problem, and there are special populations at much higher risk. You have referred to one. I would say rural people, in general, are also suffering greatly, and it is one of the main reasons that we are seeing this very troublesome decline in life expectancy. Right now, despite the fact that we are producing the majority of the innovations in medical products, we are almost in last place among high-income countries in terms of life expectancy and the disability and multiple chronic diseases that go along with it.

Unfortunately, our tools at FDA specifically are very limited for what you described because we are limited by law in dealing with price or of products when they come to market. This is a policy issue, though, for all of the administration and for Congress to consider. The one thing that we do that when we have a product, like a set of products like this, that looks so effective, so far, is working with the manufacturers to get more products on the market because the competition does bring the price down, but what you are referring to is most unfortunate in many ways. There is a saying that I love. It makes you feel bad in a way, but it was in the Atlantic during the pandemic, and technological solutions drift into societies, penthouses. Diseases seep into societies' cracks, and the problem is, here we have a highly effective treatment. Who is getting most of it? The wealthy and highly educated people. Who needs it the most? It is the people that you described who may have lower income and are in the need. So, this is a major policy problem. I am sorry, the FDA is limited in what it can specifically do, but I can assure you that, for example, CMS is thinking hard about what am I to do about this.

Ms. BROWN. Well, I thank you for your thoughtfulness, and I thank you for this work that you are doing, and I look forward to continuing and staying in a good contact with you. And with that, I yield the balance of my time.

Chairman COMER. The Chair now recognizes Mr. Palmer from Alabama for 5 minutes.

Mr. PALMER. Thank you, Mr. Chairman. Commissioner Califf, in your testimony, you said the use of CBD raises safety concerns, especially with long-term use. And you mentioned a couple of things that were problematic, including harmful male reproductive system exposure, particularly concerning for children during pregnancy. The FDA is engaged in monitoring the use of CBD. Is that correct?

Dr. CALIFF. It is a little complicated because CBD does not fall directly under any particular regulatory scheme that we have.

Mr. PALMER. Should it?

Dr. CALIFF. So, when people do report things to us, we note it, and we have had funding from Congress to study the problem from independent studies that have been——

Mr. PALMER. I appreciate that, but my question is, should the FDA be more involved in monitoring CBD because it is becoming extremely popular throughout the country.

Dr. CALIFF. We would very much like Congress to establish a regulatory pathway for CBD.

Mr. PALMER. Well, I have an article from the National Institute on Drug Abuse, and it talks about vaping. We also talked about vaping. I am not going to get into that, but I do have major concerns about the products coming in from China, but also have concerns about the lethality of vaping, whether it is tobacco or marijuana. And is that something that the FDA is actively engaged in monitoring?

Dr. CALIFF. To the extent that we can. Again, as we discussed earlier today, the regulation of marijuana is another area where we would benefit greatly from Congress reaching agreement on a regulatory pathway that enables the prevention of harm from being done.

Mr. PALMER. I am glad you brought that up because I agree with you. This body in the 1990's recognized that the tobacco industry had worked to increase the amount of nicotine in tobacco. Nicotine is not the carcinogenic that causes people to get lung cancer. It is the smoke, the tar, and the other things from inhaling the smoke. You have some of the same issues with marijuana, that there is tar and other things that are ingested into the lungs.

But the thing that concerns me about this as well is, and this Congress acted, I think, effectively in dealing with the tobacco industry in the 1990's. But what concerns me right now is that we are not doing anything, to my knowledge, to regulate what is going on in the marijuana industry and, particularly, the genetically modified products. In the 1960's, 1970's, 1980's, as I reminded my colleagues, THC content was about 2 percent. Now it is anywhere from 17 percent to 28 percent, and that is the addictive part of marijuana that affects the frontal lobe that impacts judgment. And what we are starting to see now, again, it comes in different forms. You do not just smoke it. You could take it as a gummy. You could get it as an oil.

And what is happening is more and more children are coming in contact with it. And there is a report from the National Center for Biotechnology Information that are found in one of the medical publications that says that in terms of addiction, 9 percent of those

people who just experiment with it become addicted, 17 percent of those who start as teenagers become addicted and anywhere from 25 percent to 50 percent of daily users. Is that another area where the FDA needs to engage because we see more and more states legalizing this? So, it is not a DEA problem. It is a consumer problem.

Dr. CALIFF. I believe that this is a similar area where harm reduction through a regulatory strategy is probably our best approach, and we need more research on exactly what the facts are. Remember that the tobacco industry was engaging in genetic manipulation, basically, going way back just through the old-fashioned Mendelian radiation of the plant, and then development of mutations that will lead to more and more nicotine in the product. And now we have chemical synthesis, which can imitate almost any of these in a highly efficient way, to produce the kind of effects that you described.

Mr. PALMER. Increase addiction.

Dr. CALIFF. So we are concerned and we would like see a regulatory pathway. We talked earlier about the fact for the most part, the FDA is a referee, and we need a rulebook and you guys write the rulebook, so we would really like to see a rulebook in this area.

Mr. PALMER. Commissioner Califf, I appreciate your answers. I yield back.

Chairman COMER. And I have to comment on that. We write a lot of rule books, that we have trouble with this administration complying with the rules like they sing to their own drummer there, but anyway, march to their own drummer. Anyway, the Chair now recognizes Mr. Frost from Florida for 5 minutes.

Mr. FROST. Thank you, Mr. Chairman, and good afternoon, Commissioner. Like many of my constituents, I am deeply concerned with the H5N1 avian flu outbreak. It has impacted birds, livestock. At least one person in Orlando lost several of our Lake Eola swans, which is in the center of my district. It is a symbol of our city. While it does seem clear that the avian flu is not currently able to spread easily among people, folks are still wondering about how safe they are. It is brought up a lot in my district. Commissioner, how is the FDA, in coordination with the Department of Agriculture and the CDC, ensuring that Americans have access to reliable and up-to-date information about this?

Dr. CALIFF. Well, thanks for bringing this up. It is a very important issue today. As you have noted, avian flu has been around for a while, but it is only recently that it has now infected cattle and now cattle and multiple cows in multiple states, and so this is really an all-of-government effort. There are Zoom conferences multiple times a day now involving FDA, CDC, Agriculture, as you said, but also many other areas of government that have a stake in the game of interstate commerce and Department of Justice and issues that are related. So, we are all working together, and you should see frequent communications as we work through this, remembering that the most recent episodes with the cows is a relatively new thing, so we are starting with a lot of uncertainty and working our way through it.

Mr. FROST. And since 2006, the Federal Government stockpiled antivirals designed to prevent severe illness and death from the flu. Will this medication be effective against avian?

Dr. CALIFF. Well, this relates to the discussion that we just had. It is very useful to know the molecular or genetic composition of the virus and in this case, if you look at the composition of this virus, there is nothing in it that should confer resistance to the current antivirals that we have stockpiled, so we feel good about that. I should note it is always the case when you have an actual illness, you have to empirically prove that it works, and so fortunately, right now, there is really only one infected human that we know of. So, it is not something that we can test, but it looks good at this point.

Mr. FROST. Thank you. I appreciate it, Commissioner. Another subject that is really important to me and it is personal to me are allergies. I am a survivor of anaphylactic shock just a few years ago that almost killed me. I also want to make sure that the other 20 million Americans with food allergies know that what they are taking or what they are eating is safe. A recent study found that 93 percent of all medicines contain an allergen, and many popular over-the-counter allergy drugs contain lactose. Do you believe that the FDA has the power to require labeling of prescription and over-the-counter medicines for food allergens and gluten?

Dr. CALIFF. We definitely have the power to require labeling when it is indicated.

Mr. FROST. Three years ago, President Biden signed into law the FASTER Act requiring labeling of sesame as a food allergy, and also requiring HHS to submit a comprehensive government report on food allergies within 18 months. That report has not yet been submitted, and it is very frustrating to Americans with food allergies and their families. Does this report fall under the responsibility of the FDA, and, if so, would you be able to provide an update on the status of it?

Dr. CALIFF. I will have to get back with you on that because I am not familiar with that particular report. But we are very familiar with the fact that allergies in the U.S. are apparently growing and that there is a great need to make sure we get this right.

Mr. FROST. OK. Yes, we would love to follow up on that. I think we even gave a heads up about that question so you could be prepared, but it is all right. We will follow up about it.

Mr. FROST. Thank you. I yield back.

Mr. PALMER. [Presiding.] The gentleman yields. The Chair now recognizes the gentlelady from Michigan Representative McClain for her 5 minutes of questions.

Mrs. MCCLAIN. Thank you, and thank you for being here today. Commissioner Califf, you assumed the Office of the Commissioner of the FDA in February 2022, correct?

Dr. CALIFF. That is correct.

Mrs. MCCLAIN. Thank you. When you assumed office, were you aware that a manufacturer who made more than 40 percent of the country's infant formula was voluntarily recalling all the baby formula it made at its Sturgis plant?

Dr. CALIFF. I was very familiar because it happened on the day I was confirmed, so I did not know before——

Mrs. MCCLAIN. So yes, thank you. So, I will take that as a "yes." In the days and weeks that came after you assumed office, were you aware that there was a shortage of infant formula across the country?

Dr. CALIFF. Well, in the first days and weeks, there was not a shortage, but as the shortage evolved, I was very much aware of it.

Mrs. MCCLAIN. So yes, thank you. Were you aware that 10 states reached rates of over 90 percent of out-of-stock and nationwide, 74 percent of stores had no infant baby formula?

Dr. CALIFF. Those numbers do not sound right to me, but there was a lot of out-of-stock and absence of formula.

Mrs. MCCLAIN. Directionally, what do you think they were? Could you say we were reaching crisis mode, or we were just like short one or two cans?

Dr. CALIFF. It is closer to crisis and sure wanted to——

Mrs. MCCLAIN. OK. Thank you. Mr. Chairman, I would like to enter into the record two internal email exchanges within the FDA, the first dated February 4, 2022, in which the FDA officials are discussing the potential for infant formula supply issues and asking for media support from the White House to educate the public; the second on February 19, 2022, in which the FDA officials were discussing the supply issue that were already happening.

Mrs. MCCLAIN. Now, despite these discussions within the FDA, media reports, the President was not aware of the problem, even though it was headlining in nearly every news channel and every paper across the country for 3 months. So, my question is, did the FDA not raise concerns about the potential shortage even before the recall?

Dr. CALIFF. As you know, there is a record that says there was a supply disruption task force that was put up during the COVID crisis. It was also used for this purpose, working to——

Mrs. MCCLAIN. So, it was elevated?

Dr. CALIFF [continuing]. To the task force which has——

Mrs. MCCLAIN. Did the FDA raise concerns about a potential shortage even before the recall? Yes or no.

Dr. CALIFF. I cannot speak for before the recall, but at about the time of the recall.

Mrs. MCCLAIN. OK. Well, let me help you because I can tell you the FDA did, in fact, raise the issues to at least nine different White House officials, and President Biden took no action. So, I would like to enter into the record an email between the FDA and the nine White House staff, including members of the National Security Council, Domestic Policy Council, and the Special Assistant to the President for Public Health.

Chairman COMER. [Presiding.] Without objection, so ordered.

Mrs. MCCLAIN. Thank you. This email dated February 17, of 2022, which was the day of the voluntary recall, shows the White House in communication with the FDA about the recall. So, I am just helping you out there.

Mr. Chairman, I would like to enter another email into the record, an email dated February 20, 2022, just 3 days after the voluntary recall, which shows the FDA Chief of Staff already raising

concerns about infant formula shortages and communicating this concern with the White House.

Chairman COMER. Without objection, so ordered.

Mrs. MCCLAIN. Commissioner, here is my question. Why did it take 3 months for President Biden to invoke the Defense Protection Act?

Dr. CALIFF. I cannot speak for President Biden and that particular decision. I will note, as I have already said, you know, I do not have the emails that you are referring to, but——

Mrs. MCCLAIN. I will get them to your office, and I will promise you I will get them to you in a timely fashion. I guess, my question is——

Dr. CALIFF. But this evolved over time, so the exact timing of when the DPA should have been brought in is something that is a matter of discussion.

Mrs. MCCLAIN. "A matter of discussion." That is your answer. I mean, so your office has been in communication with nine White House staffers. Either the FDA did not tell him or he did not act. Which is it?

Dr. CALIFF. Yes. I think you have the emails, and I cannot really comment beyond that.

Mrs. MCCLAIN. Well, you know, what baffles me is you make about $200 grand. You are supposed to be in charge, but when the you-know-what hits the fan, everybody runs for the hills. I am going to switch topic.

Dr. CALIFF. Well, just hold on a minute. I——

Mrs. MCCLAIN. It is my time, sir, when asking about its handling of this is unbelievable. I mean, you do not have an answer. I would love to have an answer, but I am going to switch gears.

Dr. CALIFF. Well, you overestimated my salary, which is——

Mrs. MCCLAIN. It is about $191,000, so that is pretty close. But, Commissioner Califf, it costs millions of dollars to prepare premarket tobacco product applications, "PMTAs." Manufacturers have had products pending at your facilities for years. I know we have talked about this, and you know the concern of all the illicit and illegal products coming over from China. When do you anticipate getting some results from these American companies that have actually been waiting for over 4 years on their tobacco products?

Dr. CALIFF. As we have already discussed, we are 99 percent done with almost 27 million applications. We have, you know, 1 percent left to go. These are big decisions, and they are going to be rolling out. We expect to be caught up, for example, with the ones that are largest from the American Pediatric Group that follows us by the end of this year.

Mrs. MCCLAIN. Wonderful. Thank you, sir. I yield time.

Chairman COMER. The Chair now recognizes Representative Lee from Pennsylvania.

Ms. LEE. Thank you, Mr. Chair. As we have discussed today, the FDA has a critical responsibility to ensure that our food supply, medications, and medical products are safe and effective, but the FDA does not hold this responsibility alone. The Agency does not have the resources to singlehandedly ensure the integrity of every product produced by every food, drug, and device manufacturer.

The private sector also has a critical role in ensuring that their products are safe, a responsibility that they need to take seriously.

Recent reporting has uncovered how Philips Respironics, a Pittsburgh-based company and one of the largest medical device manufacturers in the world, received hundreds of complaints about its CPAP machines and ventilators prior to issuing a recall in 2021, a recall that ended up being one of the largest in history. Not only did the company receive hundreds of complaints from hospitals, providers, and patients as far back as 2010, but its own internal evaluations indicated their machines were toxic, yet the company withheld this information from the FDA and the public for more than a decade. They continued to sell these hazardous machines enabling their stock prices to soar to the highest levels in decades while the most medically vulnerable in our communities—our infants, our seniors, our veterans—suffered. In Pennsylvania, there are now more than 700 personal injury lawsuits and class actions against the company due to irreparable harm its devices caused patients. Philips is one of the most egregious examples of what can occur when corporations do not take their responsibility to public health seriously.

From COVID–19 vaccine manufacturing failures to dangerous levels in children's applesauce products, we have seen the private sector repeatedly fall short. Dr. Califf, what is the private sectors' responsibility in ensuring that medical devices that are brought to the market are safe and effective?

Dr. CALIFF. As we have discussed multiple times today, the primary first line responsibility is with a regulated industry. This is a situation in which we oversee the industry, but the industry has that primary responsibility to produce safe and effective products, whether it is a device, a drug, or a food.

Ms. LEE. So, what investigative action or enforcement actions does the FDA have, or does the Agency need to hold companies like Philips accountable for regulatory noncompliance and to deter future wrongdoings?

Dr. CALIFF. This has come up with regard to almost every commodity now, that it would be better for public health, I believe, if we had direct recall capabilities across the spectrum of products that we regulate when we find problems, such as you are referring to. I would also like to see a bulking up of our post-market surveillance capabilities. After all, every American has an electronic health record now, and there is a lot that we can do so that we find out about these problems earlier than we currently are. And we need to make sure the manufacturers actually report in a timely fashion when they do get problems that they are aware of.

Ms. LEE. So, over the years, the FDA has promised to overhaul the way that it detects dangerous medical devices by allowing more real-time data and medical registries. What progress has the FDA made toward those goals?

Dr. CALIFF. Well, you know, this is actually work that I have been involved in, in my academic life, for 30 years. So, if you just think about it, everyone has an electronic health record. Every important medical transaction essentially is digitally captured now. We have multiple blocks in the system that keep us from putting the data as best we can, so we are very dependent on voluntary

registries where either companies pay for it or health systems pitch in, and then the FDA buys the data.

I am pleased to say there is a lot of discussion with NIH and other parts of HHS now about having better data pooling capabilities, so that we know about these things in real time. And we now have a model globally where it is happening in Israel, where 100 percent of the population has real-time electronic health record accessibility to detect problems but also, importantly, to find advantages. Sometimes there are surprises where something works better than expected, but right now we do not know about it in real time.

Ms. LEE. OK. Looking at the time, I already know that I am not going to get through this next question, so I want to respect yours and my colleagues' time and yield back.

Chairman COMER. The Chair now recognizes Mr. Burchett from Tennessee for 5 minutes.

Mr. BURCHETT. Thank you, Mr. Chairman. Thank you, Commissioner. I appreciate you doing all of this without a bathroom break, so it is great admiration for you there. I have a question about the 2018 Farm Bill. It is about the cultivation, sale, and transportation of hemp-derived products. Since 2018, what regulations has the FDA put in place regarding hemp-derived products?

Dr. CALIFF. Well, I mean, we have a law from you all defining hemp as less than 0.3 percent THC, and you have given us money to study the problem, and our conclusion, as it relates to human health, is they are not safe enough to be called a dietary supplement or a food. And so, we have asked Congress to put together a regulatory pathway that will be appropriate so these products are available, but they are labeled, they are identified. And in cases, for example, gummy bears packaged for children, there is a way for us to take action quickly in those situations.

Mr. BURCHETT. Have any outside groups requested that the Food and Drug Administration regulate hemp-derived products?

Dr. CALIFF. Yes, we have had multiple citizens petitions, but as I have said, the requests have been to regulate these as dietary supplements, and they do not meet the definition of a dietary supplement because of elevated liver enzymes and other health problems that we believe make them unsafe as supplements. But they could be regulated in other ways and made available if Congress thinks that is the right thing to do.

Mr. BURCHETT. Are you an M.D.? It is not in my notes, but you were saying some medical things there, and I am curious.

Dr. CALIFF. I am a board-certified cardiologist, 35 years of intensive care unit and outpatient practice, sadly, not practicing right now.

Mr. BURCHETT. Yes, sir. So, you would question whether we have a heart then if you are a cardiologist. Is that correct?

Dr. CALIFF. Let us just say the heart and the brain are two different things.

Mr. BURCHETT. Let the record reflect that our commissioner is punch-drunk from being up here so long, but thank you, brother.

I am concerned about hemp, and I will tell you why. It is not in my notes, and it always makes my people nervous when I do this, go off the thing. My daddy fought in the Second World War, and

I can remember and I have seen videos of, you know, "help us grow hemp to save the world." You know, they have made rope out of it, and then, of course, it is a cousin of marijuana, but it does not have the THC level. And they come down here and we passed this thing in the Farm Bill, and all of these folks that want to grow hemp, they all say, "Oh, we have got the greatest thing in the world." But dadgummit, I am a United States Congressman, and I have got a little farm, and I checked into growing hemp. It is not going to make you a fortune, but I have to get a dadgum fingerprint to do it.

It just seems to me that the big boys in the cotton industry, and I am sure they will be rushing up to my office right after I say this, but they wrote these dadgum regulations. You and I both know it. They do not want the competition. They do not want hemp in there. You can watch the videos. You know, these people say it is not the miracle that they claim it is because there is a huge labor factor involved in it, and it really ticks me off that these folks have been fed this bill of goods, and, you know, it is just not happening. It is not happening like it should. And I am wondering, have you, anyone, you and your office had any meetings with the cotton industry officials in which hemp-derived products were mentioned?

Dr. CALIFF. I am not aware of any meetings for the cotton industry. That would be an unusual industry for us to meet with, but——

Mr. BURCHETT. Due to the fact that you are not ingesting it, correct? OK. Well, you see that is another problem with the product. It goes to two different, separate groups, and so I think that is by design actually, the way, so that it keeps it more complicated. Are you aware in the first 2 years of the Biden administration that the value of hemp production in the U.S. decreased by 71 percent? No?

Dr. CALIFF. Not aware.

Mr. BURCHETT. OK. I will get away from the hemp thing, and I have only got 30 seconds. The Center for Tobacco Products, I feel like they have continued to not tell the truth in some cases to the American people. They tell us that vaping is harmful or more harmful than cigarettes, yet—let us see—Dr. Nancy Rigotti of Harvard concluded U.S. health agencies and professional medical societies should reconsider their cautioned position on e-cigarettes for quitting smoking. The burden of tobacco-related disease is too big for potential solutions such as e-cigarettes to be ignored. Would you say that that is—I am out of time, but you get where I am going at—is it more harmful than cigarettes if is not over-used, if it is not abused?

Dr. CALIFF. Here is what I would say. Combustible tobacco kills people. I was just over in the U.K. because we are having a regulator. I went to Oxford, where Sir Richard Doll did the British doctor study, the doctors who smoke died 10 years earlier than the ones who did not. Vaping—if combustible tobacco didn't exist, you would be horrified by what is in the residue from vaping. When you think about that going into your lungs——

Mr. BURCHETT. Sure.

Dr. CALIFF [continuing]. Over the course of decades, it is pretty horrifying, but it is much less toxic in terms of all the things that cause cancer and heart disease, the vaping, then the combustible

tobacco. So, that is why the term has been used, "harm reduction," to say if you have got someone using combustible tobacco, they are a lot better off if they are vaping, at least by those criteria, but compared to using neither, there is no question that there is no benefit of vaping other than if it helps you get off of combustible tobacco.

Mr. BURCHETT. Tobacco is the one product, if you use as directed, will kill you. So, I apologize, Mr. Chairman. I went way over. Mr. Raskin, I apologize to you, too, brother. Thank you, guys. Thank you, sir.

Chairman COMER. The Chair now recognizes Mr. Garcia for 5 minutes.

Ms. GARCIA. Thank you, Mr. Chairman. Well, thank you, Dr. Califf. I appreciate you being here and all your work and the work of the FDA. I was going to talk a little bit about a different topic, but I just want to clarify some of the truly insane attacks on vaccines and just what happened during the pandemic that we heard a little bit earlier today, which I found to be really wild. I just want to reiterate that during the pandemic, we lost 1.3 million American lives. In my city alone, we lost almost 1,300 lives back home in California in the city of Long Beach, and we know that many of the folks that we lost would have lived if they had had access to the vaccine or had been vaccinated. We know that for a fact. We know the success of vaccines, and certainly, today, with more data, we know how effective they have been.

What is concerning now, as we know, is early childhood vaccinations are reaching new lows. We are having other diseases come forward, like measles and other diseases, that we are now not addressing because all of this vaccine denial that is happening, unfortunately, not just across this country, but also here in Congress and in this chamber. Vaccine hesitancy outside of what happened to COVID–19 is going to cause this country great harm. And instead of doing the responsible thing, earlier today, we had folks on the other side attack vaccines with, in my opinion, conspiracy theories and with treatments that we know are ineffective and have shown not to work.

We also know this is not just a matter of personal choice. Across the country, there are millions of people who do not have the choice, who cannot get vaccinated because it might be too young, they might be immunocompromised or have other underlying health conditions. And so, America's high vaccination rates is something that has helped our country for so long that the FDA has been so involved with, and it is very concerning that our vaccination rates and our vaccine process is being attacked. I also want to note that there have been comments made over and over again about vaccines, about somehow vaccines causing turbo cancers or vaccines causing miscarriages or that the COVID vaccine somehow has no effect on healthy people, that are all false. And I know that you know this, your team knows this, and I just want to reiterate that for the public.

What I did want to say, and I have less time to do so, but I want to just to transition and just thank you and your team for what you are doing as it relates to listening to the LGBTQ+ community, myself as an openly gay person. I really appreciate the FDA's move

and decisions allowing particularly gay men to be a part of the solution. When it comes to health, when it comes to blood donations, when it comes to other forms of surrogacy, the FDA has really stepped forward and especially on the recent change in guidelines as it relates to the LGBTQ+ Americans and gay men being able to donate blood. I think that as a gay person, it is comforting to know that if there was an emergency where my blood or other blood was needed, that we would have that same right, and thanks to all of you.

Dr. Califf, in the time I have remaining, could you describe the FDA's draft proposal and how this helps advance equality while also expanding the donor pool as relates to the recent changes you are all making?

Dr. CALIFF. All right. Simply, first of all, let me just say I appreciate your comments. Just back on the vaccines, just one point I want to make, all medical interventions have risks as well as benefits. In the earlier discussion, if you want to be alive and not be in an intensive care unit, you are better off getting vaccinated. There are some people that have side effects, I just want to note that because it is important to take care of those people also, but the benefits far outweigh the risks.

Simply put, the question that you asked, people had raised this issue about donation for many years, and we did a study which showed that a questionnaire about behavior can do much better than just the time-based thing related to the LGBTQ community. So, we are well along in that now, and it looks like it is really going to work, and we will be consistent with what other countries are doing. So, we are really glad we were able to come to this conclusion.

Mr. GARCIA. Great. Well, thank you very much for your work and for your team's work. I yield back.

Chairman COMER. The Chair now recognizes Mr. Fry from South Carolina.

Mr. FRY. Thank you, Mr. Chairman. Commissioner, thank you for being here. Congress enshrined harm reduction as a kind of a pillar in the 2009 Tobacco Control Act. The FDA's 2017 strategic plan embraced that harm reduction with the former FDA commissioner, noting that successfully implementing harm reduction could dwarf the introduction of any new medical technology and its positive impact on our public health. Unfortunately, the Center for Tobacco Products' current leadership under the Biden administration seems to have abandoned harm reduction as a foundational principle of its tobacco policy by refusing to authorize other tobacco products that have been pending before your Agency for years. Your Agency is failing to acknowledge the need for real change to provide better options for 28 million American smokers.

A recent study from Yale University found that for every 0.7 milliliters of e-cigarette, e-liquid that goes unsold due to flavor restrictions, 15 additional cigarettes are sold. It was also found that e-cigarette flavor restrictions in place for at least a year yielded 20-percent increases in sales of cigarette brands disproportionately used by underage smokers. Can you explain why the FDA and the CTP have authorized 900 new cigarettes in the time that it has authorized only a handful of vapor products?

Dr. CALIFF. First of all, we have not abandoned the principle that you described, but it is a little more complicated than that. It is the responsibility of the company to produce a data set that shows that the benefits of combustible tobacco reduction exceed the risks due to getting teenagers addicted. Vaping products get people addicted to nicotine if it is a new user, so we have always got to balance that risk of getting millions of teenagers addicted to the benefit to adults with combustible tobacco. So, there are 23 products now in the market that have met that standard, and other companies are welcome to submit their data and produce the data showing that they meet that public health standard.

Mr. FRY. Does CTP still believe in the continuum of risk of nicotine products, and does the FDA think it is helpful for adult smokers who would otherwise continue smoking cigarettes to switch from combustible cigarettes to smoke-free alternatives? Yes or no.

Dr. CALIFF. There is not a "yes" or "no" answer to that because for adults, the best thing to do is to stop using tobacco products altogether. The second best would be to switch to a vape, but the very best would be, as we already discussed, if you look at the residue from vaping relative to no use of any tobacco product, it raises a number of issues over the long term.

Mr. FRY. I think the concern that I have, sir, and I think the concern that many people share is that there seems to be an abandonment of a congressional, not only a directive, that we are going to pursue harm reduction as an actual strategy in the country. And if you have 900 cigarettes that have been approved and only a handful of vape or other products, that seems to be divergent to what Congress has outlined for your Agency. Would you not agree with that?

Dr. CALIFF. I am not familiar with the 900 term, so I would have to go back and look at that, but we have not abandoned the idea that the company should show that it can successfully transition people from combustible tobacco to vaping in a way which does not increase the risk to teenagers of getting addicted to nicotine and, therefore, being susceptible to switching to tobacco.

Mr. FRY. So, in addition to vaping, you have other products like Zyn or something similar to that. Would you consider that to be a harm reduction product?

Dr. CALIFF. You know, we discussed this earlier. The term, "harm reduction," tends to be used by industry to cover a lot of different areas, but if there is a product that can cause someone to stop using combustible tobacco and not get teenagers addicted to nicotine, that is a benefit.

Mr. FRY. Commissioner, you know, reading about the FDA, there seems to be some pretty heavy backlog within the Agency. How are you utilizing your workforce to innovate the FDA, and what type of metrics are you using to make sure that you are being productive not only for companies that have products that go before you, but for the American people?

Dr. CALIFF. As we discussed earlier today, I think everyone was surprised by the over 26 million applications that came in, and there was a big backlog, and we have now cleared 99 percent of that backlog. But just like all other parts of FDA, when applications come in, we keep track of where we are, and as we are em-

ploying better technology and we are just going through some organizational changes, you are welcome to read the Reagan-Udall report that we commissioned to guide us there. So, we are hard at work. We want to meet the timelines like we do in all the other product areas, and we are going to do that as fast as we possibly can. You make a good point there.

Mr. FRY. Thank you, Commissioner, and thank you, Mr. Chairman. I yield back.

Chairman COMER. The Chair now recognizes Ms. Pressley from Massachusetts for 5 minutes.

Ms. PRESSLEY. Thank you, Commissioner, for joining us today. First, let me just also acknowledge and thank you for your responsiveness and your swift action on my outreach to you regarding formaldehyde in chemical hair relaxers, also the shortage of children's Tylenol and Motrin. Personally, as someone living with alopecia totalis, I also appreciate your efforts in that regard, and finally, for the purposes of my question line today, reproductive justice.

Dr. Califf, last year the FDA took pivotal steps to protect medication abortion access, including by allowing abortion pills to be prescribed by telehealth and distributed by retail pharmacies. Medication abortions accounted for 63 percent of all abortions performed in the United States last year. If mifepristone is pulled from the market, access to routine medical care would be jeopardized for people across the country. As part of their draconian, unpopular goal for a national abortion ban—let us call it what that is—forced birth, which for many will result in forced death, Republicans continue to try to block access to medications, like mifepristone, by spreading baseless conspiracy theories. The fake news is rampant.

I have a teenage daughter, and we like to play a game called "Two Truths and a Lie". So, if you will indulge me, we are going to do some variation of that right now. I want to use my platform to clarify some of this disinformation by playing a game called "Fact or Fiction". Dr. Califf, I will say a statement and you will reply with just one word stating if it is fact or fiction. Let us start with this. Fact or fiction: the FDA conducted a rigorous review of extensive research on mifepristone.

Dr. CALIFF. Fact.

Ms. PRESSLEY. Correct. That is a fact. Mifepristone has been on the market for almost 24 years, and more than 100 studies have affirmed its safety since. Fact or fiction: judges know better than public health experts if medication abortion is safe.

Dr. CALIFF. I cannot comment directly on that because the Supreme Court is currently adjudicating a case that involves it. But I am on record, and so are all of us, that it would be bad for the entire system of drug development and availability of medications in the United States if judges begin overruling the FDA as a matter of routine.

Ms. PRESSLEY. Thank you. So that is fiction. The FDA, not the courts, determines the safety of drugs. Fact or fiction: mifepristone as a form of medication abortion is safe and effective.

Dr. CALIFF. Fact.

Ms. PRESSLEY. Correct. That is fact . Research shows that less than 1 percent of patients experience serious side effects, posing

fewer risks even than Advil or Tylenol. The facts are adding up. Mifepristone is a safe, effective, and routine form of healthcare that remains necessary and legal across the Nation. Now, this may be a game for today's hearing, but unlike Republicans, I have no interest in playing games with people's lives, and this is gravely serious. For many, especially black women, pregnancy and childbirth can be life threatening.

Now, I know this is a shock to the far-right extremist old white men making these decisions, but there are hundreds of reasons why someone might want or need to terminate a pregnancy with medication abortion, and policymakers and judges should not be the ones making decisions for them. If Republicans and anti-abortion extremists have their way, access to mifepristone will be cut in every state, blue or red, even in my district, the Massachusetts 7th, where abortion care is legally protected. Since I have been elected to Congress, I have been proud to lead the Abortion Rights and Access Task Force under our Pro-Choice Caucus, fighting alongside my colleagues for mifepristone access. I will continue to fight to affirm abortion care as the fundamental human right that it is, and I urge my colleagues to do the same. Thank you, and I yield.

Chairman COMER. The Chair now recognizes Mr. Burlison from Missouri for 5 minutes.

Mr. BURLISON. Dr. Califf, in May 2022, you made an appearance on CNN and claimed that the leading cause of death in the United States is "misinformation." Do you recall being on that interview? Do you recall making that statement?

Dr. CALIFF. Yes.

Mr. BURLISON. OK. You are right because the claim that you went on to say that in COVID, that you need to get vaccinated, saying, "Somehow the reliable, truthful messages are not getting across, and it is being washed out by a lot of misinformation, which is leading people to make bad choices." Now I would like to draw your attention to a tweet that I know that you are familiar with. On the post forward, it says, "You are not a horse. You are not a cow. Seriously, you all, stop it." Another sarcastic tweet from the FDA read, "Hold your horses, you all. Ivermectin may be trending, but it is not authorized or approved to treat COVID–19." The FDA put out these messages in 2021 and made similar posts on the other platforms to discourage people from using ivermectin to prevent or treat COVID. In January 2022, the FDA was sued by a number of doctors who claimed that you are practicing medicine as an organization. As part of that settlement, you were forced to delete these. Is that correct?

Dr. CALIFF. That is correct.

Mr. BURLISON. So, in fact, the U.S. Court of Appeals said the FDA is not a physician, and even tweet-sized doses of personalized medical advice are beyond your statutory authority. Is that correct?

Dr. CALIFF. That is what the court said.

Mr. BURLISON. Pretending that ivermectin is dangerous or claiming that it is horse medicine, would you not agree that that is the exact definition of misinformation?

Dr. CALIFF. I would not agree with that. There are very well-done randomized trials showing no benefit of ivermectin.

Mr. BURLISON. And you knew that in 2021?

Dr. CALIFF. I was not at the FDA.

Mr. BURLISON. No, you did not know that in 2021.

Dr. CALIFF. I mean, I was not at the FDA in 2021.

Mr. BURLISON. Dr. Califf, I will ask the questions. Even to this day, you have to correct misinformation about ivermectin. Let me ask this. Ivermectin won the Nobel Prize, did it not?

Dr. CALIFF. It won the Nobel Prize for the treatment of worms.

Mr. BURLISON. In humans. In humans, right? And next to penicillin and aspirin, it is considered one of the wonder drugs for use and its effectiveness in humans, correct?

Dr. CALIFF. For treating a variety of infections that would commonly be known as worms, not for COVID, and it is a medicine for animals also. Both are valid uses.

Mr. BURLISON. Yes. At the end of the day, you created, in my opinion, and I think that it is obvious because you are still to this day having to correct people who think that a form of treatment that has been used how many times would you say, historically, has ivermectin been successfully used in medical treatments?

Dr. CALIFF. Successfully used for worms, but no effective treatment for ivermectin——

Mr. BURLISON. It has been administered in humans billions of times over the last, what, 30 years, correct?

Dr. CALIFF. Again, for the treatment of worms.

Mr. BURLISON. Dr. Califf, let me ask this. Do you think that tweets like this garner credibility to an organization like the FDA? Do you think that snarky tweets that I would think that my teenage daughters might write, do you think that that garners credibility with the FDA and the American people?

Dr. CALIFF. I cannot really comment on that, and, again, I wasn't at the FDA when that tweet was put out.

Mr. BURLISON. Well, I am glad that the courts told you to remove these tweets because it is snarky. I think it is demeaning to the American people and certainly demeaning to people, I believe, in my district. Thank you, Mr. Chairman. I yield the rest of my time.

Chairman COMER. I am going to try to get a quick question in here, Commissioner. You had mentioned in a previous question, talking about hemp-derived CBD oil, that is non-THC or 0.3 or less. You mentioned that you didn't think the FDA could ever approve that as a nutraceutical. Is that the FDA's position or not because there are a lot of people in the industry, in the hemp-derived CBD industry, that believe that CBD should be treated as a nutraceutical just like supplements and vitamins at GNC and Vitamin World and places like that.

Dr. CALIFF. You are correct, and we have had a number of citizens' petitions from people that have had that belief. But the research shows, for example, elevation of liver enzymes, which are very concerning, that if people take this over time, that there is going to be damage to the liver, which could lead to things like liver transplants.

Chairman COMER. And I have to say this, and I have seen this in Kentucky with many different CBD manufacturers, there is a big difference. They are CBD entities. Because it is the wild west because the FDA will not regulate this product, there are compa-

nies with labs that would be as good as anything that Merck or Johnson & Johnson would have, and then there are people operating out of the garage of their house. So, the reputable CBD manufacturers in America, I believe, strongly hope that the FDA will come in and not just take samples because these companies are not all the same. You agree with that, right?

Dr. CALIFF. I would say that is a characteristic of every industry that we regulate, and often the good players are penalized because of things that the bad players do. I come back to the referee analogy. That is where a good referee can be very helpful, but the referee needs a rule book that says here are the rules, and you guys write the rules, so we would really like it if we had a set of rules.

Chairman COMER. I am trying to play a small role in that moving forward, but thank you. Now, the Chair recognizes Ms. Crockett from Texas for 5 minutes.

Ms. CROCKETT. Thank you, Mr. Chair, and Dr. Califf, thank you so much for being here. You are a brave man. I do not know who would want to sign up for your job, especially in a time in which it seems like we do not believe in science or we do not know what data is or we are just going to ignore it. I am not really sure. I do not know how long you were asked about ivermectin. And let me tell you something. I do not know if you have ever testified in court, but you will be a great witness because you refused to answer the way that he wanted you to, which would have been, again, putting out misinformation because I do want to do a quick level set on something, and I do not know how we continue to come back to this, but let me just ask you a few questions. Was COVID–19 real?

Dr. CALIFF. Yes. I had it myself twice. I think twice, once or twice.

Ms. CROCKETT. Did people die?

Dr. CALIFF. Just in the U.S. alone, over a million people. It was in the top three causes of death for many months. You know, I was an intensive care unit doctor. When I came to FDA, I stopped practicing, but my friends in ICUs were overwhelmed. Hospitals had to have trucks backing up to the hospital because there wasn't enough room for all the dead people.

Ms. CROCKETT. And did vaccines save lives?

Dr. CALIFF. Yes. Thank you for asking that again. People that are up to date on their vaccines have a significantly lower risk of being dead or admitted to an intensive care unit compared to those who are not up-to-date on the vaccine, and worst of all are people not vaccinated at all. That is true on the individual level. If you look at counties in the U.S., the counties with a higher vaccination rate have lower death rates from COVID. If you look at countries, you see the same general relationship. So, the vaccines have been highly effective.

Ms. CROCKETT. Thank you so much.

Dr. CALIFF. Not perfect, but highly effective.

Ms. CROCKETT. I understand. I do not know that there is any perfection. I know that there is none in this chamber. Nevertheless, as a result of an administration that believes in science and data, we now have ARPA-H, which ARPA stands for Advanced Research Projects Agency for Health, and my district, luckily, was the recipi-

ent of an ARPA-H customer experience centers. And I am so excited because this means that as we are looking at trials, as we are looking at diversifying them, we will have a great opportunity right there in Texas 30. It is a huge investment in science to make sure that we can save lives and when the next pandemic arrives, we will actually be prepared and have science so that we can stay on top of this because the last time I checked, and, Doctor, correct me if I am wrong, having a leader suggest that we should inject bleach, are you aware of anyone being cured of COVID–19 because they injected bleach into their body?

Dr. CALIFF. I am unaware of any such thing. If I might comment in general, and this relates back to the discussion about ivermectin, I came along when no one knew what caused a heart attack. That was what I focused on. We tried 100 different things for the treatment of heart attack. Only a couple of them worked. The others did not. And the only reason we knew what worked is we went from the idea to doing a well-conducted study, a randomized trial, and then if it worked, then all the practitioners began to adopt it and use it. So, we now treat heart attacks by going to the cath lab, opening the artery, and some medicines that work.

Ivermectin has been studied multiple times in randomized trials. No benefit, but it is highly effective for the treatment. I use the word "worms" as a generic term for the kinds of infections that typically occur in places like Asia that can be devastating. It got a Nobel Prize because it is effective for those, and it has been a lifesaver, but it has been ineffective in COVID.

Ms. CROCKETT. I completely understand. The last area that I am going to touch on in my last 45 seconds, because I am a woman out of the state of Texas, there is no way that I am going to have a conversation and not talk about reproductive access. So out of curiosity, would you consider the medical management of a miscarriage to be potentially a lifesaving usage. Yes or no.

Dr. CALIFF. I have to decline to answer that because it is currently under adjudication by the Supreme Court.

Ms. CROCKETT. That is perfectly fine. That is perfectly fine. I am going to tell you yes, but I am going to give you another question that you can answer. Would you consider erectile dysfunction as a lifesaving usage for Viagra?

Dr. CALIFF. Not lifesaving.

Ms. CROCKETT. Not lifesaving. OK. Well, I am going to tell you that based on my research, that mifepristone actually has lifesaving characteristics, yet Viagra does not, and for those that do not know, Viagra, from my understanding, is actually nearly 10 times greater as it relates to risk of death, yet for some reason, it is not sitting in the court right now. And I do appreciate the fact that you laid out that when it comes down to getting drugs approved, they actually go through trials. It is not just randomness.

You take the randomness, you then say maybe there is some evidence here, and then you put it through the wringer. After putting it through the wringer for decades, women's lives have been saved, and as a representative from the area that Roe v. Wade actually initiated, I am appalled because for whatever reason, some people want us to go back to horse and buggy in this country. And I think, since now maybe we have the internet, maybe we should take ad-

vantage of it, and we should not say that we should remain in the times of horse and buggy.

And so, with that, thank you for the work that the FDA does. I respect your research. I recognize that the courts do not do research. I also recognize that this chamber seemingly does not care about research, but because of the work that you do, there are lives that are being saved, and I need you to be funded to the fullest extent to make sure that we can continue to save American lives. Thank you.

Chairman COMER. The Chair recognizes Mr. LaTurner from Kansas.

Mr. LATURNER. Thank you, Mr. Chairman. Commissioner, thank you for being here today. FDA holds the responsibility of ensuring the safety and integrity of our Nation's food, drugs, and consumer products, a responsibility that not only impacts our economy, but also the health and well-being of every American citizen. However, this FDA has failed to meet its mission statement and is defined by crisis from persistent drug shortages to the most significant disruption to the infant formula market in history. We cannot afford to overlook these critical failures. The well-being of all Americans depends on it. Commissioner, I look forward to hearing from you today on how to address these pressing issues.

Despite the backdrop of food and product safety issues plaguing your organization, FDA continues to chase nutrition-related policies like front-of-pack labeling, which are arguably outside of FDA's purview. Can you explain to the Committee what authority you feel FDA has to pursue nutrition-labeling policy while heavy metals exist on our food supply, illicit Chinese tobacco products remain accessible, and 263 drugs remain in shortage?

Dr. CALIFF. We actually have a law that instructs us about food labeling that we are adhering to in this case, and I would remind you, we have a shortened life expectancy in this country, particularly in rural areas that is largely driven by diet and poor nutrition. I am just from South Carolina. It seems to me that putting the information on the front of the package is probably more likely to get the useful information so people can make wise choices. That does not seem to me like something that should be that hard to get to. If you put it on the back, if you are like me, when you go to the store, you are unlikely to look at it. If it is on the front, you are going to see it.

Mr. LATURNER. Can you tell me where you derive the authority to do it, though, specifically?

Dr. CALIFF. Yes. We are glad to get with your staff and go through the details of that, but we believe we do have that authority.

Mr. LATURNER. I look forward to seeing that.

Mr. LATURNER. Do you feel it is a best use of taxpayer dollars to shape American eating patterns in lieu of addressing these other critical issues? I listed a few issues that seem like a pretty big deal.

Dr. CALIFF. Certainly, tobacco is a huge one, but I would have to say if we look at the fact that we have the lowest life expectancy of any high-income country, it is being driven by chronic diseases, which are being driven by diet, and so to say that we should pay no attention to diet is a mistake. Now, shaping what we are doing

is proposing to give people the information they need so that they can make healthy choices and reduce these alarming rates of obesity, diabetes. I am a cardiologist, vascular disease. I tell my cardiology colleagues we have got no problem with business in the future in cardiology.

Mr. LATURNER. I would only have a limited amount of time. I pointed to front-of-pack labeling as an example, but it appears the Agency has a number of outstanding rulemakings and goals that are not related to food safety: the definition of "healthy," a symbol for healthy, the dietary guidelines for Americans, dietary guidance statements. The list goes on. Can you please tell the Committee and consumers how all of these pieces fit together? My concern is that not only are you pursuing actions that you do not have the authority for, but you are also painting a terribly confusing landscape of rules and advice about what to eat.

Dr. CALIFF. Well, I would be happy to work with your staff on going through this in more detail. But in short, what we now know about diet, it is a pattern of eating over time that is important in how long people live and whether they are burdened by chronic diseases. It is not one specific thing. It is multiple constituents of the diet when eating regularly in a pattern create the kinds of health problems that are really ravaging our country right now. If you look at rural areas in particular, we are seeing alarming premature death rates that are going in the wrong direction, actually, for the first time in 50 years.

Mr. LATURNER. You said that earlier. My question is specifically all of these different initiatives, how they work together, and I look forward to getting an answer on that to my actual question. It has been brought to my attention that illicit flavored disposable e-cigarettes now make up a majority of the entire e-cigarette market, which most of these products are coming from China. Can you speak to the factors that have allowed this issue to materialize and what your Agency plans to do to rectify the situation?

Dr. CALIFF. Yes. Thanks. I mean, we have been over this several times already this afternoon, but in brief, no one anticipated 27 million applications for vaping products when the door was open for applications. It has been a problem that is quite large and that we are gradually making progress in.

Mr. LATURNER. What are you doing about it?

Dr. CALIFF. Warning letters, civil money penalties, injunctions, and seizures, all of the above, and I hope that we will continue to be able to increase our presence out there in the field. Right now, we get no user fees from the vaping industry, and that money would enable us to put a lot more people in the field to take down these operations that you are talking about.

Mr. LATURNER. It sure feels like warning letters are not getting the job done. Can you walk us through whether and how you personally have communicated these concerns to DOJ and Customs?

Dr. CALIFF. We have had direct meetings, and I have personally gone to several places of import to meet with the Border Patrol and Customs people who are there when the stuff comes in. By the way, if you want to get an education on this, go to the International Mail Facility.

Mr. LATURNER. What about the DOJ?

Dr. CALIFF. Direct person-to-person meetings with DOJ. I have the key person's cellphone number to call in off hours.

Mr. LATURNER. I am over time. I yield back, Mr. Chairman. Thank you.

Chairman COMER. The gentleman yields back. The Chair now recognizes Ms. Tlaib from Michigan.

Ms. TLAIB. Thank you, Mr. Chair. Thank you, Commissioner. We are almost done. I am really pleased that you are here. I had, in the last 2 weeks, a handful of community events, and FDA issues did come up. I want to start with this. You know, how much of what FDA is doing covering specifically food safety? I mean, how much of your resources right now is dedicated to food safety?

Dr. CALIFF. For detail, I would refer you to the Reagan-Udall report that we commissioned last year that has the detailed information.

Ms. TLAIB. Is it like 50 percent or?

Dr. CALIFF. Nowhere near 50 percent.

Ms. TLAIB. OK.

Dr. CALIFF. Although the "F" in "FDA" stands for food.

Ms. TLAIB. Yes.

Dr. CALIFF. On the medical product side, we have had very good funding because of the user fees, but not on the food side.

Ms. TLAIB. Mr. Chair, I do want to submit for the record an article, "The FDA's Food Failure."

Chairman COMER. Without objection, so ordered.

Ms. TLAIB. I need to talk about this because it comes up a lot. FDA right now has the authorization to regulate water to keep deadly toxin out of produce, right?

Dr. CALIFF. The water is actually mixed. We regulate bottled water. The water supply itself is regulated by EPA, as just noted. Water on farms as it goes from where cattle may be, for example, the plants, that is an area——

Ms. TLAIB. Yes, Commissioner. So, I am going to read from the article—I think this is important—just as background, and I know it was, like, a couple of months maybe after you got confirmed. "By the time FDA officials figured out it was spinach that was making people sick in 10 states, sending three people into kidney failure, it was too late. It was mid-November 2021, and the package salad's short shelf life had passed. There was no recall. By the time FDA officials got inspectors on the ground, spinach season was over, the fields in the production facilities were empty, which made it impossible to pinpoint the source of contamination. The cause of the outbreak was likely never fixed." Have we fixed this kind of issue, again, what was suspected because of previous kind of contamination, it could be the water that touches the food, used to clean the produce?

Dr. CALIFF. You know, when you say is it fixed, you know, what I would say is the economist rated the U.S. Food Safety as tied for first in the world——

Ms. TLAIB. I know, but, Commissioner——

Dr. CALIFF [continuing]. But is it completely fixed? Of course not.

Ms. TLAIB. Yes. Look, I work on Get the Lead Out Caucus, and my colleagues know I am a leader on this issue on quality of water. I want to help you. This is more me trying to show my colleagues

that if we really cared about food safety, which every single one of our constituents does not use every single medication that everybody talked about, but they sure had gathered produce, touch the food industry in every way. And so, I just want to get to the bottom of what we can do together to ensure that you have authorization to oversee water quality that touches our food.

Dr. CALIFF. All right. We are just finalizing now. You know, there are 10 rules of FSMA, Food Safety Modernization.

Ms. TLAIB. Yes.

Dr. CALIFF. The agricultural water rule is one that is very pertinent, and it has to do with what farms should do, for example, if there are cattle upstream from where the produce is. And so, you know, there is a list of things we need. We can be in touch with your staff.

Ms. TLAIB. So, we do not really have anything right now that gives you any authority over the use of water on produce?

Dr. CALIFF. Only in reaction to what happens, but not——

Ms. TLAIB. So, after contamination?

Dr. CALIFF. Yes, not preemptive.

Ms. TLAIB. OK. Well, that is important for us to know, and I hope the Chair and I and others can work on this. The other question I have, and it is regarding food, too, and I am sorry, I know your medical background, but food is so incredibly important here. Does the FDA have authorization to oversee food packaging, right? How about PFAS, the use of PFAS? What are we doing about the use of packaging around PFAS, which is——

Dr. CALIFF. As PFAS relates to the surfaces of food containers, and, like, I was surprised to hear that we even regulate dishwashers when I came in because of this, yes, and it is a big——

Ms. TLAIB. So, how do we do it?

Dr. CALIFF. We have studies that sample but at very low rates because the funding is quite low.

Ms. TLAIB. We do not really enforce it?

Dr. CALIFF. Not to the extent we could. Let me just say, you know we are going through, as we have discussed, the largest reorganization in the history of the FDA food is the entire focus of——

Ms. TLAIB. Yes, Commissioner. I mean, I hear that we have some of the highest rates of cancer in the world. Is that correct?

Dr. CALIFF. We do.

Ms. TLAIB. Yes. I really think we should really prioritize. So, when we talk about reorganization FDA, I do hope we can work all together in a bipartisan way to make sure that food safety is at the center of making sure that we have resources. Again, this is just me highlighting to my colleagues and really educating the American public that we need to do more around food safety.

Dr. CALIFF. I appreciate that. I do want to point out, our new head of the Human Foods Program is Jim Jones, who had a career at EPA. He is an expert on the kinds of things that you have raised, and our reorganization plan would call for really beefing up the chemical safety part of FDA because we have had a very small staff historically in that area.

Ms. TLAIB. Yes, and I agree. I mean, I think the EPA is moving, you know, it is slow, but they are moving toward trying to, again, prevent exposure of PFAS through other rightways. But the fact

that we are trying to stop it within water within, again, contamination on our environment, earth, and so forth, I think we have to really be as aggressive when it comes to our food quality. Last question, if I may, and I promise this last question you gave somebody else. Do you believe our country is experiencing a vaping epidemic?

Dr. CALIFF. To the extent, "epidemic" is defined as millions of people. yes.

Ms. TLAIB. OK. What do you think we need to do as a Congress to protect our residents, especially our children right now? And I know we got questions about it, But, like, what do you think we should do because vaping comes up so much for all of us, no matter for a Republican, Democrat?

Dr. CALIFF. Well, I think it has to be prioritized. We need more resources.

Ms. TLAIB. Is it the disposables? We are not authorizing——

Chairman COMER. That will be the last question. Feel free to answer that.

Ms. TLAIB. Thank you, Mr. Chair.

Dr. CALIFF. The vaping industry does not pay user fees, and so we have a limited staff dedicated to this. We really need to ramp up our staff. That would be the most important thing you could do, and you are doing a good job of staying on our case. I will say that, so that needs to continue. It is part of the process.

Chairman COMER. The Chair now recognizes Mr. Cloud from Texas for 5 minutes.

Mr. CLOUD. Thank you, Chairman, and thank you, Commissioner, for sticking with us through the day. I appreciate you being here. Your Agency, of course, is responsible for the evaluating the safety and effectiveness of medications that millions of Americans rely on, and I am sure that your scientists and those working there view themselves as committed public servants. I wanted to talk to you though, about something that is concerning, I think, to a lot of Americans, and that is potential conflicts of interest.

In 2018, the Journal of Science found that 11 out of 16 medical examiners who left the FDA ended up working for companies they were previously responsible for regulating. That is roughly two-thirds or more than two-thirds. These wealthy and powerful pharmaceutical companies recruit former FDA employees with lucrative job offers in order to leverage their connections. Existing law imposes only a very limited restrictions on this revolving door. Former employees are only prohibited from lobbying the FDA for very few specific matters, and they are only subject to a 2-year cooling off period. Meanwhile, you know, former FDA employees can go and collect, you know, pretty substantial paychecks from companies once regulated.

Just 2 months after leaving the government service, the lead medical officer for the FDA's Office of Vaccine Research and Review took a high-level job at Moderna. There is another one. Recently, the medical officer who decided on behalf of the FDA whether the clinical data from Moderna vaccine medicine approval standards also took a job shortly after that with the company just months after the vaccine received license. And so, I think you can see why many of Americans can look at history of this and be very,

very concerned about what is going on. Especially, you know, coming out of COVID FDA, along with a number of agencies, I think we can all look back and see there were a lot of lessons learned and was not handled really in the best. And so, right now, we are trying to restore the American populace's faith in a lot of these institutions that you are now leading and have just taken up the mantle on recently with again.

Can you speak to that issue? You know, with regard to these two FDA officials specifically, did either of these recuse themselves from any matter at the FDA while seeking these jobs that you are aware of?

Dr. CALIFF. Well, I mean, this last point you made is a very important part of the system regardless of how you feel about the other parts of people moving from FDA to industry or industry into FDA. You are prohibited from seeking a job in the area that you are regulating unless you recuse yourself. So that is something that——

Mr. CLOUD. The FDA has refused to acknowledge on these two individuals, Dr. Doran Fink and Dr. Jaya Goswami, I believe is the pronunciation, whether or not these two recused themselves of their involvement in these areas that they were leading before going to Moderna. So, why has the FDA refused to provide the information?

Dr. CALIFF. I am unaware of what you are describing. I will certainly go back and look into that. Again, if they were not seeking employment while they were regulating, then they did not violate anything.

Mr. CLOUD. Do you know that they sought guidance on approval with the FDA—I am sorry—the FDA's Ethics Office before taking those jobs?

Dr. CALIFF. I would expect that they would have, but I do not know that. You know, we will have to go back.

Mr. CLOUD. Can you understand the concern, and what recommendations would you provide? I think it was 1981 to 2019, 9 of the 10 commissioners went into work for pharmaceutical companies from leaving their office. You were one of those as well. I am not suggesting any impropriety at this point, but you can certainly see, I think, how this would create a huge concern, a conflict of interest, when the American people are looking at this. What recommendations would you suggest that we bring up to make sure that the American people can know that the decisions being made because here is the thing. You are supposed to give oversight to these companies, whether you are in food or drug industry, and you know that you are not going to get a job. Not you specific. I am speaking, you know, someone who wants one of these high-paying jobs, after leaving the Department knows that, you know, they are not going to be hired by someone who was very strict on them, and so there is a built-in incentive, of course, to be lax in these things. And so, what can we do in Congress to provide a level playing field that will help restore the public's trust in this area?

Dr. CALIFF. Glad to engage in a discussion with you on that, but I do want to point out something about this. Inside the FDA, we are dealing with highly technical issues that require a lot of expertise. There are many people who work in industry and then volun-

teer to come to FDA for a much lower salary because they are attracted to the issue of understanding the science and making good decisions based on it. By the same token, there are people who work within the FDA for a period of time. They have skills and knowledge about an area. And, you know, it is an issue to say, well, they could never work in an industry where they might develop a cure for cancer or whatever the thing may be. So, this is a delicate area and needs to be looked at. You are perfectly right to raise——

Mr. CLOUD. I am not saying that there is no legitimate reason. This is why I am asking what are your recommendations as someone who is actually running, you know, the Agency right now. What recommendations would you provide that would not be onerous? But you know, 9 out of 10 going straight to the pharmaceutical companies straight out of office is, you know, pretty circumspect when the American people are looking at that. So, what would you recommend for us as Congress that would be reasonable provisions that would allow us to bring the full faith of these agencies back to the United States?

Chairman COMER. His time has expired, but please answer the question.

Dr. CALIFF. Yes. I mean, it is a complicated area. I would say, No. 1 is just making sure we adhere to what we already said. You have raised some questions about this.

Mr. CLOUD. Exceptions are given all the time to these is my understanding, you know. So, there are rules, but hey, we waive them all the time because it is a self-check kind of thing.

Dr. CALIFF. I do not think that is true at all. I would speak very highly of our Ethics Office. Two-thousand-sixteen, the first time around, I spent a lot of time bringing in new people, and I do not think exceptions are given all the time to these, but we can always do better and happy to engage on it.

Mr. CLOUD. So, no recommendations so far?

Dr. CALIFF. Well, it is a very broad area, so I am reluctant to just off the cuff make a specific recommendation.

Mr. CLOUD. OK. Well, I look forward to working with you.

Chairman COMER. They have called votes, but we are going to try to get go to Mr. Connolly and then Mr. Donalds, and then just two votes will not take long. We will be right back. We will recess.

Mr. CONNOLLY. Chairman, I think Mr. Moskowitz is ahead of me.

Chairman COMER. We will go to Moskowitz then.

Mr. MOSKOWITZ. Do not worry, Mr. Chairman. It will not be the usual, and I will try to use some time back, but first of all, thank you for coming today, Commissioner. I think you have established that if any of my colleagues get worms, you will make sure that they get ivermectin, so we do not have to, like, rehash all of that nonsense.

I want to turn your attention, though, to a little bit of the aftermath of COVID in the pharmaceutical space. I mean, do you think it is appropriate that with all the supply chain issues that America had during COVID, that we have not really fixed in a broader sense, but in the medical sense, in the pharmaceutical space, I mean, should we still be getting a majority of our own or counter drugs from Wuhan? Should they still be produced there? Should we

still be depending upon Wuhan, China, to be making drugs that we sell in a significant basis on shelves in this country?

Dr. CALIFF. Well, I mean, I would say I am not sure it is specifically Wuhan, but the key starting materials for drugs are mostly coming from China, and I do not think that is good for us. We do not need to have no drugs from China, but we need to have a firm manufacturing base that we can be confident about in these times of stress.

Mr. MOSKOWITZ. I know you were not necessarily there, but during the two bills, one in the Trump administration, one in the Biden administration, where we spent $7 trillion or $8 trillion combined after COVID, how come the FDA was not advocating, or if they were—I would love to hear it

—with all that government money was spent, why were we not establishing that we should start manufacturing those products here?

Dr. CALIFF. I was not there at the time. I would just say, you know, pretty much the time I came in February 2022, we really saw how stark the problem was, and we started advocating then, but, you know, we live in a country where the pharmaceutical industry is for profit. If people are not getting the prices they want or the purchaser is getting a lower price overseas, that is where they go. So, to fix this, it is going to take some kind of intervention, which is well beyond the FDA. We are certainly advocating that intervention is needed.

Mr. MOSKOWITZ. All right. Let me turn your attention. I know you got a bunch of questions on cancer drugs. My dad was diagnosed with pancreatic cancer. He lived 18 months, and he passed away about a month before I ran for office. He was on cisplatin. At that time, there were no issues. Do you think it is acceptable in America that families would get told by their doctors that we are going to have to push off a treatment because there is a shortage of a chemotherapy that is helping, extending the lives, keeping people alive? Do you think that is acceptable in this country, and why is it that we are not better prepared to handle when there are these manufacturing issues, whether it is in India or China? Why are we not better prepared to handle these things?

Dr. CALIFF. Here is what I would say. First of all, it is unacceptable. I mean, I have a close relative with pancreatic cancer right now. I know how frightening it is. I would just say, you know, what has happened is we have health systems, hospitals, pharmacies, and we have manufacturers who are mostly overseas now. If we take cisplatin as an example, 5 years ago, it was $400 a dose. It is a generic drug. I gave it as an intern in 1978. Now, it was $13 a dose. You cannot make cisplatin for $13 a dose and maintain quality. So, people running the company say, why should I make it? And we do not have a system in place that says this is an essential drug. We are going to put something into effect which causes the market to behave.

Mr. MOSKOWITZ. Well, I do not want to interrupt. I mean, you are the FDA, you know, perhaps, you know, that is something you guys should be looking at. I mean, there are all sorts of ways to be working with manufacturers all day long on trying to incentivize them to make lifesaving drugs that may not be——

Dr. CALIFF. Well, I mean, if I may, we have no authority to give incentives. We are prohibited by law from dealing with pricing. But I would refer you to the HHS report that came out last week with our heavy input that goes through all the details here. So, I am completely in tune with your concern, and I think people around the Administration know every time I am on a call I bring it up.

Mr. MOSKOWITZ. There has been reports in some of the vaping products in Florida seeing fentanyl in them, you know. What are we doing about some of these things coming in from China, some of the illegal vaping products?

Dr. CALIFF. I am very concerned about what you raised. We just had an annual meeting in Atlanta, mostly parents of children who have died from overdose. Anne Milgram, the DEA administrator, was there and gave the details about how these products are getting into the mainstream of America through cartels predominantly. This is really a combined effort. FDA has a role that has now become mostly a law enforcement issue with DEA and we are working together as closely as we can, but I am not pretending that we have this problem solved at this point. It is a big deal.

Mr. MOSKOWITZ. Thanks, Mr. Chair.

Chairman COMER. The Chair now recognizes Mr. Donalds from Florida.

Mr. DONALDS. Thank you, Chairman. Commissioner, thanks for being here. Listen, I support the FDA's efforts to reduce youth smoking rates under their current authority granted by Congress. However, I do not support the unnecessary and unfounded regulations, like the FDA's proposed tobacco product standard for characterizing flavors in cigars rule, which is purely based on, frankly in my view, far more politics than science. What are some of the examples of the unintended consequences that might arise out of this rule?

Dr. CALIFF. Well, first, the intended consequences will be reduction in death rates, which is a pretty important one, in my view. In terms of unintended consequences there is always going to be some illicit market when rules like this are put into effect.

Mr. DONALDS. So, then do you think it is wise for the FDA to proceed?

Dr. CALIFF. I think it is very wise to reduce the death rates and population——

Mr. DONALDS. But, Commissioner, you did also acknowledge, and we are seeing it, frankly, in a lot of markets associated with smoking, but right now we are focused on flavored cigars. So, your contention is that it is OK to put in this rule around flavors in premium cigars because you have adults who are choosing to smoke flavored premium cigars.

Dr. CALIFF. Now, if you want to talk about flavored cigars, I would just say youth right now are smoking cigars more than they are smoking cigarettes. Flavored cigars are highly attractive to youth, and so it is a major concern that we have. Premium cigars is a different issue that is in the courts right now, so I cannot comment on it.

Mr. DONALDS. All right. So secondarily, California enacted a flavor ban on all tobacco products at the end of 2022. California already suffers from the second highest rate of cigarette smuggling

where nearly 50 percent of all cigarettes used by consumers are purchased out of state. Further, in 2020, 1 in 6 cigarette packs in California were smuggled into the state from international markets. In which ways does an illicit tobacco market impact the United States of America?

Dr. CALIFF. You know, I just was out in California about 4 months ago, and I met with the Public Health Department there. Their longevity is so much higher than the average of the United States. Largely, due to the reduction in things like the use of tobacco, they have very low rates of use of tobacco compared to the rest of the U.S. So overall, it is a net positive.

Mr. DONALDS. But, Commissioner, we are going to acknowledge the fact that, yes, there are black markets propping up, whether it is illicit cigarettes or, if we want to go back to the previous topic of premium cigars, in part because of the policies of the United States. Do we acknowledge that?

Dr. CALIFF. You know, as I have already discussed, I am a cardiologist. I am used to life and death. Almost everyone prefers to be alive. I would rather reduce total mortality and deal with the illicit market than to tolerate 460,000 Americans dying of tobacco-related illness per year, which is what our current rate is, and that is at lower from what it used to be. I am taking care of these people. We also have people dying. It is not good.

Mr. DONALDS. Commissioner, we also have to acknowledge the fact that you are not omnipotent. You cannot control the actions of people. Do you truly believe that you have the ability to control the actions of Americans, if they choose? Adults, now, move away from children for a moment. Adults, if they choose to smoke a cigar or if they choose to smoke a cigarette. And by the way, I do not agree with smoking cigarettes. I am not a cigarette smoker, but at the same time, do we acknowledge the reality that when you put up these barriers, what you also do is create an illicit market for these products, which could be more harmful to the users that use them?

Dr. CALIFF. I would never pretend to be able to control the behavior of people but imagine if we had taken that attitude. When I started out as a cardiologist, the average patient I took care of was 50 years old, typically a man smoking cigarettes, dying at a rate of 30 out of every 100 people with a heart attack in the first 30 days. Now the typical patient with heart disease is in the 70's because the rates of use of tobacco dropped so much, not because someone——

Mr. DONALDS. Commissioner, do you think it is because of informing the public, or do you think that is because of government regulation?

Dr. CALIFF. I think it is a combination of both of those.

Mr. DONALDS. Commissioner, I would argue it is far better to get people to change behavior by informing them of the consequences of said behavior as opposed to putting up arbitrary rules from the FDA or anywhere else.

Dr. CALIFF. I like that in general, but this is a highly——

Mr. DONALDS. It is not in general, Commissioner. That is a reality of the human condition.

Dr. CALIFF. When you are dealing with people suffering from addiction, nicotine is a terrible addiction, very difficult to beat. This is an entirely different issue.

Mr. DONALDS. Commissioner, we have not got to a conversation about addiction. We are just talking about FDA rules around, frankly, flavored cigars and also some of the California, which are on cigarette bans.

Dr. CALIFF. Nicotine is a highly addictive substance that we are talking——

Mr. DONALDS. I am well aware that it is, Commissioner, but, again, I would argue that information and education is far better than regulation and elimination. I yield.

Chairman COMER. The gentleman's time has expired. Pursuant to the previous order, the Committee stands in recess, subject to the call of the Chair. The Committee will reconvene 10 minutes after the floor vote. The Committee stands in recess.

[Recess.]

Chairman COMER. The Committee will come back to order.

The Chair now recognizes Mr. Waltz from Florida for 5 minutes.

Mr. WALTZ. Thank you, Mr. Chair, and thank you for your patience, Commissioner Califf. I want to talk about kind of your current policies in terms of hybrid telework. We have here, just for American people watching from your website, that says the White Oak Campus, your main campus, is open but yet is open with maximum telework flexibilities. And Mr. Commissioner, I sent you a letter back in January. I haven't received a response yet, so I will just ask you these questions today. And it is essentially, can you just talk about your telework policy and why we are still teleworking, and when you plan to bring everybody back in in-person?

Dr. CALIFF. Well, thanks for the question, and I think to answer this question, it is useful to start from before the pandemic because when I was Commissioner in 2016, we had a 4 out of 5 days on-campus policy because we did not have enough offices for the number of people that we had. So, it is actually a requirement, and we had our Zoom capabilities and all that built up well before the pandemic.

But, you know, when I arrived in 2022, the pandemic was well underway, and we had instituted a policy of measurement. Now the primary accountability of the American public is getting the work done. We are meeting all of our metrics and our user fees quite well. That is a matter of public record. And when you look at the output of the employees, it is quite high. Now, within that, we have a number of people who work in laboratories. They have always gone to the facility to work because that is where the laboratory is. We actually have 270 facilities all around the U.S. because we have a large inspectorate and other activities and labs that are located all around the U.S., those people are obviously going to work every day in-person.

Mr. WALTZ. Just in the interest of time, Mr. Califf, my understanding, and I am hearing consistently from industry, No. 1, that the FDA granted in-person meetings without a hybrid component prior to COVID. So, have we gone to more hybrid because of COVID? And are you back to pre-pandemic levels in-person, because the concern is and the concern in my letter, and I would ap-

preciate an answer to some of the questions in it, is that lifesaving drugs—I am getting this from chief medical officers, I am getting this from providers and others—cannot get the same type of due diligence. You cannot have the same type of meeting. And in fact, I have talked to a number of companies that said their meetings have been delayed because they did not have the right type of Zoom capabilities when you could just come in and have the meetings. So, it is actually delaying the approval process.

Dr. CALIFF. Well, first of all, I know that——

Mr. WALTZ. These are, like, people are dying, and the pandemic is over. The Administration declared it over last year.

Dr. CALIFF. The approval process is definitely not being delayed because those metrics are kept, and we have got a record number of approvals and our timelines have been met. We offer the option of in-person or hybrid meetings now. Many times, the industry chooses hybrid because to have an in-person meeting, they got to fly everybody to White Oak to be there, and it is more convenient and they get a better attendance themselves from hybrid.

Mr. WALTZ. I am hearing from industry that they would prefer in-person, and then those are delayed because of investments. We need more investments in Zoom, more investments in those kinds of meetings, more investments in your infrastructure.

Dr. CALIFF. That may be true of some of the industry, but it is definitely not true of all of the industry. And I would expect that in the future there will be much more in-person from both sides wanting it, FDA and the industry. But I would be shocked if we did totally away with hybrid because often that is what the industry——

Mr. WALTZ. Why in the future would there be more in-person?

Dr. CALIFF. Because people like to be in-person when they can.

Mr. WALTZ. So why are we not there now?

Dr. CALIFF. Because often, people really find it more convenient to not have to fly everybody to White Oak, so there is a transition, you know, period going on.

Mr. WALTZ. And can you describe what is the transition issue?

Dr. CALIFF. Well, you know, there are a limited number of meeting rooms that are completely up to speed, that is, you know, coming in the place for——

Mr. WALTZ. Up to speed for?

Dr. CALIFF. For the hybrid meetings that we often have to have because, often, industry people on both sides of that equation, people who want to be there in-person and others who want to participate.

Mr. WALTZ. So, you are saying it is industry really driving the demand for hybrid that you are making the investments?

Dr. CALIFF. I would not want to say that. I would say often it is both sides. The industry, you know, would like to have either option is what I would say.

Mr. WALTZ. I think that from what I am hearing consistently, and I would implore you to take a deeper look into this, the industry just wants to have meetings, however they have to happen. They certainly do not want them delayed because of a lack of rooms that have been upgraded for hybrid, especially for things like ALS where people are literally dying month to month with these delays.

Dr. CALIFF. I am not arguing with your basic points other than to say was from everything I can see, we are meeting our timelines, and we have got a record number of approvals that have occurred. So, by any metric you would use, the place is pretty darn efficient right now.

Mr. WALTZ. Just on the time I have remaining, I think maybe we need to relook at the metrics. I do not know. But I am just telling you what we are consistently hearing, and if they were being improved and you were having in-person meetings, and they were not being delayed——

Dr. CALIFF. You can evaluate it, so let us be clear about that. Our job is to evaluate, not just to approve. I mean, we approve it when the data supports approval.

Mr. WALTZ. But you cannot get to really have those conversations about the data if you are delaying because of meeting rooms.

Dr. CALIFF. Again, I would be surprised if there are delays occurring because of meeting rooms.

Mr. WALTZ. OK. Thank you, Mr. Chairman. If you could please ask your team to look at the letter. I am on four committees and I have never had to wait 4 months for a response just to some basic questions.

Dr. CALIFF. All right.

Mr. WALTZ. Thank you.

Dr. CALIFF. I appreciate that.

Mr. WALTZ. Thank you, Mr. Chairman.

Chairman COMER. The Chair now recognizes Mr. Langworthy from New York.

Mr. LANGWORTHY. Thank you, Mr. Chairman. Commissioner Califf, my constituents, many of whom do not have the same access to a doctor's office as my colleagues in urban or sprawling suburban areas, often they are the ones most impacted by the FDA's inaction and lack of clarity on prescription to over-the-counter, or in other words, Rx-to-OTC switch. What this can often result in is a lack of expanded over-the-counter access for medicines that have already gone through an approval process at the FDA and deserve serious and timely consideration so that constituents, our taxpayers can have more easy access to the care into the help that they need. Commissioner Califf, can you explain why we only see a small percentage of the prescription to over-the-counter switch annually, and what can we do to increase that number?

Dr. CALIFF. Sure, appreciate that, and I also appreciate the importance of rural people, especially, of having access to medications. I mean, what the regulations require is that the company that wants to make that switch has to produce the evidence that if they go to over-the-counter, that the person purchasing the product can understand the instructions and use it appropriately, and therefore, does not need an intermediary to do the prescribing and the interaction with a person as a patient. So, I would say whenever a manufacturer produces that evidence, you know, we are anxious to get it and to take action, if they have got the data to support what they want to do. So, it is really a matter they actually cannot just make the switch because they have to show that a consumer can actually understand the instructions and apply the medication appropriately.

Mr. LANGWORTHY. No. Unfortunately, what we are hearing, Dr. Califf, is that for too long the switch process has been muddled by, you know, moving goalposts, challenges, engaging in a dialog with the FDA, and a culture at the FDA that seems to reward denying reviews and approvals rather than trying to get things done. But I have limited time, so I would like to move on.

Essentially, pharmaceutical companies are disclosing their inventions to the FDA years before disclosing them to the Patent Office, which can elongate commercial monopolies inappropriately by 10 years. Due to inconsistent filing with both the FDA and the Patent and Trademark Office by branded companies, many of the most expensive drugs on the market are artificially blocked from generic competition. Now this leads to billions of dollars in lost savings to patients and to taxpayers.

President Biden released the pharmaceutical competition executive order that encouraged the FDA and the patent tradeoffice to collaborate on this issue, and FDA has also conducted listening sessions where the issue was apparently discussed extensively. However, there seems to be no recent progress on this front. So, what real solutions is FDA in fact considering to address this problem, and when can we expect to receive an update?

Dr. CALIFF. We would be happy to give your staff an update any day. I disagree with the view that there is no progress being made. There is a very active collaboration with the Patent Office in an effort to reduce the number of inappropriate patents that get in there and block the generic competition. So, we will give you an update on what has happened with that. We had a long discussion about this earlier this afternoon but let me just say that the Patent Office as a primary responsibility for determining if there is something unique that merits a patent. That is not an FDA call.

You are correct that we see the pipeline of what is coming from Pharma. That is commercial confidential information that, by law, we cannot release to anyone else. But what we want to do is make sure that there is good communication so the Patent Office understands when it is actually a valid new patent that would extend that protection from competition.

Mr. LANGWORTHY. OK. Thanks. In my remaining time, I really want to switch gears here. According to the American Academy of Pediatrics, numerous studies have linked the range of health issues with the consumption of plant-based beverages by children. Furthermore, there is considerable confusion and misinformation about the substitution of non-dairy products for cow's milk. The FDA itself determined that based on 13,000 public comments, "Consumers do not understand the nutritional differences between milk and plant-based milk alternatives." So, Commissioner, can you comment on the FDA's efforts to enforce dairy product standards of identity, particularly the use of the term "milk" and the actions your Agency is taking to mitigate the risks posed by the chronic mislabeling of non-dairy products using established dairy terms?

Dr. CALIFF. Well, I am glad you referred to the nutritional content because that is a primary deficit here, and we are requiring that that nutritional information be prominently displayed as part of the effort. What we are not doing is specifying exactly what can be called milk because—how do I say—the cow is out of the barn

already. It has been decades that terminology has been used, and whenever those kinds of issues, when we make a rule to require it, we call it something when it has been different, we have lost such cases in core. But what I think is really important is when people purchase something, they actually understand the nutritional content, and that is heavily emphasized in what we are currently putting forth.

Mr. LANGWORTHY. Thank you very much. I appreciate you answering my questions, and, Mr. Chairman, I yield back.

Chairman COMER. The gentleman yields back. Now I recognize myself for 5 minutes. I have had a lot of members yield me time, but now I will ask my questions.

Commissioner, in this hearing, you have said that the term, "harm reduction," is an industry term or a term that industry uses, but to be clear, the Institute of Medicine used this term in the title of its report titled, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction." So, it is not just the industry that uses this term. The Institute of Medicine uses it, and the concept of harm reduction has been embraced in other countries. That is, they accept and communicate that there are options that are less risky than a traditional cigarette. Are we ever going to get to that point in this country? Do you accept this idea?

Dr. CALIFF. I definitely accept the idea. Your point is well taken, and industry is not the only entity to use it. But what I want to avoid in speaking of harm reduction, we have talked about combustible tobacco kills people. Neither using vaping or combustible tobacco is the healthiest thing you can do. Vaping compared to none of the above has residues that are quite concerning for long-term use. So, if you are a combustible tobacco user, if you switch to vaping, that is less harm. That is good as long as the product is not packaged in a way that is encouraging you to get addicted to nicotine. One of the main harms I want to get away from is millions of youth being addicted to nicotine by vaping products. So, we got to find that middle ground, and I accept there is a point here. I am just worried that when we use the term, "harm reduction" now, it is often part of a vast advertising campaign. That is not taking account of the addiction side in youth.

Chairman COMER. But you admit that vaping is less harmful than cigarettes. I mean, we all——

Dr. CALIFF. "Admitting." It sounds like I am confessing of something. No, I agree. I agree.

Chairman COMER. So, let us talk about all the applications that have been submitted, millions of applications. I think you have approved 25 or something?

Dr. CALIFF. Almost 27 million.

Chairman COMER. Have been applied?

Dr. CALIFF. Right.

Chairman COMER. Have requested application, but you have not approved but just a handful. The reason for the backlogs, are you working on it? Are you trying to approve more, or you just throw in the towel in and say we are just not going to have anything or?

Dr. CALIFF. No, no. We are working every day and——

Chairman COMER. So, you think there will be more approvals?

Dr. CALIFF. As a Commissioner, I meet with the Center for Tobacco Products leadership every week and we go over this, but again, we can only approve a product by law. If the company produces the data that demonstrates that they meet the public health standard, that is the reduction in risks that we just talked about, to adults who use combustible tobacco offsets the addiction risk.

Chairman COMER. Right. And you have heard a lot of people ask this question. On both sides of the aisle, we do not agree on a whole lot in this Committee in a bipartisan manner, but the FDA's refusal to approve these new tobacco products has created a thriving market for illegal and unsafe products, primarily from China. These products received warning letters from FDA, but I do not think China loses a whole lot of sleep over a warning letter from a U.S. Governmental Agency, especially in the Biden Administration. So, a lot of people have questions as to why there are so many of these Chinese products, counterfeit products on the market, they ask us. That is why so many different members have asked you about it. What is the reason? What are we supposed to say? We say it is FDA's responsibility, so why is the FDA enabling these Chinese products? I believe there is a solution here.

Dr. CALIFF. I would not use the term, "enabling," but I would say that this is a huge production issue coming out of China into our ports. We need to stop the use of illegal products.

Chairman COMER. But this Administration has proven it is unable to do anything at the border with respect to security, but would a foreign manufacturer rule not address this problem, a rule that pertains to foreign manufacturers from the FDA for this?

Dr. CALIFF. I mean, as we have said many times today, you are the referees, you make the rules, so if you choose to do that, you may. I would also say a lot of profit is being made in the vaping industry. If they had user fees, we would put a lot more——

Chairman COMER. Are these Chinese companies paying the user fees?

Dr. CALIFF. Whoever sold the product would have to pay the user fee.

Chairman COMER. Last question with respect to CBD. What do you foresee over the next 12 months from FDA with respect to CBD? Do you see any action? You know, you mentioned you are close, you are communicating on the Center for Tobacco, but what about the shifting gears here with CBD oil, industrial hemp and things like that? Is FDA close to making any decision on anything?

Dr. CALIFF. I think it is Congress' decision to make. So, we would really look forward to working with you all as quickly as possible to come up with a regulatory pathway that you think is reasonable and enables us to take action.

Chairman COMER. Well, my time has expired, and I am going to yield to the Ranking Member. This concludes the questioning phase, unless Mr. Connolly is on his way back or anything. OK. Well, we appreciate you being here, and I am going to let yield to Ranking Member Raskin if he has any closing remarks.

Mr. RASKIN. Thanks, Mr. Chairman, and, Commissioner Califf, I just want to thank you for your great devotion to the task here and you are a model public servant trying to advance the public interest at every turn. The scope of issues that you have to address on

daily basis is staggering, and the challenges faced by the FDA are mammoth. And we should not be adding to your burdens by beating you up for pet ideological causes, and I was disappointed that some of our colleagues went that direction today.

I just wanted to clear up a couple of little things. One is the Inflation Reduction Act is not responsible for drug shortages, and contrary to Republican claims, it has already substantially lowered costs for lifesaving medications even as it is projected to reduce the deficit by $237 billion. And you ask how we pulled off the feat of reducing to $35 a month where people have to pay for insulin shots if they are diabetic, while at the same time saving hundreds of billions of dollars for the taxpayers. It is simple. We took a strong stand that the Federal Government should be able to negotiate with Big Pharma for lower drug prices. And so, we have saved hundreds of billions of dollars, at the same time that we have dramatically reduced the cost of prescription drugs despite the unfortunate and categorical partisan objection of our Republican colleagues.

So, the shortages we are seeing today are primarily in generic medications, and Republican opponents of the Inflation Reduction Act claim it has already stifled the production of brand name drugs, which is just false. HHS recently published a white paper with multiple recommendations for what needs to be done to address drug shortages, none of which involve repealing the Inflation Reduction Act. Rather, they focus on ways in which the private sector can work with the FDA to shore up drug supply chains. And the commissioner has laid out a number of other ideas here today, and we would do well to defer to his expertise and to take it to heart.

We would also be remiss not to clarify that ivermectin is not effective against COVID–19, and there is no reason to think anything wrong of people who wanted to check it out for those purposes, as the good commissioner testified today, but it did not work. The Fifth Circuit never said otherwise. And it is not the role of the Fifth Circuit to determine whether a drug is safe and effective, be it ivermectin or mifepristone. That is FDA's job, and it is a job that relies on the quality and the integrity of the science and the research.

Some of our colleagues chose to blame the FDA exclusively for infant formula shortages when they could have joined us on our side of the aisle in our investigation into Abbott Nutrition and its role that it played. Democrats never received all the documents we were promised by Abbott, and our friends across the aisle could choose to help with that and provide the American people the accountability and the transparency we all deserve. Across the aisle, we share concerns about the illegal vapes coming into the country from China. I hope our colleagues will join the Democrats in supporting a whole-of-government approach to counter smuggling of illicit substances and products including adequately funding Federal law enforcement agencies. We should be concerned not just about illegal substances coming in from China, but from any country and every country of concern.

So, we thank you for your patience and your seriousness today. Mr. Chairman, I thank you for calling the hearing, which I think has been very productive, and I yield back to you.

Chairman COMER. The gentleman yields back, and I will conclude by again, Commissioner, thank you for being here today. I think this was a very substantive hearing. We covered topics from seafood inspection, all the way to just about every other topic that I think could be imaginable throughout the past five-and-a-half hours.

I will attempt to correct my colleague across the aisle. The Inflation Reduction Act was the title, but I think it will be known throughout history as the Inflation Creation Act, and that is why I do not believe a single Republican voted for it. And with respect to transparency that Mr. Raskin said that we deserve, I agree. We deserve transparency. Hopefully, in our investigations, the administration will turn over the pseudonym emails, and the tapes, and all the other items have relevance to our other investigation that we have ongoing. With respect to——

Mr. RASKIN. But is that one still ongoing? I was not sure.

Chairman COMER. Yes. Oh, it is. Yes, I know you need to stop watching CNN. You need to go to Main Street and ask people.

But at the end of the day, we appreciate your attendance. We have requested a lot of information, and hopefully, we will follow up with each individual member that asked questions. As I travel America and travel Kentucky, we have a lot of people in the private sector that are concerned with the pace at which FDA moves to approve medical devices. There is a lot of concern, as I have stated to you in the last 2 days, with respect to the uncertainty around the tobacco products, the lack of enforcement of the Chinese illegal vape products that are the ones that are creating so much havoc with our young people and across America, and so much uncertainty in the CBD industry as well. So, we look forward to working with you on that.

With that, and without objection, all members will have 5 legislative days within which to submit materials and to submit additional written questions for the witnesses, which will be forwarded to the witnesses for their response.

Chairman COMER. If there is no further business, without objection, the Committee stands adjourned.

[Whereupon, at 5:43 p.m., the Committee was adjourned.]

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