RESTORING TRUST IN FDA: ROOTING OUT ILLICIT PRODUCTS

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM U.S. HOUSE OF REPRESENTATIVES

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WITNESSES

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

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* Statement for the Record, Aliance for Pharmacy Compounding; submitted by Chairman Comer, and Rep. Biggs.

* Article, *Richard Williams*, "Measles Outbreak, RFK Jr.'s Health Agenda & Surprising Health Wins"; submitted by Rep. Krishnamoorthi.

* Article, *CBS News*, "FDA planning for fewer food and drug inspections due to layoffs, officials say"; submitted by Rep. Lee.

* Article, *Lancaster Farming*, "Raid on Farm Sparks Debate Over Raw Milk Oversight and Government Overreach"; submitted by Rep. Luna.

* Clinical Research, "Transthyretin V142I Genetic Variant and Cardiac Remodeling, Injury, and Heart Failure Risk in Black Adults"; submitted by Rep. Mfume.

* Public Law 116–291; submitted by Rep. Mfume.

* Report, GAO, "Cancer Clinical Trials"; submitted by Rep. Mfume.

* Article, *Axios*, "Drug industry worries about FDA delays"; submitted by Rep. Subramanyam.

* Article, *Axios*, "FDA cuts threaten medical product review programs"; submitted by Rep. Subramanyam.

* Article, *The New York Times*, "FDA Layoffs Could Raise Drug Costs and Erode Food Safety"; submitted by Rep. Subramanyam.

* Article, *The Washington Post*, "Veterinarians working on bird flu, pet food safety are fired in HHS purge"; submitted by Rep. Subramanyam.

* Article, *The Washington Post*, "Worries grow over risks to Americans as Trump cuts health, safety agencies"; submitted by Rep. Subramanyam.

* Article, *L.A. Times*, "Trump's Assault on Science Will Make Americans Dumber and Sicker"; submitted by Rep. Subramanyam.

The documents listed are available at: docs.house.gov.

ADDITIONAL DOCUMENTS

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* Questions for the Record: to Mr. Bentley; submitted by Rep. Foxx.

* Questions for the Record: to Dr. Williams; submitted by Rep. Krishnamoorthi.

* Questions for the Record: to Mr. Miller; submitted by Rep. Foxx.

* Questions for the Record: to Mr. Miller; submitted by Rep. Garcia.

* Questions for the Record: to Mr. Sadfar; submitted by Rep. Jack.

These documents were submitted after the hearing, and may be available upon request.

RESTORING TRUST IN FDA: ROOTING OUT ILLICIT PRODUCTS

Wednesday, April 9, 2025

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

The Committee met, pursuant to notice, at 10:04 a.m., in HVC–210, U.S. Capitol Visitor Center, Hon. James Comer [Chairman of the Committee] presiding.

Present: Representatives Comer, Gosar, Grothman, Cloud, Palmer, Higgins, Sessions, Biggs, Mace, Fallon, Donalds, Perry, Timmons, Burchett, Greene, Luna, Burlison, McGuire, Gill, Norton, Krishnamoorthi, Khanna, Mfume, Brown, Stansbury, Garcia, Frost, Lee, Crockett, Subramanyam, Bell, Min, Pressley, and Tlaib.

Also present: Representative Moskowitz.

Chairman COMER. This hearing of the Committee on Oversight and Government Reform will come to order. I want to welcome everyone here today.

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

I apologize for my laryngitis. We are going to try to fight our way through this. So, I will recognize myself for the purpose of making an opening statement.

Again, welcome to the Committee on Oversight and Government Reform. Today, we will examine solutions to ensure the Food and Drug Administration keeps our Nation's food and drug supply safe for all Americans. There might not be another Federal Agency that more profoundly impacts every American's daily life than the FDA. The FDA oversees the safety of the food, drugs, and medical devices we rely on. These responsibilities make it a key pillar of public health in the United States, but Americans are not getting healthier. Americans' life expectancy is 4 years less than other developed countries despite spending more than any other country on healthcare. Six in 10 Americans suffer from chronic disease. One in 5 Americans live with a mental illness. Nearly 20 percent of America's children are considered obese. Twenty percent of American children.

So, you would think the FDA under the Biden Administration would have prioritized making Americans healthier, right? Wrong. President Biden's FDA pushed burdensome gender identity requirements on clinical trials that made compliance more expensive. They turned a blind eye to the Chinese Communist Party targeting our children by flooding our streets with illicit tobacco and nicotine

products. They neglected infant formula facility inspections that led to mothers and fathers across the country being unable to buy the formula their children needed, and they failed to work hand in hand with U.S. Customs and Border Protection to root out illicit pharmaceuticals, food, tobacco, and CBD.

We are facing a national epidemic of chronic disease, mental health, and obesity, and the FDA under the previous Administration sat on its hands. Thankfully, President Trump and Secretary Kennedy are taking action to make America healthy again. Soon after his return to office, President Trump signed an executive order removing unscientific pseudoscience compliance burdens for clinical trials. The FDA recently restarted approvals of safer alternatives to traditional tobacco products, and I am hopeful more will come soon to bring greater clarity to the market. Secretary Kennedy announced Operation Stork Speed, which will provide families with access to safe infant formula for their babies and prevent shortages going forward. And President Trump's efforts to re-secure the Southern border have returned law enforcement's ability to stop the influx of illicit pharmaceuticals, food, tobacco, and CBD coming into our country.

This Committee has spent years investigating failures at FDA, and our findings are clear. The Biden Administration stifled innovation with red tape and put bureaucrats before health of the Nation. Reform is essential. The FDA must prioritize innovation, safety, and the health of all Americans. The FDA needs better systems to identify and address drug shortages. Quick approval of innovative medicines and techniques identified with AI in support of President Trump's promise to cure cancer is a necessity. The FDA must work with food producers to make our food healthier while not upending supply chains. Incentivizing domestic manufacturing of pharmaceuticals is essential to improving the safety of prescription drugs and will enable more research. Clearly and effectively regulating hemp products will reduce confusion and prevent intoxicants and poisonous contaminants from infiltrating the market.

These examples are just scratching the surface of the dysfunction and failures within the FDA. Today, I am hopeful we can take a deep dive to better understand how we can improve the FDA to make Americans healthier. I now yield to the Ranking Member for his opening statement.

Mr. SUBRAMANYAM. Thank you, Mr. Chair. Today's hearing comes at a critical moment for public health and safety. All Americans should be able to trust that our government is working to ensure their food and medicine will be safe and affordable, but over the past 2 months, the Trump Administration has purged thousands of FDA workers, putting this essential mission and American lives at risk. Last week, the Administration purged 10,000 people at HHS, including 3,500 FDA employees. This was on top of a purge of approximately 1,000 FDA workers in February, and Secretary Kennedy subsequently admitted that 20 percent of last week's purges should not have happened. He tried to brush it off saying, "We will make mistakes," but how long will it take them to realize the full extent of the mistakes that they have made? How long will it take for them to try and very possibly fail to undo them, and how many Americans will get sick or die in that time?

The FDA is supposed to make sure that our children have the vaccines they need to survive outbreaks of preventable diseases, like measles, which has killed at least two children in the U.S. since February and sickened more Americans in 2 months than the entirety of 2024. The FDA is supposed to protect us from counterfeit drugs and contaminated infant formula, which are serious bipartisan concerns, but how is the Agency supposed to stop dangerous, illicit products from entering American homes and threatening American lives when under-funded Food and Drug inspection teams are being cut even more? A hundred and seventy employees from the FDA's Office of Inspections and Investigations were reportedly let go last week.

And let me tell you some of the expertise we are losing because of the Administration's actions besides that. They fired people responsible for regulating e-cigarettes and ensuring that predatory companies cannot market vapes to children. They fired people responsible for monitoring drugs for side effects and updating warning labels. They have fired the scientists monitoring bird flu and taking steps to prevent it from killing people. They fired the scientists with expertise in fighting heavy metals, toxins, and additives in our food supply. And they fired the people who monitor prescription drug shortages and ensure that Americans have access to affordable prescription medication. How is this making Americans healthier? We all know the answer to that question. It is not. People are going to die.

As a dad, I am especially concerned by the Administration undoing the progress we have made to protect babies from contaminated infant formula and formula shortages, and we should all be concerned by the risk posed by contaminated meat and produce. This chaos will keep us in the dark about looming shortages for essential drugs like antibiotics and chemotherapy drugs, and it will leave people no choice but to pay for pricey brand-name drugs because there are no FDA employees to approve generic versions. In the name of efficiency, this Administration even fired employees who were critical in approving new medications, meaning Americans will have to wait longer for new treatments, if they get them at all. And on top of that, we just heard last night from the President that pharmaceutical tariffs will be next, making the drugs we all rely on even more expensive.

One of the Americans impacted by these cuts is one of my constituents, a former teacher who spent 35 years working at the Department of Education. She has idiopathic pulmonary fibrosis, a terminal lung condition that took her aunt's life and is slowly taking hers. It is a rare disease that does not get much funding, but she had hope. A drug to slow down the disease received the FDA's breakthrough therapy designation in 2022, and the trials show that it might actually stop the progression of her disease. Her doctor anticipated FDA approval this year, but the FDA's funding cuts and the firing of researchers and staff who sit on the approval committees have made this impossible.

This Administration is stripping both hope and lifesaving medications out of the hands of Americans who need it most. The FDA can and must do more for Americans. Addressing our country's chronic disease epidemic, ensuring our children are set up to live

long and healthy lives, getting more lifesaving medications to those who need them, and ensuring that food on our shelves is safe and wholesome should be at the top of that list of things to do. But rather than making it better and more efficient, this FDA is left ransacked and reeling from the chaos and destruction of the Trump Administration. It is unclear whether the Agency can even perform some of its most basic functions anymore.

I do not know how much clearer I can be: these health cuts will kill people. They will make us less safe and less healthy. I was not elected to watch people suffer from diseases awaiting new treatments while this Administration dismantles the offices that offer that hope. It is the responsibility of this Committee to conduct meaningful oversight. If we are not talking about this and doing something about these cuts, we are not doing our jobs. I yield back.

Chairman COMER. The gentleman yields back. Without objection, Representative Moskowitz is waived onto the Committee for the purpose of asking questions at today's hearing.

I am now pleased to introduce today's witnesses. Mr. Guy Bentley is the Director of Consumer Freedom at the Reason Foundation, focusing on taxation and regulation of nicotine, tobacco, alcohol, and food. Mr. Jonathan Miller is the General Counsel of the Hemp Roundtable and partner at Frost Brown Tood Attorneys. Jonathan is known for being a leading advocate for hemp and CBD legislation and has continually worked to promote policies that benefit the hemp industry. And just so my colleagues on the other side of the aisle know, my friend Jonathan Miller is a former Chairman of the Kentucky Democrat Party, so we try to be bipartisan in this Committee, despite what you read in the papers, Mr. Miller.

Mr. Richard Williams is a senior affiliated scholar at the Mercatus Center at George Mason University. He is an expert in cost-benefit analysis and risk analysis associated with food safety and nutrition. Mr. Shabbir Safdar is the Executive Director of The Partnership for Safe Medicines. He leads a coalition representing much of the pharmaceutical supply chain. And Mr. David Kessler is a former Commissioner of U.S. Food and Drug Administration under Presidents Bush and Clinton.

Pursuant to Committee Rule 9(g), the witnesses will please stand and raise their 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?

[A chorus of ayes.]

Chairman COMER. Let the record show that the witness has answered in the affirmative. Thank you all. You may take a seat. We appreciate you being here today and look forward to your testimony.

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

I now recognize Mr. Bentley for his opening statement.

STATEMENT OF GUY BENTLEY
DIRECTOR OF CONSUMER FREEDOM
REASON FOUNDATION

Mr. BENTLEY. Chairman Comer, Ranking Member Subramanyam, and Members of the Committee, thank you so much for the opportunity to testify today. My name is Guy Bentley, and I am the Director of Consumer Freedom at the Reason Foundation, a non-profit public policy think tank. The Consumer Freedom Project analyzes and promotes policy solutions that improve public health while avoiding unintended consequences and protecting consumer choice.

I would like to focus on three points: first, the current state of the tobacco market; second, how we got here; and third, what can be done to reduce the illicit e-cigarette market while ensuring adult smokers have legal access to a range of safer alternatives.

The focus of this hearing is rightly on rooting out illicit products, including illegal e-cigarettes, but there is some good news amid the disorder. Youth vaping has declined more than 70 percent since 2019 and is at its lowest level in 10 years. Youth smoking fell by 68 percent and is at its lowest level on record. These declines followed the decision to raise the age of purchase for tobacco products to 21, for which there was bipartisan support. Cigarettes remain the most widely used tobacco product, with 28 million adult smokers and more than 400,000 deaths per year attributable to smoking. There are also 18 million adult vapers who are using e-cigarettes to quit smoking, but thanks to the FDA's regulatory bottlenecks, since 2019, illicit products have flooded the market, with almost 90 percent of e-cigarettes being sold illegally, mainly consisting of disposable products from China.

Despite the huge demand for safer nicotine alternatives among adult smokers, the FDA has authorized just eight vaping devices for sale and 34 vaping products in total, and only in tobacco and menthol flavors, which have little appeal to most e-cigarette users. E-cigarette authorizations account for just .2 percent of all tobacco product authorizations, compared to 22 percent for combustible cigarettes.

So, how did we arrive at a situation where it is easier to release a new cigarette onto the market than the safer products invented to displace cigarettes and the illicit products thrive? The answer is the FDA's approach to the pre-market tobacco product application pathway, which is how e-cigarettes are evaluated and authorized for sale or not.

The PMTA pathway, established as part of the Tobacco Control Act, was supposed to facilitate innovation for safer alternatives to cigarettes. In reality, it presents an almost insurmountable barrier. In 2022, an independent review of the FDA's performance as a tobacco regulator was published by the Reagan-Udall Foundation, which criticized the FDA's lack of transparency and timeliness in authorizing e-cigarettes into the legal market. It is unfortunate that in response to a report that emphasized the need for timeliness and transparency, the FDA issued a 5-year plan of generalities with no substantive changes to the PMTA pathway.

With a large illicit market now in place, the FDA has taken steps to ameliorate the problem with the creation of a multi-agency task force last year, increases in seizures, injunctions, and civil money penalties. But the only way to sustainably resolve the problem of the illicit e-cigarette market is to streamline the PMTA process to have regulated companies sell their e-cigarettes in the United States and reduce death and disease from smoking. Reforming the PMTA process would lessen current burdens on FDA staff reviewing e-cigarette applications, hasten the creation of a regulated marketplace, and restore public trust.

The FDA insists its current approach to authorizing or denying e-cigarette products is guided by science and is appropriate for the protection of public health, but despite the best of intentions, a regulatory regime that results in a de facto ban of almost all e-cigarettes, incentivizing the illicit market, is not appropriate for the protection of public health. When it is easier to bring a cigarette onto the market than a vape or a nicotine pouch, both of which the FDA acknowledges are dramatically safer, that is not appropriate for the protection of public health. And an Agency that fails to correct the misperceptions around e-cigarettes, with the majority of Americans now believing that e-cigarettes are just as or more dangerous than combustible cigarettes, that is not appropriate for the protection of public health. It is within FDA's current powers to change this dynamic and pursue a different path.

Thank you, and I look forward to your questions.

Chairman COMER. Thank you. The Chair recognizes Mr. Miller.

STATEMENT OF JONATHAN MILLER
GENERAL COUNSEL
HEMP ROUNDTABLE

Mr. MILLER. Mr. Chairman, Ranking Member, I am grateful for the opportunity to testify before your Committee today. Mr. Chairman, I am especially grateful for your decades-long leadership on behalf of Kentucky hemp farmers. You and I started on this journey in 2012 and worked across the aisle to secure hemp's legalization in the Bluegrass state. Indeed, hemp's policy success has always been a bipartisan hallmark, and it is no wonder. Hemp products are made in the USA, harvested from crops grown by American farmers, manufactured by innovative U.S. entrepreneurs, and sold by small businesses dotting the Nation.

Unfortunately, the U.S. hemp industry continues to encounter avoidable bureaucratic headwinds in the marketplace, and this turmoil is due in large part to statements, actions, and indecisions of the FDA. When Congress passed the 2018 Farm Bill, it explicitly legalized the sale of hemp and its derivatives such as CBD, but just a few hours after the Farm Bill was signed into law, the FDA reasserted its opinion that it was illegal to market CBD as a dietary supplement. We have watched in bewilderment as FDA has jerked back and forth with contradictory opinions.

First, the Agency affirmed its ability to regulate CBD under current law, but then FDA stalled, even ignoring congressional appropriations report directives to take expedited action. Finally, in 2023, the Agency stated that it cannot regulate CBD under existing regulatory pathways, essentially punting responsibility to Con-

gress. This regulatory uncertainty resulted in a collapse of the CBD market, as demonstrated on this chart behind me, denying economic opportunity that was promised to farmers.

[Chart].

Mr. MILLER. The FDA's inaction does not just threaten CBD. A new industry focused on the adult market has emerged to meet consumer demand for hemp-derived cannabinoids like delta–8 and delta–9 THC. These products provide plant-based options for adults seeking functional health and wellness benefits. Furthermore, a promising new hemp beverage industry has soared into popularity, meeting adult consumer demand for non-alcoholic options through domestic inputs from our farmers. The only upward line on this chart represents the price of hemp flour, which recovered when it started being widely used for adult products, offering a lifeline to U.S. farmers.

Unfortunately, lack of uniform quality control standards for hemp products at the Federal level has forced responsible farmers and small business owners to compete against unscrupulous actors who generate headlines by distributing poorly manufactured products that are sometimes inappropriately marketed to children. A political backlash has ensued. Language was added into the 2024 House Farm Bill that purported to crack down on the bad actors. Unfortunately, the language went much farther. It would have federally banned 90 to 95 percent of the hemp product marketplace, including most non-intoxicating CBD products and animal feed, which offers great promise to farmers, while undermining a decade of progress for hemp fiber production.

I want to be very clear. The hemp industry is united behind an appropriate response to these challenges, robust regulation of hemp products, not misguided prohibition. We support an approach that includes the following four pillars: restrict youth access, increase quality control standards, standardized labeling, and standardized packaging. FDA could act today on applying this four-pillar approach to hemp products. We are hopeful that new leadership at the FDA will reverse the past course of inaction and take deliberate steps to robustly regulate hemp. This approach is precisely in line with the new Administration's focus on providing adult consumers the freedom to make their own healthcare choices with holistic solutions that are grown on American farms.

If laws must be changed, we urge Congress to act now. There are two viable pathways. First, we hope you will consider Senator Ron Wyden's effort in the last Congress, S. 5243, that would ensure that the FDA regulates applying the 4-pillar approach. A parallel effort could be to invest more authority in the states to properly regulate their own markets. In the absence of Federal regulation, many states, like our Kentucky home, Mr. Chairman, have filled the policy void by developing new laws and regulations that balance market access with consumer safety. We urge you to implement a Federal framework that authorizes the sale of hemp products and develops uniform standards for labeling, packaging, and testing, while allowing states flexibility on more complex issues.

In the meantime, we have taken the additional step of establishing the U.S. Hemp Authority, the industry's self-regulating organization, which sets rigorous standards for safety, quality, and

transparency across the supply chain. The hemp industry may be unique in that we are coming to Congress to ask, please regulate us. Thank you for your consideration.

Chairman COMER. The Chair now recognizes Mr. Williams for his opening statement. Dr. Williams?

STATEMENT OF RICHARD WILLIAMS
SENIOR AFFILIATED SCHOLAR
MERCATUS CENTER

Dr. WILLIAMS. Thank you. Mr. Chairman, Ranking Member, and Members of the committee, thank you for inviting me to testify about the FDA today.

As I was nearing the end of my career at FDA, we were working on a rule governing how dietary supplements are made. After a year of looking, my staff could find virtually no benefits. When I suggested to the program office that maybe we should not regulate, the response was, "but, Richard, we have to get these guys somewhere." So, we ended up with a regulation, not because it would make supplements any safer, but because we could start exercising control over that industry. With approaches like that, is it any wonder the FDA has lost the trust of the American people?

During the course of my career, one of my employees asked me, "who do we work for?" I thought about it. Well, they are FDA managers, the Health and Human Services Secretary, and the President, but then I made up a person. She is a 30-year-old widow with two kids working in a diner in the Midwest. That is who we are working for. We should only be concerned about getting results, safer food, and helping people eat more nutritious diets. Again, when I look over my 27-year career, I was saddened by the fact that we had not made food any safer, and American diets have gone horribly wrong. But we justified our regulations to say we would prevent hundreds of thousands of cases of food-borne disease, and people would use the food labels to change their diets—preventing cancer, heart disease, and diabetes. None of that happened.

FDA justifies budget increases with the same information every year, coupled with new challenges, but increased funding for FDA means more regulations, more control over the economy, and higher prices. I do not think people care about giving FDA more money or seeing them exercise greater control. They just want safe and healthy food. FDA never talks about those actual outcomes as they do not want to be held accountable for failures. In fact, they fight fiercely against any notion of accountability.

FDA has to get the science right. For example, FDA ignores the biological science of evolution that shows us that tiny amounts of exposures to substances, natural and synthetic, are not harming us. In fact, when we are exposed to tiny amounts, well over half of all chemicals and all radiation, they not only do not harm us, they are actually beneficial. In addition, given the massive testing of food and colored additives, it is unlikely that that is where the significant risks are. FDA needs to cut out ineffective programs and regulations, and going forward, needs to produce far fewer regulations. Ineffective programs include things like food standards.

These are recipe standards from the 1930s that ensure manufacturers are producing foods just like mother used to make.

If we cut out useless programs and we have far fewer regulations, resources will be freed up to meet new challenges. For example, a better use of FDA resources would be to produce information that helps food producers, particularly the small ones. A good example would be letting producers know the root causes of foodborne outbreaks. The challenges are real. We need to know whether chemicals like PFAS and microplastics present health risks, and, if so, which ones of the many varieties are actually risky? We also need to address food coming into this country with intentionally added poisons from some of the most powerful enemies we have ever faced.

FDA must embrace new science and technology. To start with, FDA must be fully committed to precision health, including nutrition, as we are now beginning to understand that individuals respond differently to foods. That means that some national advice and even some regulations, while it may help some, will harm others. New technologies that will make food safer and healthier include smart packaging that will alert consumers to spoilage; blockchain-enabled tracebacks, which FDA has recently begun, I am glad to say; robotics that can produce food more safely. There are new types of treatments for pathogens for manufacturers. Better foods can be produced through genetic modification and precision fermentation. And finally, for nutrition, there are new monitoring technologies that will give us real-time advice on what to eat based on our personal characteristics. FDA needs to make sure that the new technologies are safe, but also that we do not inhibit innovations that will save lives.

To restore trust, FDA should be working for consumers like that mythical waitress who cares about results for her family. Thank you.

Chairman COMER. Thank you. I now recognize Mr. Safdar for his opening statement, and I apologize for mispronouncing that. Maybe you can correct my——

Mr. SAFDAR. It is fine.

STATEMENT OF SHABBIR IMBER SAFDAR
EXECUTIVE DIRECTOR
THE PARTNERSHIP FOR SAFE MEDICINES

Chairman Comer, Ranking Member Subramanyam, distinguished Members of the House Oversight and Government Reform Committee, thank you for your leadership on this issue and for inviting me today. My name is Shabbir Imber Safdar. I am the Executive Director of the Partnership for Safe Medicines, a coalition of all members of the supply chain dedicated to protecting Americans from counterfeit medicines. You have read my written testimony, and it is long and I apologize for that, but it is very thorough. We have been doing this for over 20 years. But I want to just focus my comments on just three areas today, which I think are of great concern, and they focus on the current crop of crime and patient endangerment around GLP–1s, or weight loss injectables.

First, unlicensed vendors are selling unregulated GLP–1s to patients without prescriptions. We see these sold on e-commerce

websites like Etsy; through med spas, which are unlicensed to often distribute prescription drugs; and also through fake online pharmacies, selling them as peptides. They are often labeled as research chemicals, like this one, and not for human consumption, and yet people are being sold them with instructions to inject them anyway, and they often do. We are not the only group worried about this. In February, 38 states' Attorneys General wrote to the FDA asking them to take action on these, and the FBI issued a similar alert, also raising concerns about compounders using illegal ingredients in their products and illegal compounding.

Second, the FDA has cited patient safety issues even with legally compounded weight loss injectables. Now, compounded medicine fills a critical need in our drug supply and makes our drug supply more resilient. For example, consider a medicine that commercially comes in only an oral dosage form, like a pill, and the patient has swallowing issues, perhaps because they are a child or because their swallowing abilities are compromised. In that case, a compounding pharmacy can make a liquid form and allow that patient to take the treatment. That compounded treatment, while an unapproved drug by the FDA, is still better than skipping the treatment altogether. However, the FDA has been clear that these are not FDA approved and pose a safety risk because they are not clinically tested for safety or efficacy.

If a patient must choose between taking a needed medicine or skipping treatment, obviously you do take the medicine, but what we are seeing in compounding of GLP–1s is a different situation altogether. Opportunistic telehealth companies are enticing people who do not plan on using weight loss injectables to start therapy on these compounded, unapproved products. And GLT–1s are sterile injectables, and compounding sterile products is very challenging, something we have actually seen from reading inspection reports by state boards of pharmacy and the FDA. On top of that, legitimate and safe ingredients for compounded medications, for these medications, are actually difficult to come by, and in every case I have seen in my experience, when things are difficult to come by, criminals step in to fill the gap.

PSM recently studied freight shipments of both semaglutide and tirzepatide, the active ingredients in major weight loss injectables, coming in as freight, using the FDA imports data base. And most of these were coming in from China and India, in some cases Canada, and we found multiple entering shipments that should have been denied entry at our ports. By studying that data base, we found one shipment of semaglutide that claimed to be manufactured at a JW Marriott in Canada. Now, not surprisingly, we did check the FDA's registered facilities data base for facilities in Canada, and that JW Marriott is not, in fact, an approved manufacturing site that has ever been inspected. It was refused by inspectors, which I am grateful for, but the second one was a shipment that was stated to be manufactured at a health club in Toronto, Canada. That shipment did actually make it through, and so it came in, and we do not know where it went. I am sure the FDA's Office of Criminal Investigation probably does, but it went somewhere in the U.S. and is destined for U.S. patients, either by a legitimate or illegitimate dispenser.

A third bucket of GLP–1s that I would like to point out are these lookalike counterfeits. It looks exactly like an injector pen that would come from the branded manufacturer, but it does not, in fact, contain the active ingredient or the right ingredient. Sometimes it even contains needles that have been compromised with bacteria. This is an example of a unit of fake Ozempic that is not, in fact, Ozempic. The criminals actually peeled off the label of the real product and then printed up an Ozempic label and put it on. A very alert pharmacist in Arkansas spotted this unit and quarantined it so that it would not be given to a patient and called the investigator at the Board of Pharmacy. The Board of Pharmacy's investigator came over and used a new tool developed by the National Association of Boards of Pharmacy called Pulse. It is a scanner app, it is on your phone, and they used that tool to make an, literally, under-a-second determination that that product was counterfeit. That quick thinking by that pharmacist and that investigator almost certainly protected patients in Arkansas and around the country because the Arkansas State Board of Pharmacy then immediately moved to suspend the license to the Florida distributor, who was shipping it into Arkansas, so they could no longer do business in Arkansas.

I am very proud of the safety of the U.S. prescription drug supply. It is the best in the world, and yet it contends with an enormous, perhaps globally record-breaking amount of criminality. And despite that, none of us have to worry about walking into a bricks and mortar pharmacy and getting a safe medicine. That is something that both keeps me up at night and actually also makes me very comfortable about living in the United States. I thank you for your time and I look forward to your questions.

Chairman COMER. The Chair now recognizes Dr. Kessler. Make sure you got the microphone pulled right up to you so we can hear and C-SPAN can hear.

STATEMENT OF DAVID KESSLER
FORMER COMMISSIONER
U.S. FOOD AND DRUG ADMINISTRATION

Dr. KESSLER. Mr. Chairman, Ranking Member, Members of the Committee, my name is Dr. David Kessler. I have worked for both Republican and Democratic Presidents. I was appointed by President George H.W. Bush and reappointed by President Bill Clinton as Commissioner of the FDA. We were responsible for accelerated approval, user fees, the food label, and the regulation of tobacco products. The FDA is a national resource. In January 2021, I had the privilege of returning to Federal service and co-leading Operation Warp Speed.

[Graph.]

Dr. KESSLER. Mr. Chairman, I am in full agreement with you and share significant concerns about the safety and efficacy of illicit and sometimes licit drug products originating from overseas, particularly China. As you can see from the first graph, only 4 percent of active pharmaceutical ingredients, that is the key component of a drug, are produced in the United States. Eighty percent are produced in China and India. In my opinion, for example, we

have been conducting a reckless national experiment with compounded new weight loss drugs, the GLP–1s.

Based on the information I have received from the FDA, it does not appear that there is routine FDA surveillance of the GLP–1s that are being imported into the United States from China for compounding to assure what is in the product. We cannot have confidence in the safety of compounded GLP–1 drugs, but that is only the tip of the iceberg. The conventional wisdom is that illicit cheap copies are coming from China. That has changed. The more significant threat, Mr. Chairman, is that China is attempting to surpass the United States in the sciences.

As shown in the next figure, the highly respected Nature Global Index reveals that eight of the top universities in terms of impactful research in the natural sciences are located in China. Specifically in chemistry, all 10 of the highest-ranked universities are in China, and only in the health sciences does the U.S. hold the lead. Do you want China to eat our lunch when it comes to science and innovation? We need to recognize that China is poised to surpass us in the sciences. We need to quickly act to make the necessary investments to shore up our competitiveness and avoid putting our Nation at risk.

I know there are limitations in methodology. However, the U.S. scientists that I have spoken with increasingly see much higher-quality work coming out of China. Look at the last figure. China is increasing investment in research and development currently at approximately $500 billion as of last year. In contrast, our investment in the NIH increased only slightly from 2004 to 2016 and is now facing cuts. Whatever needs to be fixed, let us fix it, but we need to make a marked increase in our investment.

I was a kid and went into the sciences after Russia launched Sputnik in 1957 as a result of our country's decision to be preeminent in the sciences. We are facing Sputnik 2.0 today, but with China. The current cuts to scientific research at the NIH and universities needs to be reversed. Otherwise, we are ceding the scientific primacy that Congress over the last 75 years has worked on a bipartisan basis so hard to ensure. One of the reasons we have been able to lead the world in health sciences is due to a strong FDA and its rigorous standards. One of my goals as Commissioner was to ensure that if you needed access to a lifesaving drug and you lived in the United States, you would have access to it before anyone else in the world.

We saw that with COVID–19, for example, with the monoclonal antibodies. Those drugs appear to have saved President Trump's life back in October 2020. Dr. Peter Stein's office made that drug available to the President and thousands of others. Dr. Peter Stein was removed from office in the recent rounds of cuts, as were thousands of others. It is no way to restore trust in FDA when you cut the person who may have saved the President's life. These cuts appear to me as devastating, haphazard, thoughtless, and chaotic.

Mr. Chairman, I agree with your priorities of increased enforcement against illicit imports and counterfeits. I agree with your priority of improving the safety of our food. The current cuts will make achieving those priorities impossible. We need to be clear-eyed about the threat that China poses to American

exceptionalism, especially in the sciences. We cannot afford to be haphazard in our support of the American scientific enterprise, not when China's commitment to the sciences is more real than it has been in the past. America's real competition in the sciences is China. The Administration and Congress need to understand the nature of that competitive challenge and respond strategically, thoughtfully, and with appropriate strength. Thank you, Mr. Chairman.

Chairman COMER. Thank you, and now we begin our questions. The Chair recognizes Mrs. Luna from Florida.

Mrs. LUNA. Thank you, Chairman. Good morning, everyone. I want to thank you all for being here today, but what we are dealing with is not just about counterfeit vape pens or illicit Chinese imports. This is how the FDA, the Agency that is supposed to protect the American people, has utterly failed to keep toxic chemicals out of baby formula, sunscreen, and food products being sold in stores here in America. Let me be crystal clear: American parents have every reason to distrust the FDA when Red 40, a known dye, is in their child's cereals; benzene is in sunscreen, also a known carcinogen; and Chinese-owned companies are allowed to dump trash on our shelves with "Made in the USA" slapped on it. The FDA has become a rubber stamp for big pharmaceuticals, big agriculture, and the CCP, instead of looking out for the best interest of the American people.

Mr. Safdar, is benzene, a known carcinogen, safe in any quantity in consumer products like sunscreen or face wash?

Mr. SAFDAR. Congresswoman, thank you for the question. PSM focuses mostly on prescription medications and entirely in prescription medications, and so I do not have the expertise to answer your question about sunscreen.

Mrs. LUNA. OK. I appreciate your honesty there. For the American people watching, so you know, benzene is a known carcinogen, and the FDA is allowing products with detectable levels of benzene to remain on the market. If they are generally fighting for the best interest of the American people, my question would be, why are they not saying anything about this? Mr. Safdar, would you also agree that the FDA can send armed agents into Amish dairy farms, but they are not keeping toxic Chinese-made face washes out of our stores?

Mr. SAFDAR. Congresswoman, thank you for the question. I neither work on anything related to food products or face washes, so I cannot answer the question.

Mrs. LUNA. Got it. Does anyone on the panel have an answer to that?

[No response.]

Mrs. LUNA. No? OK. Just for context, here is an article that I would like to enter into the record, Mr. Chairman.

Chairman COMER. OK. Without objection, so ordered.

Mrs. LUNA. The FDA was raiding Amish farms over raw milk, which, to be honest with you, is pretty absurd given that the FDA has dropped the ball on many other things that are actually causing cancer. Mr. Bentley, you talk about consumer freedom, but isn't it true that freedom is based on informed choices? And how can

parents make informed choices when the FDA has allowed known neurotoxins, like Red 40, in kids' food without warning labels?

Mr. BENTLEY. Congresswoman, thank you so much for the question. Food dyes is, I think——

Chairman COMER. Make sure you got the microphone in front of your face, everybody. Yes. There you go.

Mr. BENTLEY. I beg your pardon. Thank you so much, Congresswoman. I appreciate the question. I think the issue of red dyes is a particularly important one, and I think there does need to be further research into its relative safety and to whether the FDA has taken a relaxed attitude or and whether these products, even if there is not a known health risk at the moment, whether a precautionary approach should be taken into removing them from the market. So, I think that is very up for discussion, and I hope new leadership of the FDA can look at these, perhaps under-examined, questions in more detail.

Mrs. LUNA. Yes, we will be making those suggestions. As I am sure you know, products based and manufactured in the U.K., even in other parts of the world, are way different than American products. And just to put it in perspective, I mean, aside from corporate lobbying and regulatory capture, do you think that there is a reason why Red 40 would still remain in American products when it is actively banned in the rest of the world? Just, if you could, yes or no?

Mr. BENTLEY. No.

Mrs. LUNA. OK. I would say that because of the utter incompetence being displayed by the FDA, I understand that you are all not the head of the FDA, but I am going to be choosing to reintroduce, and I am glad that you backed me up on this one, the Do or Dye Act, which is what I introduced in the 119th Congress, to remove some of those toxic chemicals and dyes from our food products. Dr. Williams, you are a former FDA economist. Can you please help me understand something? Why is the FDA moving faster to approve experimental drugs for billion-dollar pharmaceutical companies than it does to ban known toxins like benzene?

Dr. WILLIAMS. First of all, I worked in the food section of FDA, not in the drug section, so I really cannot comment on that. I will say that——

Mrs. LUNA. Just real quick, does anyone have a comment for that, because we are at 41 seconds. Pharmaceutical?

[No response.]

Mrs. LUNA. Nothing. OK. So, continue.

Dr. WILLIAMS. OK. I will say that in terms of color additives, there is some misinformation out there. They are not banned in Europe. Actually, Europeans do not care that much about having color in their foods. The other thing is that you really have to focus on the amount of exposure. Simply saying something is a toxin or a carcinogen does not mean a lot. What matters is what the exposure is.

Mrs. LUNA. Sir, if I can just interrupt you for a second, and I appreciate your position, but what I will tell you is if you have something that is known to cause autism with children, you have a young child's brain that is developing, I do not think that that is misinformation. I think that the American people are trusting the

FDA to ensure that they do not even have to worry about levels of additive that has something that has known detrimental effect on a child. Either which way, why are we adding fake stuff into a product that can just be naturally made? I think that that would be the biggest argument, and I would say that Big Food wants it to be a cheaper manufactured product because it is more of a net profit for them on the back end.

Look, I am already over time. I appreciate you guys being here today, but if you have anything that you can provide my office with, I would appreciate it because I think that the FDA needs an entire overhaul, and I think that the FDA currently is for sale. Thanks, guys.

Chairman COMER. The Chair recognizes Mr. Subramanyam.

Mr. SUBRAMANYAM. Thank you, Mr. Chair. Dr. Kessler, I was very interested in your testimony about how these cuts are affecting our food safety and, really, just our ability to have a functioning FDA. And so, could you just tell me a little more, these firing at HHS and FDA, in particular, we are trying to find effective strategies to bring new drugs to market in a safe manner, but in an expedient manner, but how do these cuts affect our ability to do that?

Dr. KESSLER. Imagine, Ranking Member, that, you know, there was a major airline. That major airline decided today that it was going to fire everyone except the co-pilots, and it was going to run that airline and it only had the co-pilots, OK? No pilots, the senior people are gone. People who fix the planes were gone. People who got people on the plane were gone. I think that is what we are facing with these cuts. Imagine if you try to run this Congress and there were only Congressmen and Congresswomen in the building, all right? That is what is going on at FDA today. I have major concerns. We are at risk. I think we are less safe today.

Mr. SUBRAMANYAM. I have talked to farmers who have talked about the outbreak of avian flu, and we actually had the first mammal case of bird flu in the state of Virginia, the Commonwealth of Virginia, and my district on Monday. How would these cuts impact the FDA's ability to deal with the bird flu epidemic?

Dr. KESSLER. The leading experts on avian flu are certainly at FDA and at NIH. This is not just about FDA. Dr. Jeanne Marrazzo, who is running NIAID, taught me everything about avian flu. She is no longer there. We are at risk from infectious diseases. Look, I cannot tell you whether we are one mutation away or two mutations away, all right? It has had devastating effects, I mean, on our animal livestock, and it gives me great concern, but that day is going to come, OK, and those people we need are not there.

Mr. SUBRAMANYAM. And I would like to enter into the record a *Washington Post* article titled, "Worries Grow Over Risks to Americans as Trump Cuts Health Safety Agencies."

Chairman COMER. Without objection, so ordered.

Mr. SUBRAMANYAM. April 6.

And so, how would these firings at the FDA impact its ability to make sure that infant formula is safe and that we do not have another infant formula crisis?

Dr. KESSLER. Absolutely. You are exactly right. What we heard, I think, from my panelists, whether it is hemp, whether it is e-cigarettes, these are complicated regulatory decisions. You have industries asking at this table, please, we need thoughtful regulations, right, that are well-balanced. Those people who are in charge of that policy at FDA to be able to work through, to get the right answers with the Congress, even to answer your request for information, they are not there.

Mr. SUBRAMANYAM. And you said recently, it is not too late to undo at least some of the damage that has been done. How much time do we have left before we cannot fix what has been broken, and what would you do to fix it?

Dr. KESSLER. I always believe that things were fixable, right? You know, I think we have seen that, right? You can always go in and fix. The problem is, especially in the sciences, I have been the dean of two major medical schools. This is about expertise. This is about pipeline, right? If we lose a generation of young people—I mean, young people got hit with COVID—I think we cannot underestimate the effect. They could not go into their laboratories. They had to sacrifice their training. If we now have these cuts, right, at NIH, you know, a second time, they cannot get jobs as postdocs, we are going to lose a generation of scientists. They are going to set back this country, and that is true at FDA. We have lost a thousand person years of expertise in a few weeks. I mean, if we let this go on for much longer, I mean, I think it is a matter of weeks. I mean, you know, this may not be fixable. This may affect us for decades.

Mr. SUBRAMANYAM. Thank you, Dr. Kessler. I yield back.

Chairman COMER. The Chair now recognizes the Chairman of the Government Operations Subcommittee, Mr. Sessions from Texas.

Mr. SESSIONS. Mr. Chairman, thank you very much. Dr. Kessler, thank you for being here. We have had the former head of the FDA in before this Committee several times. It was a purely political dance that he provided this committee, not only on answering the people that were not going to work, the empty parking lots at FDA, people who chose to work from home, not collaborating, working with each other for 4 years. This happened all across government, and I find it interesting that now the argument is everybody wants to come back to work when you and I know that we disagree on that issue.

[Slide]

Mr. SESSIONS. To the panel, I would like to say to you, I had an opportunity this morning to look at WebMD, and you may have your own ideas about the effectiveness or how WebMD works, but the bottom line is, is that I am looking at what might be delta–8, which is this unregulated form of hemp THC. It is called delta–8 THC. THC is an addictive product. WebMD says that marijuana, which is what THC is, use over several years causes brain effects, like lower IQ, slower processing speed, memory, and attention issues. I would direct you to this slide here where delta–8 is involved and it is marketed in such a way that it appeals to not only adults, but also to children.

WebMD further says, "hemp's legality stems from the so-called Federal Farm Bill—and I am quoting this—"the so-called Farm Bill, which removed hemp and its byproducts from the list of controlled substances." The reason hemp's low THC levels, less than .3, which was in the bill, but the bill does not mention delta–8 anywhere. And what has happened is chemists have come in and changed that viewpoint, not only of hemp, which I was, as the Chairman of the Rules Committee, very open to when the gentleman, the young Congressman, former Chairman, former head of the Agriculture Committee in Kentucky, came and asked me if I would allow this to be put into the Farm Bill. And I went through a detailed explanation with him about what hemp stood for and how it might be used.

I was told it was this: ropes, things that are used by Americans every day, but to build the market, and he did not say anything that was wrong to me. He said what was right at the time. But now these so-called loopholes, chemistry, these are dangerous products that create in, not only my congressional district, the Sheriff in McLennan County came to me and said, "Congressman Sessions, please go to our hospitals and look and see what is happening as a result of delta–8," what is happening as a result of this hemp product that has become loaded with THC.

I think what I would say to you is this: it is widely seen by many people as a dangerous product. It is dangerous not only to adults, it is very dangerous to children, children who do not recognize the difference between what might be a small product, a gummy, perhaps, or something else, and then turns into an emergency episode at an emergency room. I think one of the telling things comes from a guy whose name is Elton John, a well-known musician, who has stated that of all the things that he has seen in his life, one of the worst things that he has seen is America and anybody else that legalizes marijuana.

Marijuana is THC, and so, gentlemen, I will be watching you, and I am interested in the hemp industry, the same reason why, as Chairman of the Rules Committee, I allowed it to be in the Farm Bill. But gentlemen, we have got to understand, it is a dangerous product that causes IQ problems, it causes problems with slowness of adults, and it causes problems that are harmful to children. Mr. Chairman, I yield back my time.

Chairman COMER. Thank you. The Chair recognizes Mr. Krishnamoorthi from Illinois.

Mr. KRISHNAMOORTHI. Thank you, Mr. Chair. I want to show a visual here.

[Chart]

Mr. KRISHNAMOORTHI. And, Dr. Williams, according to the CDC, measles cases have skyrocketed during Donald Trump's time in office, with 607 confirmed cases and two tragic deaths. You do not dispute that, right? You got to turn on your mic.

Dr. WILLIAMS. Yes, sorry. No, I do not dispute that.

Mr. KRISHNAMOORTHI. And, Dr. Williams, you wrote that "This tragic measles outbreak is a direct consequence of spreading misleading information about vaccines, and, unfortunately, Health Secretary, Robert F. Kennedy Jr., has played a role in perpetuating these false claims." You wrote that, correct?

Dr. WILLIAMS. No, I did not write that. It must be another Williams.

Mr. KRISHNAMOORTHI. "Measles Outbreak, RFK, Jr.'s Health Agenda & Surprising Health Wins."

Dr. WILLIAMS. No, sir, I did not write that.

Mr. KRISHNAMOORTHI. OK. Let me mention this. On Sunday, Mr. Kennedy finally said the most effective way to prevent the spread of measles is the MMR vaccine, but he did not disavow false claims that many people have said were directly linked to the measles outbreak. And this, obviously, is something that must be addressed immediately, correct?

Dr. WILLIAMS. Yes, sir.

Mr. KRISHNAMOORTHI. Let me turn to my next topic. President Trump has put tariffs on just about everything, sending prices skyrocketing, and, unfortunately, the stock market is plummeting right now. Mr. Bentley, you wrote that "Tariffs of any kind are a direct tax on consumers," correct?

Mr. BENTLEY. That is correct.

Mr. KRISHNAMOORTHI. And Mr. Safdar, in a February 18 Q&A at the White House, the following was asked and answered of the President. The question was asked to the President, "And what about pharmaceutical tariffs?" Answer, "It will be 25 percent and higher." You do not dispute he said that, correct, Mr. Safdar?

Mr. SAFDAR. I was not at the White House, Congressman, but I will take your word for it.

Mr. KRISHNAMOORTHI. OK. Thank you. Well, look, today, according to *The New York Times* and many other periodicals, even common medicines like Tylenol and the active pharmaceutical ingredients in Advil are primarily made outside the U.S. and are now subject to tariffs. Moreover, according to *Forbes* and ING, researchers have found that tariffs will increase the price of all generics by about $42 per drug per year. So, I come back to you, Mr. Bentley. You said in this article, "Tariffs are not just a threat to the economy, they are a threat to public health," correct?

Mr. BENTLEY. Correct, Congressman. I was talking about tariffs on e-cigarettes, which would be a threat to public health because e-cigarettes are a substitute for combustible cigarettes.

Mr. KRISHNAMOORTHI. And of course, tariffs on generic drugs would also be a threat to public health as well. Now, let me turn to you again, Mr. Bentley, regarding e-cigarettes. Mr. Bentley, by 2018 and 2019, 20 percent of our kids were vaping, and the rate was doubling year-over-year, prompting Trump's then FDA Commissioner, Scott Gottlieb, to call it an epidemic. However, at this time in 2018, you call the situation "an alleged epidemic," right?

Mr. BENTLEY. Correct.

Mr. KRISHNAMOORTHI. And today, there are over 1.6 million youth vapers, yet despite millions of underage users, you said recently that "claims of widespread youth vaping are disputable." You said that in this article, correct?

Mr. BENTLEY. Correct, because youth vaping has fallen dramatically since 2019.

Mr. KRISHNAMOORTHI. I assure you that the parents of the 1.6 million youth vapers do not believe that somehow claims of widespread youth vaping are somehow disputable. Now, let me turn to

another article that you wrote here. You said, "A Question of Taste: The Public Health Case for E-Cigarette Flavors." You believe, as the title suggests, that there is a public health case for flavored vapes, right?

Mr. BENTLEY. That is correct, Congressman.

Mr. KRISHNAMOORTHI. Let me just show you some of the American-sourced vapes that are on the market currently. Strawberry Super Strudel. There is a public health case for that, right?

Mr. BENTLEY. There are 18 million adult vapers in the United States——

Mr. KRISHNAMOORTHI. There is a public health case for Strawberry Strudel?

Mr. BENTLEY. Yes, there is because most——

Mr. KRISHNAMOORTHI. And how about this one, Rainbow Road? There is a public health case for Rainbow Road, right?

Mr. BENTLEY. They all need to go through FDA review to be evaluated on their public health merits, which I completely support, but flavors are the overwhelming choice of adults, 18 million of whom are using e-cigarettes to quit smoking.

Mr. KRISHNAMOORTHI. On page 3 of your statement, 13 percent of youth who vape cite the availability of flavors as their reason for vaping, so hundreds of thousands of children who have never smoked are taking up vaping because of these flavors. This is Sour Skittles. This is a Sour Skittle vape. Sir, your defense of flavored vapes is completely unacceptable and endangering our youth today. Thank you, and I yield back.

Chairman COMER. The gentleman yields back. I will recognize myself for questions. Mr. Bentley, tobacco is still a huge crop in my congressional district. Tobacco is still legal in the United States. In 2014, the FDA collected $1.8 billion in user fees by the Center for Tobacco Products. Today, that number is $3.5 billion in user fees. Despite this increase, the FDA continues to put out unclear or incomplete guidance, causing the people in the business that want to play by the rules to have uncertainty. Why can't FDA properly regulate tobacco despite charging the tobacco companies billions of dollars?

Mr. BENTLEY. Thank you for the question, Congressman, and you are exactly right. The Center for Tobacco Products run by FDA has collected billions of dollars in user fees, and yet we have a nicotine market that is in chaos with 90 percent of e-cigarettes being bought on the illicit market. What can change at FDA to resolve the problem of the illicit market is not more funding and staff——

Chairman COMER. Right.

Mr. BENTLEY [continuing]. But the process of approvals.

Chairman COMER. And just to touch on what my friend, Mr. Krishnamoorthi said, it is my understanding that the FDA approves very few tobacco and nicotine products, even though many of the products the PMTA processes are safer than traditional cigarettes. Is that true?

Mr. BENTLEY. That is exactly true.

Chairman COMER. So, why is the FDA refusing to authorize safer products?

Mr. BENTLEY. Because the FDA interprets what is called the appropriate for protection of public health standard in a particularly

opaque and, we imagine, strict way, and that means fewer products by companies, as you say, Congressman, who want to play by the rules——

Chairman COMER. All right.

Mr. BENTLEY [continuing]. Are getting to the market.

Chairman COMER. And I would argue, to go along with what Mr. Krishnamoorthi said, the FDA's refusal to approve new tobacco products created a thriving market for illegal and unsafe products, the ones that Mr. Krishnamoorthi was talking about, from China. These products are targeted at children. What should FDA be doing to prevent these illicit Chinese products targeting our children?

Mr. BENTLEY. FDA has set up a multi-agency task force, particularly with partnership with DOJ and CBP, to try and track and halt the importation of products from China. But at the end of the day, this will be nothing really more than a bandage unless its own internal processes can be reformed, which also, fortunately, do not require more staff or more funding.

Chairman COMER. All right. Mr. Miller, we are going to shift gears to talk about hemp and hemp derivatives. So, the Congress legalized the sale of hemp, like Mr. Sessions was talking about, and hemp derivatives, by removing them from being Schedule I substances. To what extent has FDA regulated hemp derived products like CBD?

Mr. MILLER. They have not, and we as an industry are begging for that regulation.

Chairman COMER. Why hasn't the FDA refused to regulate hemp and its derivatives despite having the authority to do so and despite the leading organization representing the credible manufacturers and producers begging them to do that?

Mr. MILLER. They have gone back and forth. They initially said that they were going to regulate products, and then they have now claimed they need to have congressional authorization to allow them to regulate that. We dispute that. And I do want to mention, because Congressman Sessions raised that issue about youth use of these products, we as an industry strongly oppose the sale of these products or the marketing of these products to children and really are looking for the FDA's help to make sure that that does not happen.

Chairman COMER. How long would it take the FDA to do something like this? I mean, what are we talking here?

Mr. MILLER. Well, we——

Chairman COMER. Do we need a gazillion bureaucrats that work from home? What is involved in FDA to regulate this, especially when you have the industry wanting to be regulated?

Mr. MILLER. So, there currently are a number of safeguards under current law that the FDA could use and has chosen not to use within the Federal Food, Drug, and Cosmetic Act. For example, the law precludes manufacturers and distributors from selling mislabeled or adulterated products, and it requires the manufacture and sale of products consistent with good manufacturing practices. The law also requires reporting of serious adverse events, and it mandates strict labeling, including, if FDA desires, warning against the use of products by children. Finally, the FDA, with the

Consumer Product Safety Commission, could require child-proof packaging.

Chairman COMER. All right.

Mr. MILLER. So, there are existing——

Chairman COMER. Got it.

Mr. MILLER [continuing]. Laws out there that they can take advantage of.

Chairman COMER. Very good. My last question, Dr. Williams, we investigated the infant formula crisis extensively in this Committee last Congress. Can you talk through, quickly, how the FDA failed to prevent the crisis and what needs to be done to improve competition and resilience to ensure an infant formula crisis never happens again?

Dr. WILLIAMS. Yes. One of the main problems, particularly with supply, was that we would have manufacturers write to FDA and say we are thinking about getting into the infant formula business. The FDA would respond with please do not. They wanted to keep the number of suppliers down to six, and they did that. So, consequently, when we had one plant that had a problem that actually had been investigated, when it had stopped production, that is when we hit a huge supply problem. But there was one other problem, and this stems from the Infant Formula Act dating back, I believe, to the 1980s, where FDA produced a regulation that was addressing manufacturing of infant formula, good manufacturing practices. None of it, in my estimation, in my analysis, would help infant formula at all. Nevertheless, the FDA was determined to go forward. The problem with that was when FDA passes regulations on infant formula, that raises the price of infant formula for people who cannot get it for free. What happens is less well-off consumers extend the infant formula with water, and there is nothing more dangerous than the primary source of nutrition being extended with water for infants. So, that is another problem that I think FDA needs to be aware of.

Chairman COMER. Very good. The Chair recognizes Ro Khanna from California.

Mr. KHANNA. Thank you, Mr. Chairman. Dr. Kessler, there is a dangerous anti-intellectualism that has become fashionable in our country today: attack the scientist, attack the thinker, attack the academic. Vice President Vance says the universities are the enemy. He is calling an enemy the university where the President who appointed you went, Yale; calling Harvard, where you were educated, the enemy; calling the very university he or I studied at the enemy. And I am tired of politicians having this kind of false populism where they are attacking people who read, attacking people who think, attacking people who actually engage in intellectual excellence. What has been the alternative? Appointing people who did not do the homework, who never read a book about economics or health sciences. We see what that is turning out to be.

And I want to ask you, Dr. Kessler, because I was so concerned about the firing of Dr. Peter Marks, who has more qualifications than the entire Cabinet put together, who actually did the one thing with Operation Warp Speed that was Donald Trump's contribution. Can you talk about how offensive it is that people far less qualified, far less knowledgeable fired this man?

Dr. KESSLER. I do not think I could say it better, Congressman, than you just said it.

Mr. KHANNA. I mean, go ahead.

Dr. KESSLER. I mean, this feels a little surreal just sitting here, because everybody wants a stronger FDA, everybody wants more regulation, fix this, make sure that infant formula is safe, make sure that drug is safe, make sure that dietary supplement is safe, do a better job, go here, go there, make sure this import, right, does not contain any harmful products. But over the last several weeks, this Agency has been devastated.

Mr. KHANNA. And, Dr. Kessler, I am talking about something even deeper, because I agree with you. These cuts are going to hurt people, the lifesaving treatments are not going to get approved. But I understand people are angry in this country. They are angry that jobs have gone offshore. They are angry that wages have stagnated. But what you have is politicians exploiting it in a false populism to blame anyone who thinks, to blame anyone who reads, to blame anyone who has ideas. They are attacking the smartest people in our country and blaming them for problems that were caused by political failures, and we need politicians in this country who are going to say we are going to stand to defend intellectuals. We are not going to be afraid of that. We are going to stand to defend institutions that have led thought.

You know, Lincoln called it mob rule. It is a story that goes all the way back to the Athenian mobs taking on Socrates, and I want people in our country, politicians, to stop with the false populism, to stop attacking the people who do their homework and who are leading inventions and who are leading science and leading thinking. President George Herbert Walker Bush, who actually sacrificed and fought in World War II, what would he have thought about this Vice President attacking Yale, about this Health Secretary firing people of competence and exceptional talent?

Dr. KESSLER. I was there sitting at graduation as a dean when President Bush came to give the commencement address. These universities have contributed mightily to, not only the intellectual life, right, not only to our freedoms, but to our competitiveness, and scientific advances have been generated by these universities. That was what this Congress, back in the 1950s and 1960s, set up this system. Bush, right, had a system that gave rise to the medicines that we have available today. We have to be able to support that biomedical infrastructure. That is under attack. It needs to stop.

Mr. KHANNA. And I appreciate your service.

Chairman COMER. The Chair now recognizes Mr. Grothman from Wisconsin.

Mr. GROTHMAN. Thank you. I got to respond to a little bit of that. First of all, wages are stagnating. They are stagnating under the law of supply and demand. We just had a President who let 10 million people in this country. Of course, wages are stagnating, and I think a lot of times the business community is just fine with that. I have had businessmen complain to me, you know, I have to give my workers another raise here. Isn't that horrible? You know, can we have more immigrants around here? So, we know why wages are stagnating. They are stagnating because of excessive immigration.

As far as our universities, there is no diversity of thought there. My one other comment, you talk about people who think and read. In my experience, people who are skeptical of our medical community, our pharmaceutical community, are the most well-read people in my district. That is why they are skeptical. They go beyond just the blather you get in the mainstream media, but OK.

Now we got to ask some questions here. I will ask one of you folks. It seems to me, am I correct here, we have more pharmaceuticals per person prescribed, consumed, or whatever in this country than the world, or at least more than any other Western countries?

[No response.]

Mr. GROTHMAN. You do not know. OK. We will try to give you another question. Do we have more antidepressants consumed in this country than other countries?

[No response.]

Mr. GROTHMAN. You do not know. Stumped again. OK. OK. I will go for Mr. Williams. Americans have been grappling with—I will digress for a second. As far as bringing new pharmaceuticals on the market, do you believe the pharmaceutical industry itself has a disproportionate influence in determining which drugs come on the market and which off-brand drugs are not going to be researched?

Dr. WILLIAMS. My expertise is in food safety and nutrition, not in pharmaceuticals, unfortunately.

Mr. GROTHMAN. OK. Well, we will give you a food question then. Americans have been grappling with high inflation, especially food inflation. During the Biden Administration, grocery prices rose 22 percent. Would you simplify the FDA's food regulatory structure to lower prices? Could you give me some examples of what could be done?

Dr. WILLIAMS. Yes. I believe that is exactly what I would do. I think a lot of the problem with FDA's food regulations from my expertise—and it really is now going on over 40 years, and I continue to look at it—is that too many of FDA's regulations were not being made because it was going to keep food safer or because it was going to help nutrition. A lot of it is because of some firms controlling FDA saying we want regulations to put our competitors at a disadvantage. All those regulations have to be complied with and all of that compliance by those firms raises prices. They do not pay for the regulations. This is a big misunderstanding, particularly in FDA. It is consumers.

Mr. GROTHMAN. Yes. Can you give me a ballpark number on, what you think, food prices? Could it drop if we did not have what I will refer to as unnecessary regulation?

Dr. WILLIAMS. I wish I had that information, and I do not. But I think it would certainly help, and it would certainly help FDA to target their inspections and focus their resources on real risk.

Mr. GROTHMAN. OK. We will give Mr. Bentley a question or Mr. Miller. America does spend a great deal on medicine and a lot of that is on drugs. Nevertheless, our life expectancy seems to be less than other developed countries. Can you comment on that?

Mr. BENTLEY. Congressman, my expertise is basically in tobacco policy, but I will say an easy way that we could increase life expectancy and reduce cancer is have more authorized safer alter-

natives to cigarettes onto the market, which FDA has been stymieing for the last 5 years.

Mr. GROTHMAN. OK. Mr. Miller, you got any comments?

Mr. MILLER. I would just add that when it comes to holistic products, products made from American agriculture like hemp, these give alternatives to pharmaceuticals that a lot of Americans find tremendous relief in, and we should be promoting them, but we should also, as I have been saying, regulate them strictly.

Mr. GROTHMAN. OK. I will give Mr. Bentley and Williams and the fourth one down the line one more question or one more crack at it. It seems to me, compared to other countries, that we are over medicated, and I am not sure that it is resulting in better health. Could you comment on that?

Mr. SAFDAR. Congressman, my expertise is not in that area, but I will say that our drug supply, which is my expertise, is probably the safest in the world. In fact, the next time you go up and pick up a prescription, you probably should buy a $2 lottery ticket. You are more likely to hit that than to ever get a counterfeit medicine in a pharmacy. It is really the pride of the world.

Mr. GROTHMAN. Thank you.

Dr. WILLIAMS. I will just add to that. In fact, I think medicine has been responsible for our longevity up until now, but I think it is time to focus on prevention, and I am very glad to see that there are a number of people entering government now that are focused on prevention more than medicalizing people who are already ill.

Mr. GROTHMAN. OK.

Chairman COMER. Before I recognize Mr. Mfume, Mr. Krishnamoorthi has asked for recognition of unanimous consent.

Mr. KRISHNAMOORTHI. Yes. Mr. Chairman, thank you so much for allowing me to enter into the record, or I request unanimous consent for this article by our witness, Mr. Richard Williams, entitled, "Measles Outbreak: RFK, Jr.'s Health Agenda & Surprising Health Wins" from his website, and I give the witness a chance to remember that he wrote this, but it is from your website. This is your picture, this is your article, and this is your quote that I had from earlier.

Chairman COMER. Without objection, so ordered.

Mr. KRISHNAMOORTHI. Would you give him a chance to respond or——

Chairman COMER. If he wants to respond. It is up to the witness.

Dr. WILLIAMS. I will go back and take a look, but, yes, I do not recall that one.

Mr. KRISHNAMOORTHI. We will give you a copy of this, OK? It is serious to deny that you wrote this article.

Chairman COMER. All right. The Chair recognizes Mr. Mfume from Maryland.

Mr. MFUME. Thank you very much, Mr. Chairman. My thanks to the witnesses who are here today. I want to just say a couple of things that are quite obvious and then turn the attention a bit to clinical trials. Dr. Kessler, I am going to start by saying I am going to end with you because I found your comments to be chilling and to be a real warning to where we are and where we are headed if we do not heed——

Dr. KESSLER. Thank you.

Mr. MFUME [continuing]. The fact that we are making big mistakes right now every day as we dismantle the Food and Drug Administration. But before I do that, let me just state the obvious, and that is that everyone I think wants to protect the health of all Americans, at least everybody should, and everybody wants to root out illicit products that always find their way into our markets, and that is why ensuring the health of the FDA is so vital to this country. It has got to have the resources to protect all of us regardless of race, ethnicity, sex, or any other designation. It is critical to public health.

Since the FDA Commissioner Makary was sworn into service on April 1, Secretary Kennedy and he have pushed out and fired, as has been stated, over 4,000 Federal employees at FDA, and just last week, more than 800 staff at FDA Center for Drug Evaluation and Research were also fired. That center in particular is responsible for approving and monitoring new medications that come onto the market for side effects and for updating drug warning labels accordingly. Those fired workers, as has been stated earlier, are some of the Nation's best and brightest scientists in charge of ensuring our supply of infant formula to make sure that it is safe, our medications for our family members and grandparents, food for all of us, and many, many ways the highest quality of food safety that we can expect in this country.

So, to have trust in the FDA, its decisions, and its ability to ensure effectiveness of the drugs that are approved, that requires research, it requires clinical trials, and those trials must include all American groups that may have need for the treatment. So, effectiveness and safety cannot be ensured to all without the inclusion of all Americans in those clinical trials, which is why I am particularly disturbed that these mass firings at our Nation's health agencies, in addition to these anti-DEI efforts, and similar rhetoric across this Administration will make improving the overall health of Americans much, much more difficult. So, it was unfortunate to see that the FDA removed previously issued draft guidance on diversity in clinical trials from its website, as if to suggest that disease is racially monolithic. Clinical trials refute that. Clinical trials, when they are done correctly and with diverse participants, give us the ability over and over again to produce the best medications and to chart out the best courses.

In this Congress, we passed, several years ago, something known as the Henrietta Lacks Enhancing Cancer Research Act in January 2021. Many of you will remember this was initially led by the former Chairman of this Committee, the late Elijah Cummings, and this very Committee listened to testimony about why it was important, and it was many of you on this Committee that joined me and others on the Floor to argue for its passage, and it was indeed passed. Mrs. Henrietta Lacks and her extraordinary story of her HeLa cells, which were alive many, many years after her physical death, have been very instructive in terms of finding a way to create cures for diseases. Jonas Salk will tell you that, before he was able to finalize the polio vaccine, he had it tested against her cells long after her death to make sure that it was, in fact, effective. It has been effective in HPC vaccines and it has been effective in helping the mapping of human genomes. So, we do not want to

go back to the days prior to Mrs. Lacks when no one wanted to talk about diversity in clinical trials, and we do not want to stay where we are, where we are erasing any allusion to diversity in those trials from the website of the FDA. I just do not understand it at all.

I want to, if I might, just get your opinion, those of you who are here right now, as to whether or not you think that removing diversity from clinical trials helps the American public or advances medical science. Dr. Kessler?

Dr. KESSLER. It is absolutely essential that our clinical trials be done in a diverse population. There is great variability of biological response. I am humbled when I look at medicines and how variable they respond in different people. It is just the nature of biology. We work very hard—the pharmaceutical industry, FDA, the universities—to make sure that clinical trials are increasingly representative and diverse. If we want to understand how medicines work, if we want safe and effective medicines, clinical trials require a representative and diverse population.

Mr. MFUME. Mr. Chairman, if I might have an additional 15 seconds. I would like to ask unanimous consent that we enter into the record the GAO report to congressional committees 2 years ago entitled, "Cancer Clinical Trials."

Chairman COMER. Without objection, so ordered.

Mr. MFUME. I would like to ask unanimous consent that we enter into the record Public Law 116–291, which many of the Members of this Committee voted in favor of, that created this whole notion of more diverse clinical trials, particularly in cancer research.

Chairman COMER. Without objection, so ordered.

Mr. MFUME. And I would like to ask unanimous consent to enter into the record clinical research entitled, "Genetic Variant and Cardiac Remodeling, Injury, and Heart Failure Risk in Black Adults."

Chairman COMER. Without objection, so ordered.

Mr. MFUME. Thank you. I yield back.

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

Mr. PERRY. Thank you, Mr. Chairman. Gentlemen, thank you for being here. The average life expectancy for Americans is 78 years despite spending more than every other Western developed country, which has a life expectancy of 82 years, so we are not doing so well. Six in 10 Americans have at least one chronic disease, with more than 40 percent of children suffering from at least one health condition. I think that is astounding.

Mr. Safdar, as of March 31 of this year, the American Society of Health-System Pharmacists lists 238 drugs in shortage. These shortages include pharmaceuticals used to treat infections, heart failure, psychiatric conditions, and cancer, and include drugs such as amoxicillin, penicillin, cisplatin, and active ingredients in most chemotherapeutic regimes. As you probably know, the medications taken by Americans are manufactured largely overseas, and their active ingredients are overwhelmingly made in India and China. Can you explain to us how our dependence on foreign pharmaceutical markets has created manufacturing delays for critical medications across the USA?

Mr. SAFDAR. Thank you, Congressman, for the question. While I am not an expert in the inspection of foreign facilities, it is clear that our supply chain is global at this moment, and medicines come from and the ingredients come from all over the place. We are usually very pleased to see efforts to secure the supply chain and to secure manufacturing facilities with inspectors from the FDA, and it is part of what makes our supply chain most resilient.

Mr. PERRY. Do you think it is a good plan for the United States to rely so heavily on other countries, including ones that consider us their enemy, which would be the Communist Party of China?

Mr. SAFDAR. Well, the national security implications of that are definitely outside my expertise, but I think that the doctor here has probably got a better perspective.

Mr. PERRY. OK. Dr. Kessler, what do you got?

Dr. KESSLER. I agree with you a hundred percent. I mean, I was in charge of, you know, with my colleagues, Operation Warp Speed of sourcing for the monoclonal antibodies, for example. We are at risk as a country. We are not producing in this country essential medicines for lifesaving conditions. We need to do a better job.

Mr. PERRY. So, either one of you, or anybody, is it because the precursors or the drugs themselves are rare and unattainable in the United States of America?

Dr. KESSLER. If you look at the top universities for chemistry today—Nature Index has them—10 out of 10 are in China.

Mr. PERRY. But is that because they are unavailable in the United States of America?

Dr. KESSLER. Chemists make the drugs, right? Where are they training the chemists? Where is that scientific expertise, right? We are not investing in this country in the natural sciences——

Mr. PERRY. So, you are saying we have the material. We do not have the know-how. Is that what you are saying?

Dr. KESSLER. We do not have the know-how, we do not have the plants, we do not have the commitment.

Mr. PERRY. Do these drug shortages then enhance the proliferation of the illegal knockoff drugs? Is that a cause-and-effect relationship? We cannot get them here, so there are knockoffs produced overseas, even in our country, that are often dangerous to people in our society that think they are taking a legitimate drug. They get it on the internet or get it through the mail and then take it and then overdose. Is that a part and parcel to this?

Dr. KESSLER. It is a much better strategy, right, to have the talent, the expertise, and the commitment, and have those chemicals come from a secure supply chain, right, than through a lot of different unregulated sources. I mean, you want to lose sleep? That is what you should lose sleep about, where our medicines are coming from.

Mr. PERRY. Mr. Safdar, does the presence of a strong domestic compounding industry contribute to supply chain resilience and patient access at any time, but certainly during national emergencies or supply chain disruptions?

Mr. SAFDAR. Congressman, thank you for the question. Yes. As I said in my opening remarks, I think that there is a critical niche role that compounding plays in our drug supply, but as the FDA has said, compounded medications are not approved and they are

not tested for safety or efficacy, so they should be used as a last resort. But as you pointed out, if there is a medicine you need for treatment that would be dangerous to your health to delay, you should definitely take a compounded version if the normal product, the FDA-approved product, is not available.

Mr. PERRY. But what you say seems to imply that there is somehow dangerous. Aren't they manufactured domestically in a licensed facility with oversight of state boards?

Mr. SAFDAR. The FDA has actually been very clear that their safety is not the same as FDA-approved drugs, which should be generics or the branded products, that they take a second tier to safety. They are not to be used as a first line of treatment, and that is one of the problems we are seeing, is that we are seeing upstart and unknown and somewhat shady telehealth companies.

Mr. PERRY. You are not conflating compounded drugs made in a licensed facility under state monitoring or oversight with illicit counterfeit drugs? You are not conflating the two, are you?

Mr. SAFDAR. No, that is a whole other problem.

Mr. PERRY. OK.

Mr. SAFDAR. There are three types of danger that we have seen in the GLP–1 space, but even a medicine made in a state board of pharmacy or FDA inspected 503B, for example, outsourcing facility, is not an FDA-approved drug. The FDA has given it a status of being not approved and not tested for safety or efficacy. Now, would I take it if it was that or skip my cancer treatment? I would absolutely take it, but it is not supposed to be the first-line product. You do not start treatment on it.

Mr. PERRY. I understand. Thank you, Mr. Chairman. I yield.

Chairman COMER. Before I recognize Ms. Brown, I have four UC requests: a letter from the Alliance for Pharmacy Compounding, a letter from the Council for Responsible Nutrition, a letter from the National Association of Convenience Stores, and a statement from Peter Pitts, the president of the Center for Medicine in the Public Interest.

Without objection, so ordered into the record.

The Chair now recognizes Ms. Brown from Ohio.

Ms. BROWN. Thank you, Mr. Chairman. The Food and Drug Administration exists to protect the public. It makes sure the foods we eat, the medicines we take, and the cosmetics we buy are safe and effective. Before any of these products reach store shelves, the FDA carefully reviews their development, testing, manufacturing, and labeling, and the Agency keeps checking even after products are approved and available to make sure they remain safe and reliable. This work is vital. People need to trust that the FDA is making decisions based on science and facts.

Unfortunately, from day one, the Trump Administration has worked to undermine that trust. RFK pushes misinformation and lies, and just last week, President Trump recklessly fired thousands of workers across the FDA. These hardworking individuals, many of whom have been at the Agency for decades and dedicated their lives to public service, were locked out of the building with no explanation. This is not so-called government efficiency. It is playing petty politics with the health and well-being of the American people. These mass layoffs will delay reviews for new treat-

ments and make it harder to ensure the safety of consumer products.

Dr. Kessler, how will these staff cuts affect the Agency's ability to oversee everyday consumer items like personal care products and cosmetics? And additionally, what is the typical review timeline for those products and how might that change with less staff?

Dr. KESSLER. I think it endangers the safety of all Americans. I mean, I am told, for example, that no inspectors are cut, but what I hear is now the inspectors have to do all their administrative work themselves. Their travel cards are restricted, laboratories cannot purchase the supplies that they need, so they are not being used efficiently. They cannot do their jobs, and this just makes no sense to me. I do not understand what the strategy is. Why would you take the entire infrastructure of the FDA and blow it up?

Ms. BROWN. Thank you. The FDA plays a role in our everyday lives, right, even if we do not see it. In 2023, after hearing troubling reports from around the country, Congresswoman Pressley and I asked the FDA to investigate the link between chemical hair straighteners, often used by women of color, and uterine cancer. Shortly after, the FDA proposed a ban on formaldehyde in those products, but when the Agency missed the deadline to ask, we followed up late last August because our communities deserve answers and action.

Black women have long faced discrimination and scrutiny for how we wear our hair, pressuring many of us to turn to certain hair products just to meet societal expectations, but here is the truth. Many of these products are poorly regulated and pose serious health risks. Studies have shown alarming results. Most recently, Consumer Reports revealed that several synthetic hair braiding products used predominantly by Black women contain known carcinogens. This is not just about beauty. It is about public health. So, let me be absolutely clear. These hair products we rely on every day are putting our health at risk. Today, we sent another letter to the FDA, urging them to move forward with the banning of formaldehyde in relaxers.

With that being said, Dr. Kessler, given the historical under-regulation of personal care products marketed toward Black women, what should the FDA be doing right now to ensure these products are thoroughly tested and safe, and during your time as FDA Commissioner, did you encounter any barriers when it came to addressing equity and product safety?

Dr. KESSLER. Congresswoman, I just want to applaud you and your colleague's efforts. I think the issue you have raised is an enormously important one, and I applaud you for that.

Ms. BROWN. Thank you. So, I am assuming there were some challenges there, and by your response, I am grateful for your accolades, but I want to say this. We cannot let the new Administration drop the ball on something this important, so I plan to stay engaged and hold this Administration accountable. Passing laws like the CROWN Act to prohibit hair-based discrimination is critical, but we also need to crack down on products that impact women's health and well-being. By requiring safety testing and making sure that public health research reflects the diversity of the market, we

can help build a safer, healthier, and more trusted America. So, with that, I want to say thank you, and I yield back the balance of my time.

Chairman COMER. The Chair now recognizes Mr. Biggs from Arizona.

Mr. BIGGS. Thank you, Mr. Chairman, and thank you witnesses for being here today. As Congress looks to restore trust in the FDA and crack down on dangerous illicit products in our drug supply, it is critical that we distinguish between true public health threats and legitimate medical practices, such as pharmaceutical compounding. Compounded medications, when prepared by licensed U.S. pharmacies and FDA-registered outsourcing facilities, are a vital part of our healthcare system. These drugs are not counterfeit, they are not knockoff, they are not illicit. They are produced legally under rigorous oversight from state pharmacy boards and, in many cases, the FDA itself. These are personalized medications crafted to meet unique patient needs or to fill gaps in the drug supply, such as when the FDA added semaglutide injection products Ozempic and Wegovy to its drug shortage list back in March and August 2022, prompting compounding pharmacies to step in and fill the gap.

Mr. Safdar told Mr. Perry that compounded drugs are manufactured domestically in licensed facilities under the oversight of state boards of pharmacy and the FDA, but some narratives conflate compounded medications with counterfeit or unsafe knockoff drugs. It is true that manufacturing standards are the same for compounded outsourcing facilities in the U.S. as those for branded pharmaceutical companies, and both adhere to the good manufacturing practice system. Compounded drugs serve a critical role in maintaining access to care, particularly during times of FDA-approved drug shortages. There was a company in my district that was able to step up during the FDA shortage of semaglutide injection products. The presence of a strong domestic compounding industry contributes to supply chain resilience and patient access during national emergencies or supply chain disruptions.

Mr. Safdar, your organization, the Partnership for Safe Medicines, from 2007 to 2017, was staffed or led by a guy named Scott LaGanga. Is that right?

Mr. SAFDAR. I believe so, yes.

Mr. BIGGS. Did you follow him?

Mr. SAFDAR. I am the Executive Director that came after him.

Mr. BIGGS. Yes. So, when you say, "I believe so," what you really meant to say, yes, of course, I know that was Scott LaGanga, right? You meant to say you knew that he was the guy that was leading your organization before you were, right?

Mr. SAFDAR. I do not know the exact dates, but I know the end date was 2017 because that is when I started.

Mr. BIGGS. So, that is a real cutesy response, and the reality is you know he was your immediate predecessor.

Mr. SAFDAR. I do. He was.

Mr. BIGGS. Right, right, and so I have a series of reports sitting right here. Before I go through with them, I just want to know, is your funding sources still the same as they were under him?

Mr. SAFDAR. We are funded by our members and dues from our members, which are listed on our website under——

Mr. BIGGS. Right. I have gone to your website. I have read them. Do you get money from large pharmaceutical companies?

Mr. SAFDAR. No, sir. We get money only from our members, and our members are only trade associations or not-for-profits. So, if you are an actual company, a for-profit company, you cannot give us money. You cannot provide us funding.

Mr. BIGGS. All right. Very good. I have here now, Mr. Chairman, these following items here: an article called "Nonprofit Linked to Pharma Lobby Works to Block Drug Imports;" "Nonprofit Linked to Pharma Rolls Out Campaign to Block Drug Imports"——

Chairman COMER. Go ahead.

Mr. BIGGS [continuing]. "Nonprofit Linked to Campaign Against Drug Imports Has Deep Ties to Pharmaceutical Research and Manufacturers of America." And then, Mr. Chairman, I have now another one. It is a blow-by-blow takedown of a report by this organization. This is produced by Alliance for Pharmacy Compounding, and it deals with a report issued by Mr. Safdar's company called, "New Report Reveals Illegal Ingredients for Knockoff Weight Loss Drugs Flooding into U.S. from Foreign Sources, Endangering Patient Safety."

Chairman COMER. Without objection, so ordered.

Mr. BIGGS. Thank you. And then, also, I have a letter from the Alliance for Pharmacy Compounding, dated April 8, 2025, that was sent, I believe, to you, Mr. Chairman.

Chairman COMER. Without objection, so ordered.

Mr. BIGGS. Thank you, Mr. Chairman. I do think that attacks on compounding pharmacies by this particular organization when we are talking about whether something is a knockoff, illicit, or illegal, or a counterfeit drug is in inapt and unfortunate. And Mr. Chairman, with that, I yield back the balance of my time.

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

Ms. STANSBURY. Thank you, Mr. Chairman. I just want to ask a quick question. This is the Oversight Committee, correct?

Chairman COMER. Uh-huh.

Ms. STANSBURY. That is right. We are in the Oversight Committee. So, I have to say I found this to be a very bizarre committee hearing because here we are in Oversight, and our job is to conduct oversight over the Administration because of the separation of powers between Congress and the executive branch. And right now, the Administration is dismantling the Food and Drug Administration, and we are sitting here, and Members on both sides of the aisle are asking questions of industry-funded groups, about how the FDA is going to protect public health from medicines and food, while the Secretary is firing thousands of FDA employees. In fact, just this last week, they announced they were firing 3,500 members of FDA, and RFK, Jr. announced that he was going to fire 10,000 HHS employees across the entire Agency.

So, my question is, if this is the Oversight Committee, why are we not conducting oversight over the Administration and their mass firings and the actual deconstruction of the exact Agency that is supposed to protect the public health? That is what we should

be doing right now in this hearing room. So, I find it very bizarre that many of my friends across the aisle are asking, you know, how these folks are going to protect the public health, because they are not, because they are dismantling and taking out the top experts who do this work.

Now, some of my colleagues have already pointed out that one of the top vaccinologist, not just in the United States, but in the world, Dr. Peter Marks, was forced to resign, and in a few moments, I am going to enter his resignation letter into the record, because it is instructive. In his resignation, he says that for the last 13 years, he has tried to ensure the efficiency and effectiveness of the science and the public health, and he says at the end of his letter, "However, it has become clear that truth and transparency are not desired by the Secretary, but rather, he wishes subservient confirmation of his misinformation and lies."

I have been trying to figure out for the last couple of weeks what exactly the end goal is inside of HHS, what exactly the end goal is inside of FDA, what exactly the GOP's theory of MAHA, Make America Healthy Again, is because today, you want to take a vote on dismantling Medicaid. Your President is mass firing thousands of public health officials, including the people who make our drugs, our medications, our food, our cosmetic safety. Your President has announced yesterday that he wants to put tariffs on pharmaceuticals, and you are going after Social Security and Medicaid by dismantling the offices and the services and programs through DOGE that actually serve the people of this country. So, I do not understand it. I do not understand how this serves the public interest.

Dr. Kessler, I am very grateful that you are here today. You are a legend. You are so well known across the public health space. And I know you are not currently serving in this Administration, but help us understand the scope and the scale and why the American people need to be paying attention to what is happening inside the Agency right now.

Dr. KESSLER. Twenty cents of every consumer dollar is spent on a product that FDA oversees, all our foods, essentially, right—except meat and poultry, USDA does that—all our drugs, all cosmetics, our blood supply, our medical devices, many of our radiological devices. The Agency is absolutely essential for the safety of the American family. It is also absolutely key for our competitiveness. I mean, I am concerned that China is going to beat us scientifically, you know, if we are not careful with all these cuts that are going on, but the reason I am concerned about that, it is not about China. It is about the health of us.

Ms. STANSBURY. And Dr. Kessler, I want to end with this note. As Vera Rosenthal was leaving the Department after being fired by the Secretary, she said, "People are going to die," from these cuts. I am not being an alarmist. The day after they announced these mass firings and cuts, pharmaceutical prices tanked on the market, and that was before tariffs, and that is because the ability to get lifesaving drugs to market, the ability to save American lives, the ability to get——

Ms. GREENE. [Presiding.] The gentlelady's time has expired.

Ms. STANSBURY [continuing]. Cheap medications to our people——

Ms. GREENE. The gentlelady's time has expired.

Ms. STANSBURY [continuing]. Depends on having a functioning Agency.

Ms. GREENE. The gentlelady's time has expired. I now recognize Mr. Higgins from Louisiana.

Ms. STANSBURY. And people are going to die if they do not have the public health to protect them.

Ms. GREENE. The gentlelady's time has expired.

Ms. STANSBURY. I am sorry, Madam Chairwoman——

Ms. GREENE. The gentlelady's time has expired.

Ms. STANSBURY [continuing]. But the American people need to——

Ms. GREENE. The gentlelady's time has expired.

Ms. STANSBURY [continuing]. Understand what is happening——

Ms. GREENE. Ms. Stansbury?

Ms. STANSBURY [continuing]. Inside this Agency——

Ms. GREENE. Ms. Stansbury? The gentlelady's time has expired.

Ms. STANSBURY [continuing]. And the risk to the public health.

Ms. GREENE. No, you are lying to the American people.

Ms. STANSBURY. I am sorry, ma'am——

Ms. GREENE. You are lying to the American people.

Ms. STANSBURY. The American people need to understand their health is at risk, and this is a five-alarm emergency.

Ms. GREENE. Mr. Higgins is now recognized. Mr. Higgins from Louisiana is now recognized.

Mr. HIGGINS. It is always fascinating to witness the wailing and gnashing of teeth, is it not, gentlemen? Mr. Williams, I am going to be talking to you mostly, sir, some questions and observations regarding FDA and food safety. Let us just talk about seafood for a second, please. About a year ago, we had a hearing where Members interacted, mostly were not over spoken by other Members. Members interacted with our witnesses, and it was confirmed broadly that only about one tenth of 1 percent of seafood imported into our country was inspected for chemical and biological poisons, and we are talking about billions and billions of pounds of seafood coming into our country that is consumed by Americans, or else why is it coming here. And the only reason you do not get immediately sick in many cases is because we cook it and it kills some of the potential biological hazards and things, but the chemicals and the long-term impact is cancer or neurological disorders and serious problems can arise.

You know, one might say, a reasonable observer may say, that if you are consuming billions of pounds of poisonous seafood imported into our country, somebody might get sick, speaking to health. So, we believe there has been progress made in this arena of protecting Americans from the harmful biological and chemical elements that have been found broadly in imported seafood. Can you speak to how we are doing with that, Dr. Williams, since this year, 2025?

Dr. WILLIAMS. Yes. I guess I can start briefly by just saying originally, we had a rule on seafood called Hazard Analysis Critical Control Points, where we hoped that was going to make a big dif-

ference. Unfortunately, the problems with seafood, most of it is, seafood consumed raw, and I am thinking raw oysters from the Gulf of wherever, and that is a problem because there is not much in the way you can do about that. They are taken right from the Gulf. They are already contaminated by the warm waters of the Gulf, and when they go straight to people and eat them, they are eating in many cases dangerous pathogens. I think one of the problems that we have with imported seafood, again, it is the problem that we have with everything, is the resources that we devote to so many things at FDA that are not useful could be better used if we got rid of ineffective programs, if we got rid of regulations that do not work so we could really focus, have more resources, to target our inspections on those products.

Mr. HIGGINS. Would you agree that there is a high level of responsibility for the nations of origin to do proper inspections? And their procedures for farming and harvesting and packaging and shipping, in no way do they meet American standards that American producers are required to comply with. In fact, they are in violation of agreements that they will perform at standards equivalent to American standards. Don't you believe we should enforce that?

Dr. WILLIAMS. Yes. I think one of the problems is, where are they actually coming from? I mean, I can give an example in——

Mr. HIGGINS. We have identified many nations, and they bounce their products around.

Dr. WILLIAMS. Exactly, sir.

Mr. HIGGINS. So, the question is, because I am running out of time here, are we making progress regarding controlling poisoned seafood coming into our country?

Dr. WILLIAMS. I really cannot speak to whether or not we are actually making progress, but I want to agree with you. For example, if seafood says it is coming from Vietnam, for example, where I was, it may actually be coming from China. That is one of the things they do. They send their products through Vietnam to us. So, I think it does make it difficult for our inspectors.

Mr. HIGGINS. Well, we are going to aggressively pursue that, and this Administration, the Trump Administration, has been quite aggressive, and I am thankful to that, to protect Americans from harmful seafood coming into our country. The FDA's control over other poisons that find their way into our food supply, the colored foods, et cetera, can you just speak to that? And I will allow you to answer if the Chairwoman will allow the balance of my time.

Dr. WILLIAMS. I do not quite understand your question. Can you repeat it?

Mr. HIGGINS. The way the FDA will address poisons in our food, to add, like, say, brightness of color to children's cereal, et cetera.

Dr. WILLIAMS. Yes, the color additives, these are tested particularly for carcinogens, every single one of them, before they come on the market. There still may be things that they did not test for that might cause a problem, but they are some of the most tested substances on earth.

Mr. HIGGINS. Thank you. I appreciate your answers.

Dr. WILLIAMS. So, I think there are other issues which we should be concerned about.

Mr. HIGGINS. Mr. Chairman, I yield.

Chairman COMER. [Presiding.] The Chair now recognizes Mr. Garcia from California.

Mr. GARCIA. Thank you, Mr. Chairman. I want to first begin by thanking all of our witnesses for being here and for your testimony, obviously for all the comments that we have heard here from both sides of the aisle on the Committee. I do think that it is ironic that we are holding a hearing on restoring the trust in the FDA while we are ignoring the single biggest threat to public health today, which, of course, is Donald Trump's Health Secretary, Robert F. Kennedy, Jr.

Now, together with Elon Musk, RFK, Jr. is actively undermining the institutions that protect public health and the safety of all Americans. Now, we know that RFK, Jr. already has a history of outrageous medical opinions and a dangerous anti-vax record. Now, let us just look at the measles alone. Before the measles vaccine, we know that measles would kill 400 to 500 American children annually. Now, after, of course, that vaccine was released, that number fell to almost nothing. But now with RFK's anti-vax movement growing and his dysfunction at HHS, we have seen over 600 confirmed measles cases across 22 jurisdictions, and that, of course, is not a coincidence. We also know that this is also just the beginning. This Committee is not serious about actually taking on the public health threat of measles, which, by the way, our measles cases today is 50 times higher than we have trans athletes in college sports, yet they obsess about that every single day. The Committee is obsessed with things that do not matter but not the public health of actual Americans and children. But, by the way, children are now actually dying, and we know, of course, that is just the beginning.

RFK, Jr. said that 5G and Wi-Fi can cause brain damage, ADHD, radiation sickness. He said that pesticides are actually turning people transgender. He has even questioned whether HIV causes AIDS. He has made comments, of course, that alkyl nitrite, better known as poppers, the sum is the actual cause of AIDS. He said during a campaign event that a hundred percent of the people who died, the first thousand who had AIDS, were people who were addicted to poppers. In his 2021 book and 2023 interview with *The New York Times* and *New York Magazine*, he repeated claims that questioned the causes of AIDS, despite overwhelming evidence to the contrary. In my opinion, RFK, Jr. has been, and will always be, a tinfoil hat conspiracy theorist. He should be nowhere near HHS, medical opinion, and our research in this country.

Now, Dr. Kessler, I hate to have to even ask you this, but is there any serious medical evidence that HIV does not cause AIDS?

Dr. KESSLER. No.

Mr. GARCIA. Thank you, and that is exactly why these cuts by DOGE and RFK, Jr. to HIV research, treatment prevention are so dangerous. Public health experts were warned these actions will set us back decades. Now, despite Donald Trump's 2019 State of the Union promise to end the HIV epidemic, we have seen over 800 million in HIV research actually cut. The HHS Office of Infectious Disease and HIV policy has been shuttered. CDC surveillance efforts have been gutted. PEPFAR, The Global Fund, all, of course, lifesaving initiatives, are being dismantled.

Now, Dr. Kessler, you led the effort to fast-track approval for lifesaving AIDS programs. Can you just briefly in a sentence or two explain how DOGE is going after the work?

Dr. KESSLER. I also chaired the board of the Elizabeth Glaser Pediatric AIDS Foundation with President Bush, the son. I mean, the goal was to stop mother-to-child transmission throughout the world of HIV. It was the moral conscience of this Nation. Global health relies on America, and that has been drastically cut.

Mr. GARCIA. That is absolutely right, sir. And we also know that RFK, Jr., while this is happening globally and here back home, he has fired 10,000 people from his Agency, and then claimed that 2,000 of those was actually a mistake. So, firing people, claiming they are a mistake, gutting the Agency, taking away support from lifesaving programs, spreading anti-vaccine conspiracy theories. That is what RFK, Jr., right now, is all about, and these are not just mistakes. These are life-or-death decisions. Critical staff have been lost. Experts overseeing medicines, food safety and medical devices, as we know, have been shuttered or let go, and we are incredibly concerned.

I want to read this quote by former FDA Commissioner, Robert Califf: "The FDA as we have known is finished, with most of the leaders, institutional knowledge, a deep understanding of product development, and safety no longer being employed." It is totally unacceptable that Congress is doing nothing to prevent, of course, its absolute destruction of our public health infrastructure. We need to stop this now. And with that, I yield back.

Chairman COMER. The gentleman yields back. I just have to comment, Mr. Garcia, in all good faith. The predecessor for the Ranking Member, Mr. Raskin, said that those of us who wondered if COVID came from the lab at Wuhan, we were conspiracy theorists, and that when we suggesting that maybe former President Biden was in mental decline, that we were conspiracy theorists. And now, you know, there are just books coming out by all these Democratic journalists every day saying what we had wondered, too. I am not defending or trashing what you said about Robert F. Kennedy. It is just that, you know, conspiracy theories are in the eyes of the beholder.

Mr. GARCIA. Sir, do you think that children should be getting the measles vaccine?

Chairman COMER. That children——

Mr. GARCIA. That children should be receiving the measles vaccine?

Chairman COMER. All my children are vaccinated.

Mr. GARCIA. Thank you, and do you think that we should be getting vaccinated for COVID?

Chairman COMER. Well, I think there are a lot of questions about COVID that we need answered, but measles, yes.

Mr. GARCIA. And I——

Chairman COMER. I am going to recognize——

Mr. GARCIA. And again, our current HHS Secretary is an antivax conspiracy theorist, and that is a fact. He caused a measles outbreak in another country that caused the death, absolutely.

Ms. GREENE. No, he did.

Mr. GARCIA. He absolutely did.

Ms. GREENE. That is a lie.

Mr. GARCIA. That is a proven——

Ms. GREENE. RFK did not cause a measles outbreak.

Mr. GARCIA. Ms. Greene.

Ms. GREENE. You sound ignorant.

Mr. GARCIA. Ms. Greene, you are antivax——

Ms. GREENE. That is ignorant, and that is a lie.

Mr. GARCIA. You are an antivax conspiracy theorist yourself.

Ms. GREENE. No, I am for choice. I am for parents and people choosing.

Mr. GARCIA. You are the No. 1 antivax conspiracy theorist——

Ms. GREENE. Choosing.

Chairman COMER. All right. That was my fault.

Ms. GREENE. Vaccines kill people.

Mr. TIMMONS. Mr. Chairman, am I recognized? Am I recognized, Mr. Chairman?

Chairman COMER. Our witnesses were snoozing, so I had to spice it up a little bit.

Mr. TIMMONS. Wake up.

Chairman COMER. The Chair recognizes Mr. Timmons from South Carolina.

Mr. TIMMONS. Thank you, Mr. Chairman. So, I realize that we are here to have a hearing about "Restoring Trust in the FDA: Rooting Out Illicit Products," but I am actually going to turn it upside down, and I am going to talk about how the FDA is not approving products that will help Americans. So, I guess, normally, it is good to be leaders in the world, but not when it comes to obesity, not when it comes to chronic disease management, not when it comes to diabetes, and these are all things that I believe technology has the ability to help ameliorate, and really facilitate better outcomes. And so, what I want to talk, Dr. Williams, is about continuous glucose monitors.

I have used them. I was in a test trial, and it was one of the most enlightening experiences. It attached to my cellphone. I am not a diabetic, but the information I got from that piece of technology changed my life. It did. It changed my life, and the FDA has not approved use of a continuous glucose monitor without a prescription. Well, they just did, but you have to have type 2 diabetes who are not insulin. Dr. Williams, do you believe that any American that wants to use a CGM to understand what the food that they are putting into their body does to their blood glucose levels? Do you think that is something that should be available to the general public?

Dr. WILLIAMS. I do. I do not see any harm if they want that.

Mr. TIMMONS. These have been around for a very long time, and the technology is used by millions of Americans, unfortunately, because they need it. They have diabetes of some kind, and I do not understand why it has taken them this long, and it is interesting, because a lot of companies are using CGMs. They are marketing them, they are selling them to Americans, and it is technically illegal because they were not approved. They were approved, I guess, in March of last year, but why is the FDA not approving the use of technology that will help improve Americans' lives?

Dr. WILLIAMS. I think part of the issue lies in medical device laws, and they are really antiquated, and I had researched this years ago. The problem is, when you go to invent something, you first have to get it approved. It costs a lot of money and a lot of time to get approved. So, a lot of inventions that actually would come from physicians, they do not do it because they look at the time and the expense and having to raise money, and they do not want to do it. The second problem is, once you get it approved, if you think about how inventions work, think of computers. You make a computer, you find bugs in it, and then you change it, and you change it repeatedly.

Medical device laws do not allow for that. Every single change you make, you have to go back to the FDA. And so, that is one of the reasons I think we are not seeing the innovation that we should, particularly on these kind of monitoring devices. The ones you are talking about are just the beginning. We need to monitor what we eat, how much we eat. We need to know everything about our biomarkers, our genes, our epigenetics, and everything. Put all of that together and give people real-time advice on what to eat. It is doable.

Mr. TIMMONS. Well, and hold them accountable when they do not eat well, when they treat their body poorly. So, I mean, diet and exercise is the answer to 95–99 percent of health problems, and we have a pill for everything. We have shot for this, shot for that, pill for this, pill for that, and I think that we can use technology to create an incentive structure and possibly a disincentive structure to facilitate decisions. And, I mean, you know, if you take the technology in an Oura Ring, in a Fitbit, in a CGM, and you put it all together, and you have one device that is monitoring all of that, I mean, I think it could then communicate with your health insurance company, and you will get a benefit in your premium if you are not spiking your blood glucose level and if you are exercising every week. This technology exists. It just needs to be put into one and the incentive structures and disincentive structures need to be placed on the free market. I mean, does that make sense?

Dr. WILLIAMS. It does make sense, and one of the things that we see, particularly in the obesity sphere, is everybody wants to blame food companies for selling foods that Americans want to buy. It is a positive sum game. They do not make foods unless you want to buy them. The truth of matter is, we started gaining weight in 1980. Since 1980, we have increased our calorie consumption. This is individuals eating more by 400 calories a day. That can lead to a lot of weight, so part of it is we have to look at ourselves. We are eating too much, and maybe some of that is because people are eating out more and the portion sizes are bigger, but again, these devices can help with that, they can tell us maybe what to eat and how much to eat.

Mr. TIMMONS. Again, I have had a scale for 6 years, and it records my weight every morning, and that is another variable that we could put into the algorithm that determines the premium of your health insurance. If you are gaining weight, you need to pay more. If you are eating poorly and you are not sleeping, these are all things that factor into your health and can be used in under-

writing. I am out of time, Mr. Chairman. With that, I yield back. Thank you.

Chairman COMER. The gentlemen yields back. The Chair recognizes Mr. Frost from Florida.

Mr. FROST. Thank you, Mr. Chair. This past month, the FDA reported 15 food and drug recalls. That is about a recall every 48 hours. It was even higher in January and February, and many of these recalls are very serious. They were for things like food allergen, cross-contamination, cancer-causing arsenic and lead, which can cause severe learning disabilities in children and miscarriages in adults. The past month also saw pet foods contaminated with bird flu. While these recalls save lives, when folks are alerted in time, they also can cost working families time and money to replace recalled food. You know, this year, tuna was recalled. That is about $3 per can down the drain. Prepared salads were recalled, another $5 bucks each. Frozen dinners were recalled, $4, $5, $6, bucks a serving. These numbers might seem small, but folks managing a family budget know how grocery costs add up and what a waste it is to throw out food.

Dr. Kessler, how does the work of the FDA's labs and inspectors help catch problems before bad food hits the grocery stores?

Dr. KESSLER. The laboratories are absolutely essential at that detection. Four FDA laboratories, two labs, two medical product labs have been shut. Those recalls that are absolutely essential, the people who communicate about those recalls, the communication shops have been gutted.

Mr. FROST. Trump and Musk claimed that the mass layoffs at the VA and the Social Security Administration would not impact the services, but we are seeing that is not true. Services for veterans and seniors across the entire country are getting worse. Wait times are at all-time highs. Now, Trump and RFK, Jr. are claiming that the mass layoffs at the FDA will not negatively impact food inspections. Dr. Kessler, how could mass layoffs at the FDA impact food inspections?

Dr. KESSLER. It will have a real and demonstrable effect. Yes, the inspectors have not been touched as of today, from what I can tell, but all their support, all their infrastructure is gone, so all those inspectors cannot get the supplies they need to inspect. They have to do their own travel. The travel cards are not working. I am not sure what the strategy is.

Mr. FROST. And what does this mean for Americans' vulnerability to serious foodborne illnesses.

Dr. KESSLER. I fear that we are less safe today. You know, I wish that were not the case, but you cannot take thousands of people out of the FDA and not understand you are putting the American people at risk.

Mr. FROST. You know, I am one of the 33 million Americans living with potentially life-threatening food allergies. I have almost died, actually, because of an anaphylactic attack. Dr. Kessler, how could cuts to the FDA impact day-to-day safety of folks like me who live with serious food allergies?

Dr. KESSLER. The people who communicate, who share that information, who share that risk information, the people who write the

policies that give the industry the guidance of what to put on the labels, they are not there anymore.

Mr. FROST. Say we are lucky and these mass layoffs have no impact at the FDA with under covering potential foodborne disease outbreaks before they spread. How will cuts to FDA staff impact the people who are still there, their ability to alert the public to the threat of allergen cross-contamination or an E. coli outbreak?

Dr. KESSLER. I think the effect of these cuts, not only on the people who left—I am hearing repeat stories, I mean, about how these were done, when they were done, right, I mean, the real thoughtless, careless, almost mean aspects of how this information was communicated. But people who have enormous expertise, decades of expertise on those kind of questions, on those allergies, they are not staying at the Agency. And recruitment, getting the best and the brightest, something that we all believed in, that we dedicated our careers to be able to go into these agencies and provide that kind of public service, what signal is that sending? We are losing generations of future public servants, and that concerns me greatly.

Mr. FROST. Thank you. I yield back.

Chairman COMER. The Chair recognizes Byron Donalds from Florida.

Mr. DONALDS. Thank you, Chairman. In 2019, President Trump warned of the horrible consequences of the Chinese Communist Party filling the void if Americans could not find federally approved tobacco products. To date, the Food and Drug Administration has only approved 34 vaper products, despite millions of applications submitted to the Center for Tobacco Products. The disastrous Biden Administration instead allowed illegal Chinese vape products to control more than half the market. This is one of the such products. This is Lost Mary. The flavor is ginger beer. Mr. Bentley, does the American consumer know what the contents of this Chinese vape are?

Mr. BENTLEY. Congressman, thank you for the question. Obviously, for that particular vape, I cannot speak to its ingredients, but typically, most vape products do have to register and register their ingredients if they are going to submit a pre-market tobacco application form in order to get FDA authorization. But you highlight the important point, which is that millions of these products from American companies who manufacture, for instance, the e-liquids that smokers, looking to switch away from deadly cigarettes, want to use. Those American companies have been denied authorization for their products, and instead, illicit companies who often change their registration, can change their name, change the ingredients are unaccountable to the FDA, have managed to fill the void. So now 18 million adult vapers, exactly as you point out, do not know what they are getting, and the FDA has lost control of the market completely unnecessarily.

Mr. DONALDS. Does the FDA even have a multi-agency task force to combat the sale of illicit vapes?

Mr. BENTLEY. The FDA last year, did, in collaboration with DOJ and CBP and other agencies, set up a multi-agency task force to try and get a grip on the illicit market. But unfortunately, that is FDA passing the buck to other agencies already overstretched, like

DOJ and CBP, when the solution for them, which would not need any more staff, would not require any more funding is to change how they evaluate how to authorize these products in the first place. They can do it quicker and better as other countries, such as the United Kingdom, Canada, New Zealand, Germany, France, all of these countries have tens of thousands of authorized e-cigarette products with no problem with mass levels of, for instance, youth vaping that we all want to reduce. So, it is possible for FDA to change its practices and get the products that will save millions of Americans from smoking by switching it to a safer alternative.

Mr. DONALDS. Let me ask you a follow-up question to that. Was the Biden Administration aware of the numerous instances of illicit products that were showcased in the presence of FDA personnel at trade shows around the country?

Mr. BENTLEY. I cannot speak to what the Biden Administration may or may not have been aware of, but it was widely known that this was a developing problem. Indeed, it was predictable and predicted that the minute you take off millions of products from the market, for which there is high demand, and that we must remember are dramatically safer than combustible cigarettes, then somebody is going to supply those 18 million adult consumers with those products.

Mr. DONALDS. Well, listen, to be clear, I am not against Americans who want to use vaping products or tobacco products. I think it is important for the American people to understand that the previous Administration did not do the job of making sure that there were products on the shelf where they could clearly understand what they were consuming or ingesting. And then you have products like this that have hit the shelves in the United States, primarily because the previous Administration was derelict in their duty in making sure that they were approving applications of companies in America who could supply the demand from the American consumer. With that, Mr. Chairman, I yield back. Madam Chairman, I yield back.

Ms. GREENE. [Presiding.] The gentleman yields. I now recognize Ms. Lee from Pennsylvania for 5 minutes.

Ms. LEE. Thank you, Madam Chair. I think it is insulting that Republicans have set this hearing on restoring trust to the FDA while they are wholeheartedly backing Trump and RFK, Jr.'s efforts to dismantle the Agency. We used to do bipartisan work with the FDA, so why are Republicans politicizing it now? None of the actions taken have done anything to improve the health or safety of Americans.

If RFK, Jr. and Trump cared about things like protecting the public from unsafe medications, they would not have illegally fired people responsible for making sure that the drugs we take are actually safe and effective. They would not have fired an estimated 170 people from FDA's Office of Inspections and Investigations, which inspects factories to make sure the pharmaceutical companies are not cutting corners. They would not have fired the people and closed the labs that make sure our medicines are safe from contamination. They would not have fired the people in the offices that check to make sure that drug companies are not making false claims in their ads. They would not have forced out Dr. Peter

Marks, FDA's top vaccine regulator, while measles is killing kids, you know, the same disease we have a 97-percent effective vaccine for and damn near eradicated.

Dr. Kessler, looking back at some of the very events that Members of both sides of this Committee did work on, like the infant formula contamination and shortage, how much worse could it have been if the FDA was short thousands of workers at that time?

Dr. KESSLER. These are very challenging problems. It took a lot of dedicated people working with both sides of the aisle on any of these. I have been there in these kind of crisis moments, and I fear that that infrastructure, the ability to handle those challenging problems, we have now gutted the Agency.

Ms. LEE. Madam Chair, I would like to enter into the record an article titled, "FDA Planning for Fewer Food and Drug Inspections Due to Layoffs, Officials Say." Madam Chair?

Ms. GREENE. Without objection, so ordered.

Ms. LEE. Thank you. Dr. Kessler, what is the worst-case scenario that could result from FDA's planned cuts to drug inspections? Is there anything that keeps you up at night around that? I think that is a yes then.

Dr. KESSLER. I mean, people will die.

Ms. LEE. Excuse me.

Dr. KESSLER. You want to know the worst thing?

Ms. LEE. Yes, please.

Dr. KESSLER. All right. Go back to 1938, we forget the founding of the Agency, sulfanilamide, the 1938 Act, Congress acted. There were deaths in children because adulterants ended up in those medicines because we did not have the inspection system. We did not have the pre-approval system. We have developed the most sophisticated system, right? So, when you take a medicine today, I mean, what it says on the label is actually what is in the product. That has taken an enormous effort by the Congress over the last hundred years working with dedicated scientists and public servants. Why are we putting that at risk?

Ms. LEE. Yes. I thank you for your candor, even as you hesitated to start. I think it is important that we speak frankly and plainly while we are watching what can or will be a catastrophe if we do not change course. Before the mess we are currently in, the FDA have been working with other agencies to prevent the spread of counterfeit and contaminated drugs coming in illegally or being made locally by people who would rather make a profit than make sure people have safe medications. Dr. Kessler, are you at all confident that the FDA can continue to do important work like that with the thousands of firings that Trump and RFK have initiated?

Dr. KESSLER. I am not confident that that can continue, Congresswoman.

Ms. LEE. Just last week, Trump and RFK, Jr. also fired more than 800 staff from FDA Center for Drug Evaluation and Research, which monitors medications for side effects and shortages, among other things. Dr. Kessler, do these cuts raise the risk that people might suddenly find themselves without access to the medicines they need?

Dr. KESSLER. I think that is a real risk.

Ms. LEE. Thank you. My Republican colleagues want to sit here and pretend that everything is fine and that somehow the FDA is actually better under the Trump Administration. But just look at the fact that none of the witnesses the Republicans invited here today represent patients, healthcare providers, scientists, parents, or any of the rest of us who stand to lose from these firings at the FDA. Nobody in this country should have to show up at a pharmacy wondering if their blood pressure medication or their insulin is going to be in stock today. It is truly ridiculous and a tragedy that we have arrived at this point.

To quote Dr. Marks in his resignation letter to the FDA, "It has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies." Thank you, and I yield back.

Ms. GREENE. The gentlelady yields. I now recognize Mr. Burlison from Missouri for 5 minutes.

Mr. BURLISON. Thank you, Madam Chair, and thank you to all of our witnesses for joining us today to confront the pressing crisis at the FDA. For too long, this Agency has faltered, leaving hundreds of products approvals stalled for years at times, while illicit vapes and counterfeit drugs from China flood our communities unchecked. The FDA's inaction has handed the Chinese Communist Party an open door to peddle dangerous knockoffs, threatening our kids and our sick, all while safer options languish under red tape. It is not complicated: fix the FDA, fix their sluggish process, and ramp up enforcement and stop letting the Chinese Communist Party profit off of poisoning our children.

Mr. Safdar, can you discuss the recent incidents of counterfeit drugs, particularly the GLP–1s, that are flooding the market, the counterfeit ones?

Mr. SAFDAR. Yes, and thank you for the question, Congressman, fellow Missourian. We are seeing dangers to patients in three different areas in the GLP–1 space that are very concerning. There is look-alike counterfeits. It is a pen that maybe is an insulin pen where a criminal has pulled off the label and re-wrapped it with an Ozempic label, for example, and then sold it to an unsuspecting pharmacy—just discovered one of those in Arkansas at the end of last year. A clever and attentive pharmacist caught it and quarantined it so that it would not reach a patient. The second category is, we are seeing enormous one——

Mr. BURLISON. Pause. How did that get in the hands of the pharmacist? So, surely their supply chain is more reliable than that.

Mr. SAFDAR. The pharmacist was defrauded. What happened was, there is a distributor in Florida who had obtained units of these counterfeit products and had obtained a license to distribute some products in Arkansas. It is not clear exactly what kind of distribution license they had, and they shipped it into Arkansas. So, the pharmacist thought they were dealing with a licensed distributor who was licensed by their State Board of Pharmacy, and not until it showed up and the pharmacist had reason to suspect it, was the pharmacist able to say, OK, I know they have a license, but let me set that aside and call the inspector.

And the inspector from the Arkansas State Board of Pharmacy came over and used a new tool we have, because of the Drug Sup-

ply Chain Security Act called Pulse, made by the National Association of Boards of Pharmacy, and scanned it, and that barcode, in under a second, detected that Ozempic as counterfeit. And the Board of Pharmacy then moved immediately to suspend the license of the Florida distributor. It is a real great story of patient safety.

The second category is we are seeing criminals selling illegal research-grade pharmaceutical ingredients to Americans, and they are doing it through illegal, foreign, fake online pharmacies and even sometimes on ecommerce sites like Etsy. We have captured images of research-only on Etsy.

Mr. BURLISON. On Etsy, people are buying?

Mr. SAFDAR. Yes, unfortunately. I can even show you an example ad of what this looks like, and they are often labeled "not for human consumption," but when you get them, there are instructions to inject yourself with them, and people are, in fact, doing that.

Mr. BURLISON. That is crazy.

Mr. SAFDAR. It is crazy. The third thing is, one, we just did a study about which is freight shipments of semaglutide and tripeptide ingredients coming into the U.S. that were not made in any FDA-inspected facility. And because they are freight, they have to actually come with a bill of lading that states the manufacturing location, and we found 179 shipments that were declared in facilities that are not FDA inspected, for example, a high school in Toronto, a gym in Toronto, and JW Marriott in Vancouver. None of these—I checked—none of these are actually FDA-inspected facilities, and yet, in some cases, they were let in. And so, one of the improvements we would like to see from this next Commissioner would be to actually refuse those based upon the bill of lading because if you know that that is not an FDA-inspected registered facility, there is no reason to even let it be shipped to the U.S. There is no reason to have to turn it around here when you know it is not going to be any better when it arrives.

Mr. BURLISON. Yes. I have limited time, but I want to talk about the FDA's process of approvals. It is reportedly holding approvals for numerous generic drugs, even drugs that have shortages, about 238 drugs as of March of this year. What is the impact of this?

Mr. SAFDAR. So, the drug approval process is actually not my specialty. I am going to defer to my fellow witness, Dr. Kessler.

Mr. BURLISON. Mr. Kessler?

Dr. KESSLER. Generic drugs are an absolutely essential part of what American families rely on. We need and FDA has a responsibility to make sure we all have access to safe and effective generic drugs, but I am concerned that that requires——

Ms. GREENE. The gentleman is out of time.

Mr. BURLISON. Thank you. I yield back.

Ms. GREENE. I now recognize Ms. Crockett from Texas for 5 minutes.

Ms. CROCKETT. Thank you so much, Madam Chair. Are we tired of winning yet? We are hugely winning. We have the best of the best, right? Wrong. That was sarcasm, if you did not catch it. The fact is, we should never have partisan politics playing a role when we are talking about something such as science, but unfortunately, in today's times, Democrats believe in scientists and experts and

data, and Republicans instead believe in conspiracy theorists. And right now, that is who we have leading one of the most important agencies in this country, is a conspiracy theorist, not someone who has an actual resume to get the job done. So, why would anyone trust the Republicans on anything, let alone matters of public health and safety?

It has taken Texas' largest measles outbreak in 30 years, with more than 500 confirmed cases and the death of two children, for the Secretary of the Department of Health and Human Services to say what we already knew: the most effective way to prevent the spread of measles is the MMR vaccine. This is the same guy who chaired the anti-vax's nonprofit Children's Health Defense. Just last month, during an interview with Fox News, he suggested that somehow, being infected with measles could provide protection against cancer and heart disease.

The Republicans are implementing the most dangerous public health agenda and modern American history and people are literally dying as a result. This Administration does not believe in science. They are firing thousands of scientists and public health officials who keep our food and medicine safe, slashing funding for scientific agencies that help cities and states respond to public health emergencies, limiting public access to research and data that contradicts their misinformation. They are using financial threats to manipulate which studies the government will sponsor and blocking researchers from diversifying clinical trials. This reckless and chaotic approach will make it more difficult for the FDA to achieve its mission of protecting the public health of Americans.

But there are two issues that I want to address before my time expires. Staffing at FDA has long been a challenge. The Government Accountability Office has identified several challenges at FDA as high-risk issues. One of the bigger issues the GAO has identified is FDA's extensive workload. Last Congress, the Senate held a hearing on the sale of unauthorized and illegal vaping products and e-cigarettes. During the hearing, Dr. Brian King, Director of FDA's Center for Tobacco Products, testified that the volume of pre-market tobacco product applications is overwhelming, so FDA is instead prioritizing its enforcement responsibilities when it comes to e-cigarettes products. But just last week, Trump not only fired the Director of FDA's Tobacco Center, he closed two entire offices responsible for drafting new tobacco regulations and setting policies.

Dr. Kessler, in its 2025 High Risk Report, GAO stated that, "Stable senior FDA and center leadership remains of vital importance to the Agency." How will this vacuum of leadership impact the public health and safety of Americans?

Dr. KESSLER. It will put Americans at risk. Congresswoman, you raised a very, very important point. I am the only pediatrician on this panel today, and your constituents, please, the most important thing is what you said, if you want to prevent measles, please have your children vaccinated against that very dangerous disease.

Ms. CROCKETT. Thank you so much for that, Doc. And I only got 56 seconds, and I do not know if I am going to go through my last question because you just—I am looking at Greg to see if he is going to make me do it. Listen, I am going to go off instead. Sorry.

I appreciate the fact that you are an expert in this, and here is the reality. The Republicans, and definitely MAGA, loves to troll me in so many ways, and the reality is that I trust and believe experts. I do not believe that I know everything. I believe that I was elected by my constituents to make sure that I could keep them safe and always making sure that they are not going to be victimized if they have, say, family members that are serving abroad because of Signalgate, because of that incompetence, making sure that they have access to vaccines if they need it, making sure that they can actually provide for their family because we have real economists that are deciding——

Ms. GREENE. The gentlelady's time has expired.

Ms. CROCKETT [continuing]. Whether we are in engaging in tariff war.

Ms. GREENE. The gentlelady's time has expired. I now recognize Mr. Fallon from Texas for 5 minutes.

Mr. FALLON. Madam Chair, thank you very much.

[Poster]

Mr. FALLON. You know, a year ago, we held a hearing on the FDA, and at that hearing, I had the graphic behind me, and I am perplexed as to why things have not changed. So, I am so glad that you all are here. And I really appreciate it, because according to the law, pre-marketed tobacco product applications must be processed within 180 days, but unfortunately, the rolling average has been 3 years, and we bring this to light a year ago, and it does not seem like anything has changed. This is a picture from a shop a couple of miles from where we are right now, and it is littered with illegal, smuggled Chinese vaping products. And so, I do not want anybody to vape, I do not want anybody to smoke, but it is their choice, and yet, if they are going to vape, I want them to vape with a product that is American made, preferably, that also went through a regulatory process. Now we do not know. This is the Wild West. It does not make much sense.

Mr. Bentley, what happens, let us say, if the FDA actually discovered it, because I want to focus more on enforcement because nothing has seemed to change. What happens if the FDA becomes aware of this shop and they are selling illegal products?

Mr. BENTLEY. Thank you, Congressman, for the question. The FDA can issue warning letters to distributors. It can also institute civil money penalties.

Mr. FALLON. What do they typically do when they find this? What is the first defense?

Mr. BENTLEY. Typically, often, there will be warning letters about——

Mr. FALLON. A sharply worded rebuke.

Mr. BENTLEY. I agree, Congressman. It is absolutely nothing of a deterrent selling illicit products, and that is how FDA has left the door open here by making its own regulatory processes so complicated that, as you suggest, that American companies—who want to do their best to tell what is in the ingredients, to sell products that are safer than cigarettes—those smaller companies have not been able to get through FDA review, so other actors will jump into the void.

Mr. FALLON. Right, because there is a demand, right?

Mr. BENTLEY. That is exactly correct.

Mr. FALLON. Prohibition did not work in this country in the 1920s, did it?

Mr. BENTLEY. Absolutely not.

Mr. FALLON. No. OK. So, they send a sharply worded letter, which everyone will ignore and not care about, and they are going to continue to sell. At what level do they typically at least confiscate?

Mr. BENTLEY. Now, I would not have the precise level of how much of the illicit market has been confiscated. I would assume it to be somewhere in the de minimis region, as you demonstrate there. This is just a few miles from this building and a few miles from FDA's White Oaks campus, and the illicit market is still rampant.

Mr. FALLON. So, it is not typical that once they discover it, they do not even just take it. They do not seize.

Mr. BENTLEY. No.

Mr. FALLON. That is amazing to me, and I like that word, "de minimis." I am going to have to put that in my vocabulary, particularly with a British accent. Sounds delicious.

Mr. BENTLEY. It is very kind of you.

Mr. FALLON. Dr. Williams, so I do not know if you know this answer, but I am curious. When did we switch from mainly sugar to high-fructose corn syrup?

Dr. WILLIAMS. Well, interestingly, we have not actually switched. For example, the colas, back when I was at FDA, what we found out was they would look at the relative prices of high-fructose corn syrup and sugar, and depending on the relative prices, they might put more sugar and less HFCS.

Mr. FALLON. Well, when did the corn syrup enter the food supply in large quantities?

Dr. WILLIAMS. I am not sure of that.

Mr. FALLON. I think it was in the 1970s. Do you happen to know, Dr. Kessler?

Dr. KESSLER. It was actually in the 1940s and 1950s, but you are right, Congressman, and then it increased.

Mr. FALLON. Do you think, Dr. Kessler, that that was one of the contributing factors to America's general problem with obesity?

Dr. KESSLER. Yes.

Mr. FALLON. Yes. And it is just one of those things that I think we need to discuss more is preventative and we spend more on healthcare than any country per capita in the world, I believe. But if we are preventative, you do not get sick in the first place, it is a heck of a lot better for the individual and for the country because you do not have that expense.

Dr. KESSLER. There is an enormous opportunity to make inroads in chronic disease, Congressman, as you are saying that, and I would love to be able to spend time discussing that with you.

Mr. FALLON. Thank you. Thank you to the witnesses. Thank you, Madam Chair. I yield back.

Ms. GREENE. The gentleman yields. I now recognize Mr. Bell from Missouri for 5 minutes.

Mr. BELL. Thank you, Madam Chair and Ranking Member, and thank you to the witnesses for being here. When I came to Con-

gress, I made a commitment that public health and public safety would be at the core of my work. That mission becomes harder when agencies like the FDA face disruption, especially from actions like those recently taken by DOGE. Last month, DOGE abruptly announced it was canceling leases for 30 FDA field offices, including a critical 52,000 square foot drug testing facility in my district of St. Louis, described by former officials as the most important FDA drug testing lab in the country. This lab exposed cancer risks in the drug Zantac, and just last month, triggered a recall of acne treatments with dangerous levels of benzene. Though DOGE and HHS reversed the decision days later, the damage was done. And so, we must ask, are we putting the public at risk by undermining the FDA's ability to do its job? Are we creating conditions that allow unsafe or ineffective drugs into the U.S. market?

The FDA plays a vital role in protecting public health, from food and medicines to medical devices. A key part of that is safeguarding the integrity of our drug supply, but right now, that work is under threat. Due to staffing cuts, the FDA has frozen a pilot program for foreign drug inspections and is planning to reduce both food and drug inspections. Just last week, 800 employees were cut from FDA's Center for Drug Evaluation and Research, or CDER. Cutting CDER staff will almost certainly slow the approval of new drugs and generic alternatives which working families depend on to afford their prescriptions.

Dr. Kessler, even if no food or drug inspectors were directly fired, how does a reduction in the Office of Inspections and Investigations impact FDA's ability to conduct inspections?

Dr. KESSLER. It has a great impact, and Congressman, that laboratory in St. Louis is one of the great laboratories in the world. It has enormous specialty expertise and can detect things that no one else can detect, but there are other laboratories that work on a more routine basis that check on the surveillance of imports. Four of those laboratories were closed. That means more problematic products come into the United States. We need to have a robust laboratory system that can detect illicit and harmful products.

Mr. BELL. And Dr. Kessler, how will losing 800 staff affect CDER's ability to approve new medications, especially timely, affordable generics?

Dr. KESSLER. Those officials were the officials who communicated with the public, who came up with creative solutions to the problems we have been discussing. And those people, that is the infrastructure that supports the people who are looking at the applications. So, what you are going to see is you are going to see increasing delays. Things that we worked hard over the last 20 years to eliminate, those delays are going to manifest.

Mr. BELL. And Dr. Kessler, will fewer drug inspections make FDA better or worse at catching counterfeit or contaminated drugs?

Dr. KESSLER. It is going to make people less safe.

Mr. BELL. And quickly, what is the cost difference between brand name and generic prescriptions, and how would delays in generics affect working families?

Dr. KESSLER. We all rely on generic drugs. I worked very hard to make available lifesaving medicines, but if people cannot get access to them, if they cannot afford them, right, what good is all

that effort? Generic drugs are a very important part of the pharmaceutical armamentarium in this country.

Mr. BELL. The Trump Administration claims these cuts are to make America healthy again, but they will do the opposite. President Trump and Secretary Kennedy are slashing critical FDA functions while Republicans and Congress aim to redirect taxpayer dollars into tax cuts for the wealthy. The result? Americans will wait longer for cheaper medications, and it will be harder to trust that our food and drugs are safe. That is the last thing working families need right now. Thank you, and I yield back.

Ms. GREENE. The gentleman yields. I now recognize Mr. Burchett from Tennessee for 5 minutes.

Mr. BURCHETT. Thank you, Chairlady. These are some questions—what I am trying to do is separate hemp from marijuana, all right, and there seems to be a lot of confusion in that realm, especially when I walk into one of our hemp stores in East Tennessee, when they see me walk in there. Mr. Miller, now, do you support hemp products that contain intoxicating cannabinoids?

Mr. MILLER. We support any product that has less than .3 percent delta–9 THC, which is the measurement. Some of those products do indeed cause impairment, but at the same time, we feel very strongly that they need to be strictly regulated and, most importantly, kept out of the hands of children.

Mr. BURCHETT. OK. Because doctors at East Tennessee Children's Hospital, where I spent a lot of quality time in my formative years during my Evel Knievel phase, as I called it, and this is a hospital in my district, East Tennessee Children's Hospital, they have reported that 56 newborns and over 30 kids have been exposed or, as they say, poisoned by THC products. Does that sound right to you?

Mr. MILLER. I do not know the numbers, but there certainly is a real problem, given the lack of regulation, and, you know, really the point of my testimony is that we need to get the FDA engaged, particularly to get these products out of the hands of children.

Mr. BURCHETT. I guess I am just worried because kids are ending up at the hospital, and the public needs to be educated on this issue, and I am not seeing a lot of that. It just seems that the rules and regulations are kind of all over the place.

Mr. MILLER. I know Tennessee has been making a strong effort to try to regulate these products. My home state of Kentucky has as well. Again, we feel very strongly that adult products, when taken responsibly by adults, are a good health and wellness alternative, but we have got to keep these out of the hands of kids, and we need help. We do our self-regulation as an industry. Our U.S. Hemp Authority helps crack down internally, but only if we get the Federal Government working with the states will we ensure that this problem goes away.

Mr. BURCHETT. I have talked to several people, some in this room actually, that support the legalization of marijuana but do not support it in the hands of children, and I am wondering how are we expected to trust you all if you condone the sale of these things like delta–8.

Mr. MILLER. Well, we do not condone the sale of products like that to kids. That is a hundred percent. Delta–8 is a product that

many adults use and swear by for their own health and wellness, and as long as the products are regulated and made sure there are no contaminants, make sure they are labeled properly, and again, make sure they are kept out of the hands of children, they can be a healthy alternative for adults. But you are absolutely right, it is a real problem. These products are dangerous for kids, and we are trying to do as much as we can as an industry, but we really need government regulation to crack down on it.

Mr. BURCHETT. Is it true that compounded drugs are manufactured domestically under the oversight of the FDA or state boards? Does anybody care to answer that? Jump in there.

Mr. SAFDAR. Well, thank you for the question, Congressman. They are, but the FDA applies a different safety label to them than they do the branded or generic drugs. They are marked as FDA-unapproved drugs, and they are not guaranteed for safety or efficacy. So, while they provide an important niche part of our drug supply to make it resilient, they are only used as a last resort.

Mr. BURCHETT. Yes, Doctor?

Dr. KESSLER. One of the key questions is, those compounding pharmacies may be mixing the final ingredients, but where are they getting their ingredients from? And some of those ingredients, that API that is——

Mr. BURCHETT. I know what API stands for. None of the rest of the Committee does.

Dr. KESSLER. I am sorry.

Mr. BURCHETT. So, you will explain it to them, but I already know.

Dr. KESSLER. It is the active pharmaceutical ingredient. That first chart that I showed, 80 percent of our API is coming from either China or India approximately, so that is my concern about the compounding. Where is the raw material coming from?

Mr. BURCHETT. OK. Well, I guess, the follow-up to that was, we have got some compounding pharmacies in our areas, we do every other area, and I worry that the vast majority of them are doing the right thing, but I am afraid some of them could be doing some folks some ill will. So, thank you all. I have run out of time. Thank you, Chairlady, for your indulgence. Thank you, ma'am.

Ms. GREENE. The gentleman's time has expired. I now recognize Ms. Pressley from Massachusetts.

Ms. PRESSLEY. Thank you. For decades, a known carcinogen, formaldehyde, has been allowed to seep into chemical hair straighteners, especially those marketed to Black women and girls. These products are advertised as tools for beauty and self-expression, but to be clear, they are contributing to a public health crisis.

This is not dissimilar from the link that has been drawn between talc and talcum powder, baby powder, Johnson & Johnson, and a number of Black women who similarly suffered from ovarian cancer because of that link. Three in 5 Black women use these products, and according to the National Institutes of Health, they face a 31 percent higher risk of breast cancer. These women are also twice at risk of developing uterine cancer compared to those who do not use these chemical straighteners. And it is not just impacting consumers. Salon workers are regularly subjected to the constant inhalation of these chemicals. They disproportionately face asthma,

burns, and long-term illnesses. Despite this clear and present danger, the manufacturers of these products continue to sell them. This is not a coincidence. This is exploitation. This is profits over people.

In March 2023, I led a letter with Congresswoman Shontel Brown urging the FDA to ban formaldehyde from chemical hair straighteners. The FDA proposed a ban that was scheduled for implementation under the Biden Administration. Most recently, Trump froze all new regulations, leaving this rule in limbo. Dr. Kessler, the FDA's mission is to safeguard public health. Do you believe indefinitely delaying rules that have undergone rigorous research pose significant health risks to the public? Yes or no.

Dr. KESSLER. I believe that poses significant risks, Congresswoman.

Ms. PRESSLEY. OK. I agree, and the science has not changed, and the harms are still real and ever present. Dr. Kessler, for public health rules that have made their way through the regulatory process in the previous Administration, what should the current FDA Commissioner be doing?

Dr. KESSLER. One of the most dedicated public servants, the Chief Science Officer, took on the responsibility recently for cosmetics, because cosmetics was always the least resourced, the least regulated. And, Congressman [sic], I applaud, again, your bringing this up. This has been a real issue—Namandjé Bumpus left the Agency because she did not think it was a place she could work anymore, and that concerns me.

Ms. PRESSLEY. It concerns me as well. Thank you. In fact, just this morning, Congresswoman Shontel Brown and Nydia Velazquez and I sent a letter urging Commissioner Makary to act. There have already been some states, like Maryland, California, and Washington, that have banned formaldehyde from these products, but while these states have acted, they cannot solve the nationwide problem. It is clear that we need Federal action to protect every woman, every worker, and every person who uses these products, regardless of where they live.

In the courts, thousands of women have filed Federal lawsuits against the manufacturers of these hair straighteners, alleging that their products have caused uterine cancer, breast cancer, and other devastating health outcomes. These lawsuits are not just legal cases. They represent the lived experiences of women who have been harmed by this industry. They are mothers, daughters, sisters, and they deserve justice. It is well past time we take formaldehyde off the market. We cannot wait another month, another year, or listen to another excuse. It is time to ban formaldehyde. Thank you, and I yield.

Ms. GREENE. The gentlelady yields. I now recognize Mr. McGuire from Virginia for 5 minutes.

Mr. MCGUIRE. Thank you, Madam Chair, and thank you for our witnesses for being here today. You know, I was listening to the discussions going back and forth today, and many of you said that there were dangerous ingredients in not just cosmetics, but our foods and other places. And I believe I heard testimony that many of these dangerous chemicals are coming from China. Is that correct?

Mr. BENTLEY. Yes.
Mr. MILLER. Yes, Congressman.
Mr. SAFDAR. Yes.
Dr. WILLIAMS. Correct.
Dr. KESSLER. Agreed.

Mr. MCGUIRE. So, if these dangerous chemicals are harming the American people and they are coming from China, how do they get into our country? Would it be the cartels?

Mr. BENTLEY. Congressman, in the case of illicit tobacco products and e-cigarettes, whilst the market is underregulated, because FDA has choked off the supply of authorized legal e-cigarettes, we do not know, for some products, what is contained in them. However, I would also make a caveat that might differ from some other industries. Almost every e-cigarette currently being sold or on the market, even if it is illicit, is probably still dramatically safer than a combustible cigarette and actually can provide a public health benefit.

Mr. MCGUIRE. And how is it getting here? Is it getting here through the cartels?

Mr. BENTLEY. In terms of e-cigarettes, they are mostly from China, not from the South of the border.

Mr. MCGUIRE. Well, I understand they are made in China, but they have got to come across the border somehow. How do they get across the border?

Mr. BENTLEY. They get across the border because these products can be sold by e-cigarette distributors that can ship them in. They have tracking numbers that FDA can track, so-called STNs, so that is how they get into the border, through ports of entry. Some, however, are obviously not monitored and even outside of that regulatory system.

Mr. MCGUIRE. OK. Mr. Miller, what do you know on this?

Mr. MILLER. I know very little. We have heard reports that Chinese-made purely synthetic cannabinoids, so these are products that were made completely out of a lab and not come from nature at all. We hear that they may be coming through the country, but again, because there is not a Federal regulatory structure, we just do not have details and are unaware of the scope of their impact.

Mr. MCGUIRE. All right. Dr. Williams?

Dr. WILLIAMS. Yes. I am not aware of exactly how these things are coming in. One thing I am aware of, though, is fentanyl was just the start. They are creating things that are much, much more dangerous than fentanyl.

Mr. MCGUIRE. That is right, and, well, I have got to tell you, fentanyl is the one we know about, but you are right. I have heard there are different color versions of these drugs that are even more dangerous.

Mr. SAFDAR. Congressman, we have studied the routes by which illegal ingredients for knockoff weight loss medications have come into the country, and they come in both in freight, as I testified before. And my written testimony has some explanation of the report that we did where we studied these ingredients that came in through freight, and there are reforms that we could do to prevent that. But you are right, they primarily came from China and then

India is the second, and then these products also come in through de minimis.

Mr. MCGUIRE. With all due respect, because of time, Dr. Kessler, do you have any knowledge of how they get here?

Dr. KESSLER. In December 2019, there was a decision, unfortunately, by the Administration, if you talk about e-cigarettes, not to regulate any disposables, and that opened the door.

Mr. MCGUIRE. So, what I would say is many of these drugs do come in from the cartels. Now, thank God we have got President Trump wanting to return manufacturing of drugs back to the U.S., and the border has been shut down for the most part. I mean, we have still got a lot of work to do. There is still certainly a threat. That means less fentanyl, for example, is coming in. You think a hundred thousand people a year being killed from fentanyl overdose, epidemic, we should be jumping up and down and making a lot of noise. So not only are we stopping the fentanyl, we are stopping the flow of a lot of these other chemicals that are poisoning the American people.

Now, earlier you guys talked about high-fructose corn syrup being a danger to the obesity issue in our country. Mr. Williams, what about trans-fats? How big a deal is that?

Dr. WILLIAMS. Well, it is interesting. Originally, trans-fatty acids came on because there was a concern about animal fats. Nobody said what is the replacement, if we do not use animal fats, what are we going to use? Nobody thought about the replacement. As so often happens in these decisions, they never think about the substitute. So, we got trans-fatty acids, which were much more dangerous for heart disease than animal fats. Now it seems like we are going back. The concern is seed oil, so let us get rid of——

Mr. MCGUIRE. How do we have Crisco on the label that says zero trans-fats per serving when it has trans-fats in it? How does that make sense?

Dr. WILLIAMS. I do not know about Crisco.

Mr. MCGUIRE. Well, it is certainly an issue.

Dr. WILLIAMS. But the issue is that before you make these decisions to take something off the market, you have to know what is going to replace it.

Mr. MCGUIRE. Definitely. Well, I am glad we are bringing supply chains and drug manufacturing in America to save our people. Thank you. I yield back.

Ms. GREENE. The gentleman yields. I just want to clarify something that has been said. There is an enormous difference between state-licensed compounding pharmacies, compounding drugs on FDA shortage lists, and illegal drug manufacturers making counterfeit drugs that they sell on TikTok. We must root out illegal drug manufacturers while ensure pharmacies have the ability to respond to drug shortages. I just wanted to clear that up.

I now recognize myself for 5 minutes for questioning, and I am going to speak on behalf of a community of people here in America that largely get ignored on an extremely important issue, and that is the issue of vaccines. And while we are talking about the FDA losing the trust of Americans, there is a very important reason why for that, and I have to recognize autism rates.

Now, anytime you mess with people's children, this is getting to the heart of a family, and, you know, in the 1980s, 1 to 4 out of every 10,000 individuals had autism. Twenty years ago, it was 1 in 150. And just recently, the rate has been said to be 1 in 36, but today, there was a study that just came out of 12 million children ages 5 to 8, and it has been released by the Children's Health Defense, that the autism rate is now 1 in 33.

I mean, we are talking about something that cannot be ignored anymore. This is a crisis, and people are losing their children. They are watching their children go from being happy, active, babbling, growing, reaching milestones to completely disappearing. Completely disappearing, and parents, over and over and over again, point to vaccines. And they are called conspiracy theorists, they are dismissed, and they are completely ignored, and this cannot be ignored anymore. This is a crisis, and we are losing our children, and this cannot be allowed.

Let us talk about another reason why the FDA has lost all trust from Americans, and we can talk about the COVID vaccines. Emergency use authorization was given for these vaccines, and the FDA took approximately 21 days to give it for the Pfizer-BioNTech mRNA vaccine. Moderna, the emergency use authorization was given in 18 days—18 days—and then for Johnson & Johnson, it was given in 23 days. Now, this comes after typically vaccine development approval takes 10 to 15 years, but for these vaccines for COVID, the emergency use was given in a matter of days, and then full approval was given in months. Now, what has been the result of that? Another thing, and people that have been ignored. These are the VAERS reports. Now there are 1,662,426 VAERS reports, and it is listed here that there are 38,541 deaths, 220,494 hospitalizations, 156,527,000 urgent care, 17,913 Bell's palsy, 5,175 miscarriages, 22,247 heart attacks, 28,908 myocarditis, 77,311 permanently disabled, and these are people reporting themselves, and no one seems to give a damn. And this is why the people do not trust the FDA, along with the myriad of reasons that has been given today, and it is unbelievable. And at the same time, medicines that have been trusted for years, like ivermectin, one of the safest drugs, was called horse paste, and has been one of the best effective treatments against COVID.

Now, Mr. Kessler, did you object when Dr. Marks forced out the two top vaccine scientists at the FDA, Dr. Gruber and Dr. Krause, due to their opposition of mandating booster shots? Did you object to that?

Dr. KESSLER. I had enormous respect——

Ms. GREENE. Did you object, yes or no? Yes or no? I have a little time left. Yes or no.

Dr. KESSLER. No, but, Madam Chair——

Ms. GREENE. No, you did not object.

Dr. KESSLER [continuing]. May I respond?

Ms. GREENE. I reclaim my time. No, you may not.

Dr. KESSLER. May I please respond?

Ms. GREENE. I reclaim my time. You did not object. You did not object.

Dr. KESSLER. I had enormous respect for Dr. Marks, his judgment.

Ms. GREENE. Well, I am glad that you do, but you did not object to him when he said the booster shots should not be mandated, and people that have been vaccinated with COVID–19 are the people that keep getting COVID–19, and the people with the booster shots keep spreading and getting COVID–19—no, this is my time—where people like me, with natural immunity, do not get it and do not spread it around.

Dr. KESSLER. Madam Chair, may I please respond?

Ms. GREENE. No, and this is my time, Dr. Kessler, and my time has expired. So, I now recognize—Mr. Min has made it. I now recognize Mr. Min from California for 5 minutes.

Mr. MIN. I would like to hear Dr. Kessler's response to that last question.

Dr. KESSLER. Thank you so much, Congressman. I am a pediatrician here, and it just is very important to state, there is no scientific link between vaccines and autism. Respectfully, on the issue on VAERS, VAERS is an open reporting system, and you have to look and ask the question. You have to apply scientific principles.

Mr. MIN. Selection bias, things like that.

Dr. KESSLER. Bradford Hill, you are there, Congressman.

Mr. MIN. Facts are facts, data is data, and a random website is not necessarily the best way to get any kind of real data. And we all understand, Dr. Kessler, the importance of peer review, don't we?

Dr. KESSLER. Exactly. The issue, just because you see a reaction in a data base, you have to ask whether there is causation. There are certain Bradford Hill principles that have to be applied, and they were not being applied.

Mr. MIN. And it is unfortunate right now that science is being rejected by people going on Google, going on websites of dubious origin to try to find their own information.

Dr. KESSLER. We should all be concerned about that.

Mr. MIN. First, I want to thank the Chair and the Ranking Member for holding this hearing on the FDA. It is, as we know, the gold standard in the world for drug and medical product regulation. Its critical work has included the regulation and approval of a wide range of products, ranging from the drugs we consume to the infant formulas that we feed our children, and, of course, plays a crucial role in cracking down on counterfeit medical products and drugs. That is why I believe the FDA should be fully funded and independent. It is absolutely essential, particularly today, to ensure a safe supply chain and that our products that we consume for our health have been properly reviewed for market.

Now, under the leadership of current HHS Secretary Kennedy and Donald Trump, the great public health apparatus is in the process of firing thousands of workers at HHS, NIH, and the FDA. The FDA has seen proposals to slash 20 percent of its workforce, including 170 of those from the Office of Inspections and Investigations. And I just want to note that when we talk about efficiency—that is a word that gets thrown around a lot—we have to actually talk about what we mean when we talk about efficiency. What is the timeframe we are looking at? What are the goals and parameters we want? If I want to lose weight, the fastest way to do that is maybe just cutoff my leg. That is not an efficient way if you are

thinking beyond the immediate term, and one can argue that the cuts to FDA are having a similar effect.

In particular, I want to talk about the effects on the drug approval pipeline. And so, my understanding—Dr. Kessler, I think you are in a position to answer this—that I have been told by a lot of the life sciences companies that I represent in Orange County, California, that many of those drug approval people are actually paid for by user fees. Is that your understanding?

Dr. KESSLER. The CDER has resources that are paid for by user fees, but that does not guarantee that the application will be approved.

Mr. MIN. Of course, no, and that is not the point.

Dr. KESSLER. It is just to make sure that there are people there who can review them.

Mr. MIN. And so, I think the point I would like to make here is that by cutting these people, by terminating staff, you are creating potentially a much longer pipeline for drug approval, product approval. That is something that a lot of the companies I represent, including companies like Edwards Lifesciences and Masimo, some of the pharmaceutical companies I represent are very concerned that they are going to see much longer approval processes. And again, these are positions that are paid for out of the user fees. They actually do not cost the taxpayer anything. So, when we look at efficiency beyond anything, but the immediate term, these cuts look very counterproductive. They look like they are going to have massive negative economic impacts on our communities, on the drug pipeline.

And so, I guess, Dr. Kessler, I just want to go back to you. How do you think drug approval times may be affected by cutting a blanket cut of 20 percent of the workforce?

Dr. KESSLER. I think that drug approval times will increase, but most importantly, important medicines that we will depend on for our families, that is what I care about.

Mr. MIN. That is right. Lifesaving medications are not going to get approved now or will take longer to approve.

Dr. KESSLER. I hope not. There are still dedicated people, but I fear that those delays are going to happen.

Mr. MIN. And when we talk about efficiency, I just want to note another thing that is happening right now. The attacks on immigrants, particularly in higher education, the cuts to NIH are having massive impacts on universities around the country, including UC Irvine, which I represent. They are very worried. I know that many of the immigrants that are researching in potentially groundbreaking efforts in new life sciences products and drugs, that many of them are going back to their countries of origin. They are going to other countries and other top research institutions.

I just want to ask—this is my last question, Dr. Kessler—if you can speak about the Administration's immigration actions and how you anticipate they might affect our life sciences industry here in the United States?

Dr. KESSLER. Our competitiveness was enhanced by those people coming to universities in your district.

Mr. MIN. They made America great.

Dr. KESSLER. Exactly.

Mr. MIN. And now we are driving them out.

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

Mr. MIN. Thank you. I yield back.

Ms. GREENE. In closing, I want to thank our witnesses once again for their testimony today. I now yield to Ranking Member Subramanyam for his closing remarks.

Mr. SUBRAMANYAM. Thank you, Madam Chair. First, I would like to enter into the record some articles without objection.

Ms. GREENE. Without objection, so ordered.

Mr. SUBRAMANYAM. *L.A. Times* article February 13, "Trump's Assault on Science Will Make Americans Dumber and Sicker; *Washington Post* article from April 2, "Veterinarians Working On Bird Flu, Pet Food Safety Are Fired in HHS Purge;" article from April 3 in *The New York Times*, "FDA Layoffs Could Raise Drug Costs;" an *Axios* article from April 3, "Drug Industry Worries About FDA Delays;" a *Washington Post* article from April 6, "Worries Grow Over Risks to Americans as Trump Cuts Health Safety Agency;" finally, an *Axios* article from yesterday titled, "FDA Cuts Threaten Medical Product Review Programs."

Ms. GREENE. Without objection, so ordered.

Mr. SUBRAMANYAM. Thank you, Madam Chair. We have heard today about the need to make sure our infant formulas and drugs are safe and affordable, about the need to prevent youth vaping, the need to stop illicit products from getting to kids, and even the desire to have the FDA approve things faster. But as our experts here today said, we cannot accomplish any of this without the scientists, researchers, and staff in place, and these are the people the Administration has started firing, thousands of people at the FDA. Someone said that running the FDA after these firings is like flying a plane with only a copilot. I think it is like flying a plane with only a flight attendant. It is such a difficult task already, and now you are firing many of the people who make it happen.

And the title of this hearing is, "Rooting Out Illicit Products," but the very offices in charge of keeping us safe and healthy have been gutted, and the foremost experts on rooting out illicit products are being fired. We are worried about products coming into our country across the border, but 170 people were fired at the Office of Inspections and Investigations, and because of that, now the Agency will have to "reprioritize their workload for the rest of the year, which would mean less surveillance, less inspections, and more products that are illicit or bad for our health coming across the border."

We actually need more inspectors, 16 percent more, according to the GAO, and all this is going to do is make it harder for the inspectors who are still here to do their job, but it does not end there. The Administration is also stopping the work of Childhood Lead Poisoning Prevention Branch. Those are the people who are making sure that our children do not get lead poisoning, and just earlier this year, lead paint was found in school buildings of a 68,000-student school district in Milwaukee. The school district called this Lead Poisoning Prevention Branch for advice, and they were getting advice up until last Tuesday, but now the people who were giving them advice have been fired. And as a dad of two girls, 5 and 3, I can only imagine what is going through the minds of the parents in Milwaukee.

And so, you know, this Administration is also cutting food testing labs in California, one that tests for contaminants in baby food and for avian flu and other products. And so, America has to lead the world in science, innovation, scientific discovery, technological advancement. And the American people deserve to live in a country where we can trust what is in our food, what is in our medications, and what is in our products. But cutting science funding and gutting the FDA, causing chaos throughout the Agency is going to make every American man, woman, and child less safe, less healthy. And the Administration, if they do not reverse course, people will die. I yield back.

Ms. GREENE. The gentleman yields. I now recognize myself for closing remarks.

The good news, ladies and gentlemen, the American people are not going to die under President Trump and his great Administration because the goal is to make America great again. And as our new Administration is getting in place, we have to talk about things that previously happened under the Biden Administration, things like the failures with infant formula, where mothers were desperately seeking formula for their children and were blocked from ordering safe formulas from overseas. That was a complete failure. I cannot believe that any time in our country, mothers could not find infant formula on the grocery store aisles and were blocked from getting formula that they much needed for their babies.

We can also talk about how the FDA bans raw milk, which is ridiculous. Raw milk is sold in countries all over the world, countries like England, New Zealand, France, Italy, Germany, Norway, Sweden, Finland, and Denmark. Raw milk has been here since the beginning of time, and many Americans not only produce raw milk, they would also like to sell it, and many consumers would like to be able to buy it, but the FDA has declared war on anything natural and good, and while it allows many chemicals to be brought into America, put in our foods, and distributed all over the country. No wonder obesity is at all-time highs. No wonder Americans are sicker than most people around the world.

The FDA's failure to approve new nicotine products, which are safer than cigarettes, has spawned a massive and dangerous illegal market of Chinese vapes. No one trusts many of the products, especially anything laden with chemicals coming from China, because China, after all, has been murdering Americans for years now, and Americans are dying every single day from fentanyl that comes in our country. And if China wants to be serious about tariffs and its treatment and unfair treatment against America, the first step they should do is stop sending fentanyl in our country and poisoning our people.

The FDA has failed to effectively regulate hemp-derived products, which the industry themselves desperately wants to be regulated, and we heard that in testimony today. The FDA has the authority to crack down on counterfeit drugs, which come primarily from China and infiltrate our legitimate drug supply chain, endangering American lives, and we heard our witnesses today talk about how we cannot trust China to give us lifesaving medications. President Trump's recent executive order ending the de minimis

package exemption for low-value imports will bolster FDA's ability to restrict the flow of illicit products from China, and I think that is a great thing for every single American, no matter how they vote and how they feel about the current President of the United States.

The reality today is, it is very sad that Americans do not trust the FDA, and I will reiterate again for the many millions and millions of Americans who are still angry and want accountability, and they deserve it, for being forced to take a vaccine they should have never been forced to take and all the Americans that suffer from side effects and lost loved ones from a vaccine that should lose its FDA approval. And I am saying that, that is my own opinion, I believe that the FDA approval of COVID vaccines should be revoked, and they should be taken off the childhood vaccine schedule. Children do not need a COVID vaccine. Children were one of the healthiest and had the lowest hospitalization rates and deaths during COVID. After all, our kids are resilient, and they should not be forced and be injected with manufactured vaccines that their parents disagree with.

I thank everyone for tuning into this hearing today. I thank our witnesses for being here and thank you for your testimony.

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

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

[Whereupon, at 1:19 p.m., the Committee was adjourned.]