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IMPROVING SAFETY AND TRANSPARENCY IN AMERICA'S FOOD AND DRUGS

WEDNESDAY, JANUARY 29, 2020

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2322 Rayburn House Office Building, Hon. Anna G. Eshoo [chairwoman of the subcommittee] presiding.

Members present: Representatives Eshoo, Engel, Butterfield, Matsui, Sarbanes, Schrader, Kennedy, Cardenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Rush, Burgess, Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Hudson, Carter, and Walden (ex officio).

*Staff present: Joe Banez, Professional Staff Member; Waverly Gordon, Deputy Chief Counsel; Tod Guidry, Health Fellow; Stephen Holland, Health Counsel; Zach Kahan, Outreach and Member Service Coordinator; Aisling McDonough, Policy Coordinator; Meghan Mullon, Policy Analyst; Joe Orlando, Staff Assistant; Lino Pena -- Martinez, Staff Assistant; Alivia Roberts, Press Assistant; Rebecca Tomilchik, Staff Assistant; Kimberlee Trzeciak, Senior Health Policy Advisor; Jerry Couri, Minority Deputy Chief Counsel, Environment & Climate Change; Jordan Davis, Minority Senior Advisor; Theresa Gambo, Minority Human Resources/Office Administrator; Tyler Greenberg, Minority Staff Assistant; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; and Kristin Seum, Minority Counsel, Health.

Ms. Eshoo. The Subcommittee on Health will now come to order.

Good morning, everyone. We have a lot of work to do today, so I am going to -- don't try to test my generosity, so that we can move along and get all of our work done. Welcome to the witnesses.

I just wanted to mention something. We have a roundtable tomorrow with the appropriate agencies relative to the coronavirus for our committee. Today there is a briefing for the full House. So, it is up to members if you want to leave to go to the full one. I am going to stay here so that we can get our work done. And, so you have a choice of you can do both, but I am not going to stop the hearing to go to the full briefing, so that we can get our work done.

I would like to also welcome our colleague, former colleague Bart Stupak, who is here. Always a friend. A wonderful member of this committee for many years. Bart, welcome. It is great to see you.

The chair now recognizes herself for 5 minutes for an opening statement.

Twenty cents out of every dollar spent by American consumers goes toward food or medicine that is regulated by the FDA. Today we are going to examine 10 mostly bipartisan bills to support the FDA's immense mission. Our first panel

will consider four bills to grant the FDA new authorities to tackle challenges that threaten our drug supply.

Chairman Pallone's legislation to create National Centers of Excellence to support research and development of continuous manufacturing technology will strengthen and modernize U.S. drug production.

The Safeguarding Therapeutics Act, introduced by Representative Brett Guthrie, will protect against counterfeit medical devices.

Representative Doris Matsui's MODERN Labeling Act will make sure generic drugs have up-to-date safety labeling.

Finally, the Orphan Drug Exclusivity Act, introduced by Representative Madeline Dean, will close a loophole so that orphan drug exclusivity can't be used to deny access to certain drugs, especially drugs for opioid use disorder.

Taken together, these bills improve the drug supply chain from the very beginning to the very end, so that patients have access to quality products that are genuine and accurately labeled.

On the second panel we are going to consider six bills that affect the FDA's oversight of food products. Many of these bills take action on decisions that the FDA has long delayed.

For example, the FASTER Act, introduced by

Representative Doris Matsui, lives up to its name. The act makes the FDA move faster in requiring food manufacturers to list sesame as an allergen on their products.

The bill also allows the FDA to add other food ingredients as major allergens based on the prevalence and severity of allergic reactions. Over a year ago, the FDA issued a request for information about requiring the sesame allergen label but has not taken any steps since.

This allergen labeling is very important, especially for children, obviously, and their families. An estimated 8 percent of American children are affected by good allergies. And the NIH recently found that sesame allergy is common among children with other food allergies, occurring about 17 percent of the time.

But those parents and children cannot easily avoid sesame since it is often not listed as an ingredient. Anyone who has ever known a child with a serious food allergy knows how dire a reaction can be. The FDA needs to move faster to help curb the risks these children fact. And the FASTER Act will help the FDA do just that.

The Keep Food Containers Safe from PFAS Act, introduced by Congresswoman Dingell, forces the FDA to confront the issue of PFAS chemical contamination in food wrappers and containers.

The chemicals have been found to easily accumulate in the environment or the human body because they break down very slowly. Exposure to PFAS can lead to cancer, weaker immune systems, and liver and kidney toxicity.

The FDA has said that PFAS approved for use on paper or cardboard to prevent grease stains can potentially migrate to food. Recent studies have found that eating microwave popcorn in meals -- warning, members, it is in both of our cloakrooms -- recent studies have found that eating microwave popcorn in meals from fast food and pizza restaurants was associated with levels of PFAS in blood. But the FDA has not yet limited PFAS in food packaging.

Instead, the FDA says that because of the growing scientific evidence, it will review whether the use of PFAS in food contact applications is safe. I hope the agency takes more definitive action soon.

The panel will also consider bills to address unanswered questions around the FDA's regulation of dairy and cheese products, exportation of horse meat, and infant formula. In total, the FDA oversees more than $2.6 trillion in consumption of food, medical products, and tobacco.

I hope today's hearing will help the agency better shoulder its massive responsibility. And we certainly want to work with the agency to make sure that all of this

happens.

The chair is now pleased to recognize the ranking member of the Subcommittee on Health, Dr. Burgess, for 5 minutes for his opening statement.

Mr. Burgess. And I thank the chair. And welcome to our witnesses, welcome to the witnesses of both panels in fact, because we do have a great deal in front of us this morning.

The Food and Drug Administration is the oldest comprehensive consumer protection agency within the Federal Government. Dating back to 1906, the FDA has been the administrative body tasked with protecting Americans from adulterated and misbranded drugs and food. Since 1906, the authority of the Food and Drug Administration and its responsibilities have grown to include cosmetics, tobacco, and other public health programs.

Today, we are considering a number of drug and device policies. Representative Guthrie's bill, H.R. 5663, the Safeguarding Therapeutics Act, allows for the Secretary of Health and Human Services to destroy certain counterfeit medical devices.

Counterfeit devices do pose a risk to Americans. I actually saw this firsthand when I visited the JFK International Mail Facility with former FDA Commissioner Scott Gottlieb. To say the least, it was unsettling to realize these devices, counterfeit devices could not be destroyed but returned to sender. And many of those recycled back through several times, with the same markings on the package. They need to be destroyed when they are

encountered.

Counterfeit facilities that come through facilities like JFK, and this bill would allow for such devices to be destroyed at the point of entry. Granting authority to the secretary to ensure that the devices will be destroyed will help protect patients from bad actors who distribute these kind of devices into the marketplace.

H.R. 4712, the Fairness in Orphan Drug Exclusivity Act, seems to -- seeks to clarify conditions for exclusive approval and licensure of drugs that receive orphan drug designation under the non-profitability provision of the Orphan Drug Act. The government has an important role with respect to orphan drugs. Without government assistance, the manufacturers and the innovators for drugs for rare diseases may never be able to bring these products to market.

This legislation appropriately balances the support necessary to promote orphan drug development without allowing for orphan drug manufacturers through infinite competition. It is important we walk that fine line between competition and encouraging new cures.

Another bill aimed at innovation as 4866. This would designate certain qualifying higher educational institutions as National Centers of Excellence in continuous pharmaceutical manufacturing to support the advancement and

development of continuous manufacturing. Continuous manufacturing has many benefits, allowing for more flexible tracking and tracing in the event of a product failure, and it can eliminate hold times between steps of production, important technology, because the ability to track and trace during a product failure could minimize the risk of a drug shortage. And we have been through that in years past.

Certainly over my time on this subcommittee the subcommittee has held hearings under the food jurisdiction of the Food and Drug Administration. And recognizing former Chairman Stupak in the back of the room, I think some of those hearings were conducted under you and Chairman Dingell, which I remember very fondly

The Food and Drug Administration is the authoritative agency on labeling and nutrition, ingredients and packaging. It is important for Americans to be aware of what is in their food, from the nutritional value to what additives or allergens may be present.

H.R. 2269, the Infant Formula Protection Act of 2019, would require infant formula to be considered adulterated by the FDA if it passes the use by date. That seems a little unusual to me, but I'm happy to hear what the, what the evidence shows.

Some other bills before us today are dealing with food

requirements that overstep the authority of the Food and Drug Administration. They are the expert body on food regulation and safety. Well-intentioned legislation may result in unforeseen negative consequences, particularly where the FDA has not found a need for regulation in the past.

And, unfortunately, we don't have the FDA here as a witness today. At some point we will need to invite them in. But I do want to yield the balance of my time to Mr. Guthrie to speak on his bill.

Mr. Guthrie. Thank you to the Republican leader for yielding.

I was proud to introduce three bipartisan bills today. The Modern Labeling Act will modify how certain generic drug labels are updated.

The Safeguarding Therapeutics Act will protect American consumers from counterfeit medical devices. Like my friend Dr. Burgess, I was floored when I was at JFK Airport and realized that we just return counterfeit devices, that by law we can't destroy them. So, we will hopefully fix that this session.

And then the Continuous Manufacturing bill will expand our work on 21st Century cures to increase research and development on continuous manufacturing.

I would like to thank Representative Matsui,

Representative Engel, and Chairman Pallone for working with me on these bills.

And I yield back.

Mr. Burgess. I yield back.

Ms. Eshoo. The gentleman yields back.

I was going to recognize Mr. Pallone, but I will instead recognize the gentlewoman from Michigan, Ms. Dingell, for 5 minutes.

Mrs. Dingell. Thank you, Madam Chair and Ranking Member Burgess for convening this hearing and including important public health legislation, including my bill, the Keep Food Containers Safe from PFAS Act.

I am appreciative of the inclusion of a witness from my district, Dr. Kao-Ping Chua, who is a professor of pediatrics at the University of Michigan Medical School. His background and expertise will help the committee better understand the intersection of opioid policy and orphan drug policy. And we are grateful to have him with us today.

We look forward to learning more about these important issues as we work to ensure that Americans have access to these potentially lifesaving drugs. We thank Dr. Chua for his time and pioneering work in this area and the opportunity to learn from his expertise.

I would also like to express my appreciation again for the committee's wisdom in inviting a professor from the greatest public university in the world. Go Blue.

Thank you, Madam Chair. And I yield back.

Ms. Eshoo. The gentlewoman yields back.

Pleasure to recognize the ranking member of the full committee, our friend Mr. Walden, for his 5 minutes for an opening statement.

Mr. Walden. Good morning, Madam Chair. Thank you very much. Thanks for having this hearing. Welcome to our witnesses and guests.

As you have heard, we will have an opportunity to review legislation that is intended to improve the safety of medical products in the United States. We will also review several food-related policies.

I briefly want to extend special thanks and welcome to Dr. Doug Corey from Oregon's 2nd Congressional District for being here today. While it may seem a little tamer here in Congress than what he is used to seeing at the Pendleton Round-Up back home, I can assure you we have our fair share of excitement, among other things that might resemble what happens at rodeos right here at the hearing.

I appreciate Dr. Corey taking his time to testify, and know his valued expertise for bringing important perspective to our discussions about animals.

I am pleased we will be considered four bipartisan priorities on the first panel that aim to improve the safety of America's drug supply, bring more transparency to the

marketplace, and provide additional protections against the threat of counterfeit product.

H.R. 5663, the Safeguarding Therapeutics Act, would extend FDA's administrative destruction authority to medical devices. That only makes sense. As you have heard, under current law the FDA is authorized to destroy certain imported drugs that may pose a threat to public health. However, this authority does not extend to medical devices, including some combinations in combination products.

This legislation, introduced by Mr. Guthrie and Mr. Engel, would provide the agency with the additional tool to protect American consumers against potentially dangerous unapproved product.

Furthering our efforts to protect the country's medical products supply chain, we will also be considering H.R. 4866, which is the National Centers of Excellent in Continuous Pharmaceutical Manufacturing Act. H.R. 4866, introduced by Chairman Pallone, would direct the FDA to designate higher education institutions as National Centers of Excellence, allowing the FDA to work with the centers and industry to create a national framework for the implementation of continuous manufacturing technology.

At our October hearing on safeguarding the pharmaceutical supply chain, Dr. Woodcock spoke at length

about the potential advantages of continuous manufacturing, including the potential to reduce our dependence on foreign sources of active pharmaceutical ingredients, increase our manufacturing resiliency, and reduce quality issues that often trigger drug shortages.

Given the potential for this technology, I am pleased we are considering this bipartisan legislation to further advance its development.

We will also be considering H.R. 5668, that's the MODERN Labeling Act, which will allow the FDA to require modifications be made to outdated labeling for generic drugs. Generic drugs are generally required to have the same labeling as the brand drug they reference. However, once the brand drug is no longer on the market, the generic manufacturer is not able to update their label to reflect the most accurate and up-to-date information, often discovered through post-market use.

So, the inability to update labeling can result in information gaps for providers and patients when discussing the most appropriate treatments. H.R. 5668 will help close those gaps. That is important.

Additionally, we will consider H.R. 4712, the Fairness in Orphan Drug Exclusivity Act. This legislation will update the Orphan Drug Act to require drug manufacturers that

receive an orphan drug designation under the post-recovery provision of the act to demonstrate that successor drugs eligible for the designation do not have a reasonable expectation of recouping their research and development costs. H.R. 4712 aims to balance the need to maintain existing incentives for orphan drug development, while eliminating loopholes that may allow a drug manufacturer to actually block competition.

So, I appreciate the majority's attention to these bipartisan proposals, and hope they will continue to work with us on bipartisan legislation, particularly initiatives focused on the reauthorization of critical programs set to expire at the end of the year. One of those programs is that rare pediatric priority review voucher program, Madam Chair, I know you are familiar with.

Several members of this committee already have worked together in a bipartisan manner to introduce the Creating Hope Reauthorization Act which would extend this program. And I would ask the chairwoman to consider its inclusion in a future hearing.

Finally, we will be considering several legislation initiatives intended to address FDA's regulation of foods. And I have heard concerns from dairy and beef producers in my district related to standards of identity. And I welcome a

discussion of these matters today as well.

However, I also have some concerns that some of the bills being considered today may actually have unintended and negative consequences and ignore the science-based approach FDA takes when regulating products its jurisdiction.

So, with that, I welcome our witnesses and our guests and appreciate the hearing. Just as a footnote, as you know, we have another hearing scheduled to start in about 15 minutes downstairs. So, I will be bouncing back and forth, as will the chairman I am sure.

With that, I will yield back all 22 seconds. Ms. Eshoo. We know that you bounce well.

The chairman yields back.

All right. The chair would like to remind members that, pursuant to committee rules, all members' written opening statements will be made part of the record.

I now have the pleasure of introducing our witnesses of the first panel.

First, Dr. Chua Ping -- Dr. Kao-Ping Chua, excuse me, assistant professor at the Department of Pediatrics, as Congresswoman Dingell said, for the University of Michigan Medical School. Welcome to you.

Dr. Fernando Muzzio, Distinguished Professor, Chemical and Biochemical Engineering at Rutgers, the State University

of New Jersey. Professor, welcome to you as well.

Mr. Richard Kaeser, Vice President, Global Brand Protection, Johnson & Johnson. You are the only one that is not a doctor. Time to go back to school.

[Laughter.]

Dr. Jeff Allen, President and CEO of the Friends of Cancer Research. Welcome to you.

We look forward to your important testimony. I think you are familiar with the light. Green, we go; yellow, watch out; red, full stop. Okay?

So, Dr. Chua, you are now recognized for 5 minutes for your testimony. And thank you again.

STATEMENTS OF KAO-PING CHUA, M.D., PH.D., ASSISTANT PROFESSOR, DEPARTMENT OF PEDIATRICS, UNIVERSITY OF MICHIGAN MEDICAL SCHOOL; FERNANDO MUZZIO, PH.D., DISTINGUISHED PROFESSOR, CHEMICAL AND BIOCHEMICAL ENGINEERING, RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY; RICHARD KAESER, VICE PRESIDENT, GLOBAL BRAND PROTECTION, JOHNSON & JOHNSON; AND, JEFF ALLEN, PH.D., PRESIDENT AND CEO, FRIENDS OF CANCER RESEARCH

STATEMENT OF KAO-PING CHUA, M.D., PH.D.

Dr. Chua. Chairwoman Eshoo, Ranking Member Burgess, Congresswoman Dingell, Congressman Upton, and distinguished members of the subcommittee, thank you for the opportunity to participate in today's hearing.

I am a practicing general pediatrician and health policy researcher with expertise in opioid policy and orphan drug policy. These two areas of my research unexpectedly converged when Sublocade, a once monthly buprenorphine injection was approved as an orphan drug to treat opioid use disorder, also known as opioid addiction. This approval entitled Sublocade to a 7-year period of exclusivity during which no new buprenorphine products could be marketed for opioid use disorder.

Although FDA recently revoked Sublocade's orphan

approval, it could still receive exclusivity if this decision is overturned in court.

Today, I will explain why I strongly support passing H.R. 4712, the Fairness in Orphan Drug Exclusivity Act. This bill will close the loophole that allowed Sublocade's orphan approval and block exclusivity for Sublocade, even if FDA's decision is overturned, thus promoting public health by ensuring competition, innovation, and patient choice in the market for buprenorphine.

Over the past decade opioid overdose has claimed the lives of hundreds of thousands of Americans, including the parents and siblings of some of my patients. To prevent these deaths, federal policy makers must ensure that patients have access to safe and effective medications to treat opioid use disorder, including buprenorphine.

However, FDA nearly achieved the complete opposite goal when it granted orphan approval to Sublocade, potentially allowing the manufacturer Indivior to stifle competition and innovation for 7 years.

In addition, Sublocade's orphan approval was an abuse of orphan drug policy. This approval occurred under a 23-year-old orphan drug designation granted in 1994 to Subutex, a predecessor buprenorphine product developed by Indivior's parent company Reckitt Benckiser. To obtain this decision,

Reckitt Benckiser used the Orphan Drug Act's cost recovery prong, which requires companies to demonstrate that a drug's U.S. sales will be insufficient to recover development and marketing costs.

As it turns out, Reckitt Benckiser's cost recovery analysis in 1994 was faulty. Moreover, Subutex had $285 million in sales between 2002 and 2011. Despite both of these facts, FDA automatically grandfathered Subutex's orphan designation for Sublocade when it was approved in November 2017, without requiring Indivior to submit another cost recovery analysis showing that Sublocade would be unprofitable.

In April 2019, one of Indivior's competitors filed a citizen petition asking FDA to revoke Sublocade's orphan drug designation and refuse to grant exclusivity. In November 2019, FDA ruled in favor of the petition and denied Sublocade exclusivity. For now, this means that competing buprenorphine products can enter the market starting December 2020.

While FDA's decision is a step in the right direction, it could be overturned if Indivior decides to sue. This possibility is one of the reasons it is so important to pass H.R. 4712. If, even if FDA's decision is overturned, the bill would prevent exclusivity for Sublocade unless Indivior

submitted a cost recovery analysis showing that it did not expect Sublocade to be profitable when it was approved in November 2017.

However, such an analysis would be impossible to construct because Indivior itself has projected that Sublocade will reach $1 billion in peak annual sales.

H.R. 4712 would also require drug companies to submit cost recovery analyses for any future orphan approval under a cost recovery prong designation, thus closing the loophole that allowed Sublocade's orphan approval.

One advantage of H.R. 4712 is that its scope is limited. It would only affect orphan approvals under cost recovery prong designations. And there have only been three such designations since 1983. This limited scope does not negate its importance, as it will permanently block Sublocade from receiving exclusivity that would impede patients' access to lifesaving buprenorphine products.

In my view, passing H.R. 4712 is a common sense step that will be good for orphan drug policy, good for public health, and good for the millions of Americans with opioid use disorder.

Thank you again for the opportunity to participate in today's hearing.

[The prepared statement of Dr. Chua follows:]

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Ms. Eshoo. Thank you, Doctor. It is important to note that the two companies that you are mentioning they are really not two companies. It was an original name and then the name was changed. So, this is not a dispute between two companies.

Dr. Chua. Okay.

Ms. Eshoo. Dr. Muzzio, welcome. We are very happy to see you. We appreciate your being here. And you have 5 minutes for your testimony.

STATEMENT OF FERNANDO MUZZIO, PH.D.

Mr. Muzzio. Thank you, Chairwoman Eshoo, Ranking Member Burgess, members of the subcommittee. My name is Fernando Muzzio. I am a Distinguished Professor of Chemical and Biochemical Engineering at Rutgers, the State University of New Jersey. I am also the Director of C-SOPS and NSF Engineering Research Center that has been devoted to continuous manufacturing research for the past 15 years.

I greatly appreciate the opportunity to appear in this hearing on approving the safety of pharmaceutical manufacturing in the U.S., and to express my strong support for H.R. 4866, which I believe is essential to maintain the viability of pharmaceutical manufacturing in the U.S.

I want to thank Chairman Pallone for introducing this bill and for his leadership in this issue.

Now, the traditional approach to pharmaceutical manufacturing is called batch manufacturing. And this approach is slow. It is very difficult to optimize. And it actually provides limited ability to assure product quality. Working in our center, we have developed a far superior technology, continuous manufacturing. As defined in H.R. 4866, in continuous manufacturing you load ingredients at a controlled rate into the process, and then you operate the

process in a state of control every minute of every hour so that you can assure the quality of the product that you are making consistently. This minimizes quality failure, but it does much more than that.

So, in the last 14 years in our center we established a full ecosystem with multiple universities, FDA, NSF, more than 60 companies, and the USP. And in the center we built and demonstrated the first continuous manufacturing line to operate in a full state of control. And then working in close partnership with Johnson & Johnson we also enabled the implementation of the first continuous manufacturing system that was approved by FDA for transition from batch manufacturing to continuous manufacturing for the drug Prezista.

Since then, there have been six products approved by the Food and Drug Administration. There are many more in the pipeline. And this has become a worldwide phenomenon where every major country in the world is pursuing implementation of continuous manufacturing.

The main point of my testimony is that this presents a major opportunity for the U.S. to bring back manufacturing to the country. The reason is that batch manufacturing requires cheap labor, and that is one reason we have lost so much of it. Continuous manufacturing requires access to know-how.

And right now, the U.S. has the largest concentration of know-how on how to implement continuous manufacturing systems.

So, in the next few years you will witness a transition from batch to continuous manufacturing of a large segment of the pharmaceutical industry. The question is, where will this happen?

This transition provides a great opportunity for the U.S. It has many benefits. It could lower drug prices. It could help create many high-paying jobs. It will reduce our dependence on imports. And it will lead to faster product and process development, which is important because it will give patients faster access to cures, and it will also enable a faster response to emergencies and shortages.

Now, there is a threat. The threat is that Europe is on the march. They have already funded several centers in this area. And also, Europe has most of the companies that produce equipment for continuous manufacturing. But we have the know-how. So, if we articulate a meaningful U.S.-based response, we could actually capture much of these conversions from batch to continuous and use it to re-grow from pharmaceutical manufacturing in this country.

A suitable U.S. response is for H.R. 4866 because it provides the resources to create the partnership between

academia, government, universities, industry, and the USP, and to make the knowledge available to all sectors of the pharmaceutical industry, and to other industries that use similar manufacturing methods.

Universities are essential in this endeavor because universities provide the long-term research perspective and the research strength to create and demonstrate new technology, and to train the large number of people that are needed to implement the systems.

So, with that, I thank you once again for inviting me to be here. I will request to please incorporate my full written testimony into the record. And I will be happy to answer any questions you might have. Thank you very much.

[The prepared statement of Mr. Muzzio follows:]

********** INSERT 2 **********

Ms. Eshoo. Thank you, Dr. Muzzio. Everything that you said is music to my ears. And, of course, your full testimony will be made part of the committee's record.

It is a pleasure to recognize Mr. Richard Kaeser, Vice President of Global Brand Protection at Johnson & Johnson. You are recognized for your 5 minutes of testimony.

STATEMENT OF RICHARD KAESER

Mr. Kaeser. Thank you very much. Chairwoman Eshoo, Ranking Member Burgess, and members of the committee, good morning. And thank you for the opportunity to discuss how we can strengthen patient safety by granting the Food and Drug Administration the same authority for dealing with certain counterfeit devices as it has for drugs that have been refused admission into the United States.

My name is Rich Kaeser, and I am Vice President of Global Brand Protection at Johnson & Johnson, and responsible for combating illicit trade, including counterfeiting, illegal diversion, and tampering across all Johnson & Johnson business segments: pharmaceuticals, medical devices, and personal health care.

Illicit trade has increased dramatically in recent years, impacting nearly every industry. According to one estimate, global trade and counterfeit goods will hit $1.9 trillion by 2023. The problem is obviously a serious concern in our health care and personal care industries where patients and consumers can be injured or even die due to unsafe counterfeit and illicit products.

In fact, counterfeit drugs are the biggest market, estimated at $200 billion per year. Given that figure, it is

no surprise, but shocking nonetheless, that INTERPOL estimates that one million people die each year from taking counterfeit medicines globally.

At Johnson & Johnson we believe our first responsibility is to the patients, to the mothers and fathers, to the doctors and nurses, and all those who use our products and services. They must have unequivocal confidence in the quality, safety, and authenticity of Johnson & Johnson products. Thus, we have a strong, enterprise-wide anti-counterfeiting and brand protection strategy in place to proactively and aggressively manage risks related to illicit trade and, most importantly, to protect patients and consumers from potential harm.

Our Global Brand Protection team, which I lead, is responsible for these efforts across the company. While my team is 100 percent dedicated to this mission, effective brand protection also requires significant teamwork across our entire business, as well as extensive collaboration between industry partners, academia, law enforcement, and government agencies.

Lawmakers play a critical role in strengthening our laws to increase penalties and reduce incentives for illegal trade. We appreciate the leadership of Representatives Guthrie and Engel on this issue. As such, Johnson & Johnson

is very pleased to support H.R. 5663, the Safeguarding Therapeutics Act, which extends FDA authority to destroy counterfeit drugs and devices, and combination products valued at $2,500 or less. We believe this authority is important to protect the integrity of the supply chain by preventing counterfeit products from reaching consumes and patients.

A recent example of counterfeiting that has impacted our medical device business involves a product known as Surgicel, a blood clot inducing material that is used to control bleeding during and after surgery.

We learned that counterfeit product labeled and sold as Surgicel were entering the supply chain in the United States and other markets through unauthorized gray market distributors. A timely investigation identified and shut down an international counterfeiting scheme. We engaged our customers to notify them about the counterfeit issue, and explained that buying our products only from authorized distributors is vital to protect patients and providers.

Importantly, we also involved the FDA, and we are cooperating closely with their criminal investigation teams as they consider taking enforcement action against the parties involved. I am happy to discuss this case in more detail or cases like this that put illicit traders on notice

and have a deterrent effect. Unfortunately, in today's global marketplace we are likely to continue to continue to see illicit medical devices, drugs, and personal care products entering the legitimate supply chains. Health care products will continue to be one of the most commonly targeted industries for counterfeiters.

Counterfeit products and illicit trade present a growing risk to patients and consumers. We have an opportunity to make our world safer by ensuring the FDA has the authority needed to destroy counterfeit drugs, devices, and combination products. Together, we can work to protect patients and consumers from the threat of counterfeit health and personal care products.

Thank you for your time and attention today to this critically important issue. I look forward to answering your questions.

[The prepared statement of Mr. Kaeser follows:]

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Ms. Eshoo. Thank you very much, Mr. Kaeser.

Dr. Allen, welcome. And thank you again. You are recognized for 5 minutes for your testimony.

STATEMENT OF JEFF ALLEN, PH.D.

Mr. Allen. Thank you. And good morning, Chairwoman Eshoo. Thank you, Member Burgess and members of the committee.

I am Dr. Jeff Allen, President and CEO of Friends of Cancer Research, a research and advocacy organization dedicated to accelerating science from bench to bedside. It is an honor to testify before you today and provide our perspective regarding prescription drug labels.

When kept up to date, labeling represents the most authoritative drug-related information that is available to prescribers. However, labeling can become outdated when high quality scientific evidence is generated in the post-market setting that the drug's manufacturer does not file a supplemental application requesting a modified use be added to the drug's label.

Manufacturers have an ongoing responsibility to report signals of serious risk to the FDA. And the agency has the authority to order changes relating to new safety

information. However, there is no requirement or authority to update product labeling with new or modified uses, though manufacturers may choose to do so voluntarily when they wish to market their products in these settings.

Given the pace of research and treatment advances in the field of oncology, off-label use is common and important. To examine the extent to which labels keep pace over time, we evaluated the difference between medically recommended uses of a drug included in leading clinical guidelines, and compared that to the uses contained in the label.

Our study examined cancer drugs approved over a 12-year period. For almost every drug that we looked at, 79 percent to be exact, the clinical guidelines had more recommended uses than those described in the FDA label. Of the 450 recommended uses associated with all the drugs included in the study, 253 were not listed on FDA approved labels.

Of these off-label uses, 91 percent were graded as being based on strong existing evidence and backed by the uniform consensus of the Guideline Advisory Committee. Meaning, up to 80 percent of these drugs have additional uses reported by high quality evidence missing from their labels.

When sections of the FDA approved labeling become outdated they may lose value for prescribers and fail to communicate essential information about drugs to patients and

health care providers.

A particularly stark example is the drug oxaliplatin, which was approved in 2004 for two forms of colon cancer. Since then it has been further tested and recommended in clinical guidelines for 10 additional disease settings, none of which are on the product label. While many expert oncologists have access to information and experience with the use of oxaliplatin, there are many that still rely on the drug label when making treatment decisions. This may be most important to a general oncologist in a busy practice or community setting.

The whole premise of generic drugs is that they are materially indistinguishable from their brand name counterparts and, as such, under current law a generic is required to have the same level as its branded reference product. But over time, some original manufacturers of the older drugs will voluntarily withdraw their products from the market for reasons other than safety and efficacy, leaving only generic manufactured products on the market.

This situation is often referred to as a withdrawn reference listed drug or a withdrawn RLD. And here is the problem: in these cases the labels of the remaining generic drugs are still required to match their original reference product, even though it has been withdrawn. And even as data

may continue to evolve, these labels essentially become frozen in time and are unable to be updated.

In collaboration with numerous stakeholders, members of this committee have developed the MODERN Labeling Act to address the prevalence of outdated labels in cases where there is a withdrawn RLD. The legislation addresses this problem by establishing a process for updating labels to reflect new information relevant to the drug and its optimal use. Restoring the relevance of approved labeling is an important public health goal. While other high quality sources of prescribing information play an important role in clinical care, labeling is the sole source of information that reflects the scientific and methodological rigor of the FDA approval process.

Patients and prescribers can have the assurance that the use of medicines in conformity with the drug labeling is supported by a positive benefit-risk assessment. The MODERN Labeling Act would aid in maintaining up-to-date drug labels for certain generic drugs and restore the relevance of the label, foster greater trust in medical products for physicians and patients.

I again thank you for the opportunity to testify on this important topic, and look forward to answering your questions.

[The prepared statement of Mr. Allen follows:]

********** INSERT 4 **********

Ms. Eshoo. Thank you very much, Doctor.

We have now concluded the opening statements of our witnesses for our first panel. And we will now move to member questions. And I am going to recognize myself for 5 minutes to do so.

First I want to go to Dr. Muzzio. I said on the heels of your testimony that what you said was music to my ears. I spent a good part of last year researching, studying the whole issue of API, of the status of drug manufacturing in the United States, being dependent upon a foreign country that has the API, the core ingredients for drugs, and found it chilling.

This subcommittee had an extensive hearing on the subject, and FDA did testify on the importance and the really looking to the future relative to continuous manufacturing.

Now, I am thrilled to hear about what you are doing. You almost make it sound simple, that, you know, that we have the silver bullet. Can you tell me or describe the status of where we are with continuous manufacturing now? Is it still nascent and being researched?

How many companies are using it in the United States?

What would the average cost be for establishing a continuous manufacturing system in our country? Because, as you said, I think most of it has gone overseas, mainly to

China and to India -- that is where generic drugs are made. In fact, my chief of staff showed me her prescription bottle and she decided to, given the subject matter, because I talk about it all the time with my staff, she peeled back her label with her name on it, and the date, and all of that, and it came from India.

So, can you answer those questions for me?

Mr. Muzzio. I can try. Thank you very much for those questions.

Ms. Eshoo. Okay.

Mr. Muzzio. So, we have to distinguish the making of the drug substance, the API, from the making of the finished product.

Ms. Eshoo. I understand that.

Mr. Muzzio. Yes.

Ms. Eshoo. I understand that.

Mr. Muzzio. Both can be greatly improved by continuous manufacturing methods. The current status is that for finished product, for solid dose product -- tablets and capsules -- the technology is now robust. It has been implemented at about I would say 10 to 15 brand-based companies. And so, if we want to extend it and really have a major impact, the key issue is to make sure that the know-how required to implement the technology becomes available to the

other sectors of the industry, the generic, the over-the-counter manufacturers, et cetera.

The brand-based companies have the know-how in house.

Ms. Eshoo. Uh-huh.

Mr. Muzzio. We also, critically, should create places where companies can come and get the help they need in demonstrating the technology for their product and in facilitating the manufacture of clinical supplies without having to spend $15 or $20 million to first get a system implemented. That is a very high entry cost for smaller pharma, generic pharma.

Ms. Eshoo. Let me ask you this.

Mr. Muzzio. Yes.

Ms. Eshoo. Given the work that you are doing and what this bill promotes, does it shorten the time frame around actual continuous manufacturing for the pharmaceutical industry in the United States?

Mr. Muzzio. Yes. For finished product it definitely will.

Ms. Eshoo. And what kind of time frame is that?

Mr. Muzzio. Well, I believe that we could create the environment that will help the rest of the industry in just a few months because we already have systems implemented and the know-how. What we need now is to facilitate access to

put in placer the mechanisms for the rest of the industry to be able to access the know-how effectively and quickly.

Ms. Eshoo. I have only heard of one pharmaceutical company that is engaged in continuous manufacturing. Can you name more?

Mr. Muzzio. Absolutely. I mean, there are four companies that have products approved, right: Pfizer, Eli Lilly, and Vertex, in addition to J&J.

We are right now working with another half a dozen companies that are also working hard at implementing this system. I don't want to violate confidentiality, but I can tell you in my -- I have firsthand knowledge that every major household name brand-based pharmaceutical company is working on these. They have all acquired equipment. They are all preparing submissions.

So, for brand-based pharma this is now a choice that they have made to go forward this way.

Ms. Eshoo. Well, that is very promising. I want to work with all of the stakeholders to achieve the goal of bringing manufacturing back to the United States. For us to be dependent on foreign countries, sometimes real tension surrounding the relationships, I think is really dangerous for the United States of America. We owe more to the American people. So, thank you.

I will submit my written questions to the other witnesses.

I will now recognize the ranking member of the subcommittee for his 5 minutes of questions.

Mr. Burgess. And again, I thank the Chair.

Well, Mr. Kaeser, let me just start with you because you mentioned Surgicel.

Mr. Kaeser. Yes.

Mr. Burgess. A product that I used. Not frequently, because most of my surgical fields were quite hemostatic. But I recognize there are other specialties that may have a requirement for an absorbable hemostat like Surgicel.

Ms. Eshoo. You are going to have to explain these terms. We are not all doctors.

Mr. Burgess. I was having some inside --

Ms. Eshoo. I could tell.

Mr. Burgess. -- chat with Dr. Bucshon.

So, a neurosurgeon is in the middle of an operation, opens, or the product is popped out onto the Mayo stand, and he picks it up and it doesn't feel right. Is that, do I understand that correctly?

Mr. Kaeser. That is correct.

Mr. Burgess. At least at that point he has the presence of mind to say this is not right. Did he actually use the

product in that operation?

Mr. Kaeser. He did not use the product. He asked the circulator to hand off another one from another lot, another box.

Mr. Burgess. I see. So, he actually had some real product available, which is fortunate. Because I presume --

Mr. Kaeser. And for the committee, Surgicel is a hemostatic patch that is used to control bleeding during and after surgery.

Mr. Burgess. Right. Comes in a foil package.

Mr. Kaeser. Yep.

Mr. Burgess. And they pop it open onto the sterile field. It looks like a little piece of cloth with a fairly wide weave pattern. And you tamp it down into the area where the bleeding is problematic, and it provides a matrix for the body's own clotting mechanism to adhere to, and that way achieves hemostatis or lack of bleeding in that area, which is obviously a good thing before you close up the surgical incision.

And it is absorbable, so it stays in the body and is eventually absorbed. So, this product that -- did anyone end up testing it? And would it actually absorb had it been left in this person's brain or spine?

Mr. Kaeser. Yes, so the product was tested. So, the

hospital sent it back into our quality organization who conducted tests or investigation, where we identified that it was indeed not ours, that it was counterfeit, and it was also not sterile, which represents very significant risk.

Mr. Burgess. Holy smackers.

Mr. Kaeser. Yes.

Mr. Burgess. That is, I can't convey how concerning that is.

Just like Mr. Guthrie, I went to the JFK International Mail Facility with Dr. Gottlieb. We saw a number of things. And at that point I think even just the pharmaceutical products could not be returned because that was something that occurred as part of the SUPPORT Act in H.R. 6. But what was related to us that day, that sometimes this package that contains something that was highly suspect all they could do was return it to the people that had shipped it in the first place. And that on occasion a package would just simply recirculate. Well, let's try it again. And literally have the same markings from either Customs, Border Protection, or the FDA on the package.

So, this is, this is critical to be able to not just intercept this stuff but get it out of circulation -- no pun intended -- but to get it out of everyone's lives.

So, what is the role of, say, your company Johnson &

Johnson throughout the process of notification of a counterfeit medical device, and then to remove the device from the availability?

Mr. Kaeser. Well, in this particular case since we were notified by the hospital we conducted a thorough investigation. We identified the source manufacturer in India. It was coming through a distributor in Dubai through some rogue gray market distributors in Florida, and ultimately into this hospital. So, we worked very closely with FDA and other law enforcement agencies to take the counterfeiter down quickly.

We also worked with the FDA to notify customers, to communicate out. It is an ongoing investigation that goes beyond Surgicel. There are other medical devices that are at risk in this investigation as well.

Mr. Burgess. And when you say "take down," was this individual or were there individuals who were actually arrested for this?

Mr. Kaeser. Yes. In India there were arrests taken. And civil and criminal actions are in progress.

Mr. Burgess. They are in progress. Okay. I was going to ask what the result of those were.

Dr. Muzzio, just before we, before my time expires, back in 2012 we were doing FDA reauthorization for drugs and

devices. And at that time drug shortages were a thing. I know they are still a thing, but they were really significant at that point. And anesthetic drugs, and emergency room drugs, some really, some common, some common stuff, not exotic stuff, was just simply unavailable.

So, and I think at that point we heard from Dr. Woodcock at FDA about some of the things that could be done to assist with alleviating or preventing drug shortages. So, continuous manufacturing I assume has a role in this as well?

Mr. Muzzio. Yes, it does.

So, there are two different dimensions to this. First, a large fraction of drug shortages are caused by emerging quality problems. Continuous manufacturing systems are much more robust and they allow much more monitoring. So, the likelihood of undetected quality issues when you are making the drugs in a continuous method is much lower.

So, if we were making mainly from a single product using continuous systems those quality issues would be less frequent. That is one issue.

But there is another dimension that is equally important. One of the biggest advantages of continuous manufacturing systems is that they allow you to do experiments much, much more quickly that batch systems. Typically, it takes 50 or 60 experiments to develop a process

you could say. In batch manufacturing that takes weeks, sometimes months. In continuous manufacturing you can do the subject matter expert number of experiments in a few days.

So, if there is a shortage caused by a quality problem with one particular formulation and we need to develop an alternative formulation, and it is the kind of drug that can be manufactured by continuous processes, we could develop a substitute product or a substitute process in just days.

Mr. Burgess. Very good. I see my time has expired, so I will yield back to the chair for that. I may follow up with some questions for you on that.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the gentleman from Oregon, Mr. Schrader, for his 5 minutes of questions.

Mr. Schrader. So, Dr. Muzzio, I am a little unclear how continuous manufacturing alleviates the drug shortages. I don't -- I can see where it is an efficient way to do things, and the quality control could be superior because of the ongoing manufacturing process. But, you know, how is it going to bring back atropine ointment and, you know, phenobarb, and prednisone on a regular basis? These are shortage drugs out there. How is that going to happen?

Mr. Muzzio. Well, it is not a magic bullet that you could use today for everything. It has been well developed

for certain kinds of product. It could also be further developed as a technology option for other kinds of product.

But, for the products when you can use continuous manufacturing, as I mentioned, you can develop an automatic manufacturing approach very quickly. You can also use that using a relatively small amount of raw materials that might be scarce in a situation of shortage.

Mr. Schrader. But I just don't, I don't see are any of the companies you have talked about looking to do some of these drugs that there are shortages of right now?

Mr. Muzzio. At the present time, I believe most companies are focusing on their flagship products.

Mr. Schrader. Sure. That would be my thinking, too. I am a little worried about us kind of picking winners and losers in terms of different -- because brand names are already doing it. They don't need our help. It is the generics, it is small companies trying to get started.

I don't know how we would pick those that get to take advantage of the federal process, the federal money, and those that don't?

Mr. Muzzio. Well, maybe I can share one personal experience.

One of our sponsors about 5 or 6 years ago challenged us to see whether we could actually create new formulations and

processes for five or six products that they would give us. So, they brought raw materials to us and they challenged to us, can you have a working process and a viable product within a month for these six products?

So, two of the six were not suitable. But the other four we were able to within a month create an alternative formulation and a process. So, if we had the technology in place in enough locations there will be the ability to do very fast development. That would be the response.

Mr. Schrader. Okay. Okay. Well, I share the gentleman's interest in wanting to make sure we control more of our basic active ingredient manufacturing here in this country, and maybe some more discussion on how we would use this process as part of that.

I like the idea of having a ubiquitous or at least regionally based manufacturing platform that different companies could access. But picking which drugs, I think that that would require a lot of work.

Dr. Chua, the drug exclusivity, why not just get rid of criterion number two? Why even, you know, give them a -- why would a company bring it, go to market if they can't actually cover their costs? That makes no sense to me.

Dr. Chua. It is a good question. I think that cost recovery prong was in there in case a drug did not treat a

condition that was rare, which in that regard is 200,000 or fewer Americans, but was still potentially an important drug, just not one that could recoup its costs.

There have only been three of those drugs that have been designated through the cost recovery prong since 1983. So, it is not a commonly used pathway.

Mr. Schrader. You know, Madam Chair, I would just say we get rid of that criteria. It is confusing. We are adding a new layer of interpretation of a criteria that has only been used three times since 1983. And I say the manufacturing and the pharmaceutical companies have come a long, long way and, you know, they are going to be able to go through continuous manufacturing or some other process, be able to decide how to go about making these great orphan drugs. We are in a whole new era than we were I think back in 1983.

I guess a question, why, Dr. Allen or others, you know, why aren't generics able to update their labels now? I mean, that seems like an obvious thing.

Mr. Allen. In most instances they are. There is a frequently used mechanism most notably when the RLD is still in existence, if the brand is still there. The brand may make adjustments to its label to reflect changes in the context of use. And the generic relatively automatically

will reflect that.

The issue that the MODERN Labeling Act is addressing is those instances in which the original branded product has exited the market. And so those remaining generics are not able to change their label under current law.

Mr. Schrader. But why?

Mr. Allen. They still have to under law, because they have the sameness clause that was established to establish the generic market requires them to maintain the same label as the original product.

Mr. Schrader. I understand.

Mr. Allen. And when that product leaves there is nothing to, there is nothing to reflect.

Mr. Schrader. All right, very good.

Thank you. I yield back.

Ms. Eshoo. The gentleman yields back.

A pleasure to recognize the former chairman of the full committee from Michigan, Mr. Upton.

Mr. Upton. Well, thank you, Madam Chair. I appreciate the hearing. And I do have a number of questions.

Dr. Allen, just a quick thing. You know, it seems like a common sense bill, this H.R. 5668, to update the label. Has FDA actually, have they asked,

are you aware if they have asked that we actually update this?

I mean, it just seems so common sense that you would like to think that they would have just said don't need legislation.

Mr. Allen. Well, I guess to give a little bit of context, you know, at least in the oncology space, although this is a phenomenon that occurs well beyond oncology. There has been initiative by the FDA's Oncology Center of Excellence through a project they called Project Renewal that has begun to identify several of these older drug labels that have significantly drifted out of date.

They have identified 44 products so far that will benefit from a re-review. The challenge is about a quarter of those fall into this withdrawn RLD. So, a quarter of those products just simply legally are not able to be updated without the passage of the MODERN Act.

Mr. Upton. And I want to also say, Mr. Kaeser -- Kaeser, Kaeser, you know, you talked about, and Dr. Burgess has talked a lot about this, I have not actually -- I try to avoid New York, I will confess, particularly Newark or JFK. I don't know where you went. I like to take Amtrak. This Safeguarding Therapeutics, it just seems so sensible, so sensible to try and get it done, H.R. 5663.

But, in your testimony you indicated that a million people every year, according to INTERPOL, probably die because of counterfeit drugs or devices. Mostly in developing countries.

So, can you explain a little bit about what is, what are the drugs that -- and, I mean, can you break that down a little bit for us?

Mr. Kaeser. I probably don't have it down to the drug level. I would say it is mostly in developing countries. We don't see it as much in the United States as we see it in Africa, or maybe in India, or other parts of the world.

Mr. Upton. So, how large a staff do you have?

Mr. Kaeser. I have 32 people on my team, 32 direct reports.

Mr. Upton. Wow. So, and you indicated that you would talk a little bit more in detail about your work with the FDA. Would you like to do that now?

Mr. Kaeser. I would love to. FDA has been absolutely instrumental and critical in the work that we have done with the Surgicel. And it is -- OCI has been a big part of our ongoing investigations. The FDA has also been very helpful in helping us communicate to the providers, to the patients, to help safeguard the patients. So, FDA has continued to be a very strong ally for us to work with on my team.

And I do believe that H.R. 5663 is an opportunity for us to even go deeper. And we can continue to develop tools and resources from that.

Mr. Upton. You may know that when I was chair we passed track-and-trace, a bipartisan bill. I think it was at the end of the session, but we were able to shepherd it through both the House and the Senate. Has that helped give you a little bit more resources to work with the FDA to identify these counterfeit drugs and devices?

Mr. Kaeser. Yes. I look at track-and-trace and serialization as opportunities to help efforts in brand protection. But I can share with you that serialization law is a great tool. Serial numbers can be counterfeited as well. And whoever brings that serial number to market first, wins.

Mr. Upton. I yield back. Thank you.

Mr. Kaeser. Thank you.

Ms. Eshoo. Would the gentleman give me just --

Mr. Upton. Sure.

Ms. Eshoo. -- 10 seconds?

Dr. Muzzio, I wanted to ask you, you have talked about the name brand drugs and continuous manufacturing. 90 percent, approximately 90 percent of the drugs that the American people take are generics. So, are generic companies

accessing --

Mr. Muzzio. We are aware --

Ms. Eshoo. -- continuous manufacturing?

Mr. Muzzio. So, we are aware that some of the largest generic companies have been attempting to do that.

Ms. Eshoo. What does that mean, attempting?

Mr. Muzzio. Have been trying, yes.

Ms. Eshoo. Trying.

Mr. Muzzio. Trying.

Ms. Eshoo. What does trying mean?

Mr. Muzzio. We know that in a couple of cases they bought equipment, they installed it, they tried to make it work. But there is a large amount of know-how that is required that the brand companies created over, over a decade. And --

Ms. Eshoo. Do you think that there is an issue as to whether they want to make the investment?

Mr. Muzzio. I believe that there might be an issue about whether they have the ability to see the path to success, not having necessarily all of the know-how available in house.

Ms. Eshoo. I will follow up with more. Yes, thank you.

Mr. Upton. I will reclaim the remaining 10 seconds of my 10 seconds that I gave you.

Dr. Allen, I just want to say, you all, Friends of Cancer, have been, you were so helpful as we worked on 21st Century Cures. And as you know, I think as you know, we are working on 2.0 again, a bipartisan idea. We have had a number of roundtables. Just we are looking forward to hearing, you I think will participate, but we are looking still. The door is open for us to get ideas in terms of how we can expand this.

I just wanted to thank you for your work and your organization's work.

And with that, I yield back my 10 seconds.

Ms. Eshoo. I thank the gentleman. And he yields back.

The gentlewoman from California is recognized, Ms. Matsui, for her 5 minutes of questions.

Ms. Matsui. Thank you very much.

Ms. Eshoo. Thank you for your legislation.

Ms. Matsui. Thank you very much for holding this important hearing.

I am pleased we have the opportunity today to discuss a bill I recently introduced with Representative Guthrie to modernize outdated drug labels. The FDA approved label is the most independent and authoritative source of safe and effective prescribing information for health care providers and their patients.

I am greatly concerned that there is no existing mechanism to update certain generic drug labels to reflect current commonly-accepted uses despite the critical role labels play in informing treatment decisions, safeguarding the public health, and facilitating greater use of lower-cost generics.

Our legislation works to specifically address outdated generic labels in situations where the brand has left the market and, therefore, there is no ability to update the generic drug label. I know that some stakeholders have raised concerns about certain provisions in the bill. And I look forward to working with them as we move through the regular order. Introducing this bill is just the first step of this process, and because I am committed to finding the best path forward to protect consumers and modernize drug labeling while still allowing FDA to require updated labeling for drug products if new safety information emerges.

That said, we need a targeted solution now that gives both patients and providers access to accurate and updated information for the generic drug products they are using in order to make safe and effective treatment decisions.

Dr. Allen, thank you very much for being here today to discuss this important legislation. I appreciate all the work that Friends of Cancer Research has done to help

identify this issue and craft a potential solution.

Dr. Allen, under current law if FDA wanted to update an out-of-date label for certain generic drugs, could the update include any information about new or existing conditions of use, labeling standards, or additional uses?

Can generics make these updates on their own?

Mr. Allen. If there is an existing RLD.

So, thank you, and to Mr. Guthrie for introducing this bill because this is a narrow window in which these products are essentially frozen. So, when the original RLD has been withdrawn there is no mechanism to update for the situations that you have mentioned.

Ms. Matsui. Okay.

Mr. Allen. The authority for safety --

Ms. Matsui. Right.

Mr. Allen. -- still exists. And I want to be clear about that because we have gotten those questions, too.

Ms. Matsui. Absolutely.

Mr. Allen. So this still maintains that.

Ms. Matsui. Absolutely.

So, can we talk a bit more about off label prescribing. Why is this practice particularly common in cancer drugs?

Mr. Allen. I think given the pace of research and the investments that the country has made, facilitated by this

committee and others, of course, and funding entities like the NIH, you see a lot of research on drugs once they are on the market. And this continues to grow in areas around, like, electronic health data capture.

So, we continue to learn about drugs as they are used in different populations more broadly.

But, the ability to have off label use is really important in terms of access and the continuing evolution of learning. And I think what, you know, so I think the cancer community benefits from some of the guidelines that we have been talking about. But that is not the case in all therapeutic areas.

Ms. Matsui. Okay. So, if these off label uses are already widespread and well accepted, why is it still important to update a drug's label? What impact would this have on patients?

Mr. Allen. I think, as you mentioned, the drug label itself is the most authoritative, unbiased, accessible source of information. We know patients get information about medical products that range from sophisticated mechanisms like compendia, working with their doctors, and even the internet. But, to have the FDA to have the ability to have greater flexibility and authority to make sure these labels are updated, I think we need to feel confident in the most

accessible form of information. It is on their website.

Ms. Matsui. Yeah. So, while FDA does have the ability to require generic makers to change a label, these changes are limited to information pertaining to a product's safety?

Mr. Allen. Correct.

Ms. Matsui. So, in order to provide patients and providers with the safest, up-to-date, and highest quality prescribing information we need a process like the one created under MODERN.

Mr. Allen. Yes.

Ms. Matsui. And it is very strategically and narrowly written so that we can do that.

Okay. Well, thank you very much for being here, and all the work that the Network has done. And appreciate your being here.

Thank you so much. I yield back.

Ms. Eshoo. The gentlewoman yields back.

It is a pleasure to recognize Mr. Guthrie of Kentucky for his 5 minutes of questions.

Mr. Guthrie. Thank you very much.

A couple of these bills are so common sense that the questions have already been asked, it seems, moving forward. But when I was at the JFK, coming forward I wish people could sit there and see that because you see counterfeit drugs, you

see them standing in front of you, sitting in front of you. And people are, if they are going outside the normal distribution chains, and a lot of times people are doing it because of access to affordable prescription drugs. And hopefully, we, as a Congress, can get back to focusing on that and get a bill the President can sign.

But in the meantime it is just not safe. If you are going to go on websites and try to -- and we have an investigation beginning on counterfeit tickets to events -- if you buy a counterfeit ticket, you have a bad night. If you buy a counterfeit drug you can ruin your life. And so it is important.

And I just want people to understand that I am standing there and watch somebody, if it was a, if it was a drug they could destroy it. But if the drug was packaged with a syringe, so therefore a medical device, they couldn't. And so, Mr. Kaeser, can you explain under current law what happens when counterfeit products are discovered?

What is an example of a combination product which cannot be destroyed?

And why H.R. 5663 would improve the ability of the Federal Government to stop the supply of counterfeits?

Mr. Kaeser. So, the first question was?

Mr. Guthrie. Well, the first question is, under current

law what happens when a counterfeit is discovered?

Mr. Kaeser. Well, current law for medical devices, combination products, they are typically shipped back to whoever sent it. So, thus, it typically remains in the supply chain, and many times it comes back through.

So, that represents a significant risk.

Mr. Guthrie. Yeah. So, but why wasn't it destroyed?

Mr. Kaeser. Because it doesn't fall under the current law. Right? So, what you're asking for in the new law would allow us to destroy medical devices and combination products under $2,500.

Mr. Guthrie. Yeah, I understand. I just wanted you to bring that out.

Mr. Kaeser. Yes.

Mr. Guthrie. And then, so what is an example of a combination product? I mean, I saw a syringe with a vial of I guess it was insulin.

Mr. Kaeser. Yeah, that is an example.

Mr. Guthrie. And they couldn't -- if it was just insulin, they could have destroyed it. Because it was packaged with it, they couldn't, by law, which is what we need to do.

Mr. Kaeser. That is a great example.

Another one might be coronary stents, drug-eluting

coronary stents. A stent creates the scaffolding to keep an artery open. If it is coated with a drug elution, a drug that would admit to help with cell proliferation.

So, I think those are a couple good examples of combination therapy.

Mr. Guthrie. Well, I had a border -- one of our FDA agents say at JFK that they literally have packaged, opened it, discovered it. They had to ship it back because they couldn't destroy it. They can store it but then they ship it back. And it comes back to JFK exactly as they wrapped it up and sent it back.

So, people are actually ordering these. But the people who they are going to send them to are not even -- who knows that they even put -- I mean somebody could have changed the whole product inside and sent it back. This is how bad these people are who are trying to put this stuff through, and why we have to fix this. And it should not -- it should be absolutely against the law to move forward.

On the labeling, I think we discussed a lot of the reason for that. When I first started looking at it I thought it was the label on the container. But that is not what we are talking about.

Can you explain what labeling actually is? I think all of us think, as a matter of fact it is something we need to

fix, if you get over-the-counter it seems like we have so much stuff required. I can't even find do I take one or two? Is it every 6 or 12 hours? Because you got to keep peeling things back to be able to see if we take that over-the-counter, do we have too much?

But your labeling is different you're talking about. Could you just explain that?

Mr. Allen. It generally refers to the entire package of information that is submitted and associated with the drug that often evolves over time. It includes things like the package insert that you've mentioned here.

And I think that is a good point with the bill that you have introduced here will allow some of these older drugs to actually conform to a new format of labeling that the FDA put forth in 2006. Some of these drugs don't even conform to that at this point, and they can't be changed.

Mr. Guthrie. Right.

Mr. Allen. But by doing so, the intention there was to allow the drug label to be more accessible and more usable for the consumer.

Mr. Guthrie. So, currently if it is not labeled, updated label like it could be, what is happening to the patients currently? How are physicians, are they not able to use it in the prescribed way that they think would be used?

Mr. Allen. In many instances, particularly in oncology, there is the accessibility to expert-developed guidelines. Things like the National Comprehensive Cancer Network has regularly updated guidelines. But those are typically accessible to expert oncologists, perhaps in an academic setting.

So, still the most accessible source of information would be to look up the drug label around things like different doses. And those doses can change over time, depending on the context of use. So --

Mr. Guthrie. Oncologists may not have access to the best information for a specific drug for a specific patient?

Mr. Allen. Not on these outdated labels. They would have to look elsewhere than the label in order to access it.

Mr. Guthrie. Thanks. I look forward to more testimony from Dr. Muzzio on the bill. And I assume, Dr. Pallone, I mean Chair Pallone, I am out of time. But I know you -- I was going to talk about drug shortages. And you just addressed that. So thank you for that.

Mr. Allen. Thank you.

Mr. Guthrie. Thank you. And I yield back.

Ms. Eshoo. The gentleman yields back.

I now would like to recognize the gentleman from Vermont, Mr. Welch, for his 5 minutes of questioning.

Mr. Welch. Thank you, Madam Chair.

I want to talk about the orphan drug bill in particular. I want to thank my colleagues, including Representatives Carter and McKinley and this subcommittee, for introducing their bill which is very similar to a bill I introduced on orphan drugs.

We all support the orphan drug program and it provides those incentives to get drugs to treat rare diseases. But I am really concerned about what I regard as the significant abuse of the bill. Pharmaceutical companies are seeking orphan drug status for some of their best-selling drugs. That is not what that orphan drug designation was about.

In November of 2018, there was the GAO report on orphan drugs that found that 38 percent of the drug approvals from 2008 to 2017 were for drugs that had been previously approved for either mass market or rare disease use. And some of the best selling drugs on the market now have orphan status, including Humira, Remicade, and Enbrel. These drugs have billions of dollars in annual sales, and they don't need the orphan status. That is certainly as I see it.

It is also becoming a real problem in the 340(b) program because drug manufacturers want to avoid including these drugs in the 340(b) program even though they are used for many and fairly common treatments.

So, I do strongly support 4712, H.R. 4712, because it would take steps to begin to close loopholes and ensure orphan drug status is only being used for true orphan drugs.

Mr. Kaeser, I want to ask you about Johnson & Johnson's drug Imbruvica. Am I saying that right?

Mr. Kaeser. Imbruvica.

Mr. Welch. Imbruvica, as I understand it, had about $2.6 billion in sales in 2018, and sales are expected to range from $5 to $9.5 billion in 2020. And the drug currently has ten orphan indications. Is it your view at Johnson & Johnson that the orphan drug program was intended to be used ten different times for one drug?

Mr. Kaeser. Representative Welch, that is a fantastic question. But it is --

Mr. Welch. What is the answer.

Mr. Kaeser. -- way outside the scope of --

Ms. Eshoo. Pull that microphone up.

Mr. Kaeser. My microphone is on, yes.

The focus of my work is in counterfeiting and brand protection. And I would be very happy to work with my Government Affairs team, my team back in New Jersey. I could come back with something.

Mr. Welch. You know, with all due respect, I mean it is not -- we have a hearing today scheduled on orphan drugs.

So, it is not like this should be a surprise that this question gets raised. Johnson & Johnson is doing a 10-for-1 situation here with this drug.

You want to check with somebody now, use your phone? Tell us what Johnson & Johnson's position is on whether this is an abuse of the orphan drug status?

Mr. Kaeser. I would be happy to work with our folks back in Johnson & Johnson to get the right person to come back and speak to you.

Mr. Welch. Yeah, okay. I am going to express my frustration here. We hear that a lot from witnesses.

Mr. Kaeser. Okay.

Mr. Welch. And then you are gone. I mean, the hearing is now. It was noticed. We knew we were going to be talking about orphan drugs. I am asking a simple, straightforward question and you are telling me you will get back to me. And once you walk out that door you will be gone and I will never hear from you again.

So, anyway, no more.

Let me ask Dr. Chow -- did I pronounce your name correctly?

Dr. Chua. It's Dr. Chua.

Mr. Welch. Chua. Thank you very much.

What is the best way to address this issue of what I am

defining, as I see it, the abuse of the orphan drug status?

Dr. Chua. I think this is a difficult issue. I think these "partial" orphan drugs, those with both orphan and non-orphan indications it is true that they tend to be extreme best sellers. In fact, I think seven of the ten top selling drugs in the world are these partial orphan drugs. And it does raise difficult questions about whether orphan drug incentives are being used in a manner consistent with the purpose of the Orphan Drug Act, which was designed really to incentivize development of treatments that otherwise would have limited economic potential.

Mr. Welch. Well, is it your experience that if there is any room for a loophole, then the pharmaceutical companies will drive their truck through it to be able to get the highest price possible at the expense of taxpayers and employers who are paying for these prescriptions?

Dr. Chua. I think pharmaceutical companies have incentives to maximize their profit. And if there is an opportunity to -- if the rules allow for that --

Mr. Welch. Okay.

Dr. Chua. -- then there will be certain --

Mr. Welch. Well, I just --

Dr. Chua. Then yes.

Mr. Welch. Thank you. My time is up. But I just want

to strongly endorse this bipartisan legislation that would try to start addressing this abuse on pricing powered by pharma.

Thank you. I yield back.

Ms. Eshoo. The gentleman yields back.

Let me just make a quick comment. And that is that that I don't know a time when if a witness cannot give an answer that members have come forward and said they have never answered the question. It is my understanding that Mr. Kaeser is here relative to a specific issue. The one that you, the question that you asked is a very important one. But that is not his expertise.

So, we will work together and make sure that you get the full information from Johnson & Johnson. But it is a little unfair to press him. He is here representing another department, another issue. And he is being honest in saying I can't give you, I am not the one that can give you the answer.

You need, we all need to get the answer. You have raised a very important question. But we all need to appreciate that Mr. Kaeser is not the one that -- he doesn't know. He is being honest. So, we will get the information.

Who is next? The gentleman from Oregon, Mr. Walden.

Mr. Walden. Thank you, Madam Chair.

Ms. Eshoo. You are on. You are on.

Mr. Walden. As fate would have it, I have a question for Mr. Kaeser about counterfeit products. And what I want to know is how Johnson & Johnson typically becomes aware that a counterfeit of one of their products has entered the supply chain? How does that happen? Give us the steps.

Mr. Kaeser. Well, we do ongoing market monitoring. So, physical market surveys, online market surveys, constantly monitoring the internet 24/7 all around the world. So, we make it our business to constantly survey the world to see what is going on.

Mr. Walden. All right. And how do these counterfeit products typically make their way into the U.S. market? We know about some of the mail facilities, and Dr. Burgess has been up to see some the last Congress.

Mr. Kaeser. I was going to say the IMFs, right, the International Mailing Facilities are a source.

Mr. Walden. Uh-huh.

Mr. Kaeser. But it is the internet. It is the internet and unauthorized --

Mr. Walden. Direct shipping?

Mr. Kaeser. I am sorry?

Mr. Walden. Just direct shipping?

Mr. Kaeser. Direct shipping, yes.

Mr. Walden. Huh. All right. And then how would extending FDA's administrative destruction authority to medical devices complement Johnson & Johnson's efforts to keep these potentially dangerous counterfeit products out of the hands of the unwitting providers and patients?

Mr. Kaeser. Excellent question. I think this is right in front of us with H.R. 5663, would be a great opportunity for us to extend that authority to the FDA on this inbound at these International Mail Facilities.

Mr. Walden. Okay. Let me ask you this, too. When you find these counterfeit products on the internet, what kind of relationship do you have with some of the internet companies to get those products, get those ads, those whatever taken down, taken off? Do you have a good relationship there? Do they respond? Do they not respond? Some better than others?

Mr. Kaeser. Some better than others. But typically we have very strong relationships with them. We have to. But, just like J&J or any other company, people come and go. And when --

Mr. Walden. Yeah.

Mr. Kaeser. -- people go sometimes you have to start all over again.

But my team is very closely connected with these marketplaces and constantly helping to improve.

Mr. Walden. And so do any of them, like, push back and say, no, we are not going to do that, that is your problem?

Mr. Kaeser. Probably not that blatantly, no. They at least put a good face forward.

Mr. Walden. And they say, oh, we will take a look at it and never get back to you?

Mr. Kaeser. I would say they are becoming much amenable.

Mr. Walden. All right. Is there anything we need to do in that space?

Mr. Kaeser. Well, I think, I think for starters let's push 5663 through. And I do think that there are opportunities for other tools, other resources, and how we can expand the authorities into other areas.

Mr. Walden. I know in prior Congresses we have had hearings with counterfeit medicines. I remember one years ago where they brought in samples in bags and said, you pick the one that is counterfeit. And none of us could. I mean, they looked exactly alike.

Mr. Kaeser. Yes.

Mr. Walden. So, how pervasive is this?

Mr. Kaeser. It is a pervasive problem. And it is getting much worse. I think the counterfeits are very agile, they are very good. Many times the packaging that

counterfeiters use are as good or better than what we use.

Mr. Walden. Yeah.

Mr. Kaeser. Because there is really nothing good inside of it.

Mr. Walden. And where is this coming from mostly?

Mr. Kaeser. It is, I would say it is an equal opportunity world, but predominantly from Asia, a lot from China, and India, Middle East.

Mr. Walden. Uh-huh. All right. All right.

Ms. Eshoo. Would the gentleman yield?

Mr. Walden. Yes, sir. Yes.

Ms. Eshoo. Mr. Kaeser, is there, would there be a -- would the following put a dent in what you are describing, if there was a requirement for internet providers to flag and say "not FDA approved"?

Mr. Kaeser. Yes, absolutely.

Ms. Eshoo. Okay.

Mr. Walden. Yes, Dr. Burgess, I would yield to you.

Mr. Burgess. But, Mr. Chairman, just to answer part of your question, at the International Mail Facility, --

Mr. Walden. Yes.

Mr. Burgess. -- and I know it is not under our jurisdiction, but it is really pretty primitive. I mean, these are buildings that were built back in the 1930s. Some

places they lack internet access in some segments of the building. Customs and Border Protection is good about providing the FDA the space that they have. But I know it is an Oversight Government Reform Committee challenge, but perhaps we ought to help them.

And I have talked to members of that committee. The facility needs significant upgrading. And I suspect there are other facilities that do as well. Maybe that can be part of the infrastructure package.

Mr. Walden. Yeah, that would be good.

And let me just suggest there is nothing that is not actually under our jurisdiction. As a former chairman I just want to put that on the record. We start there and then make them try and claw it out of our hands.

Ms. Eshoo. Very important statement.

Mr. Walden. Is that correct? All right.

Ms. Eshoo. Yeah. That is going to be enlarged in the committee's print.

Mr. Walden. With that, Madam Chair, I will yield back the balance of my time. Thank you.

Ms. Eshoo. Thank you.

The gentlewoman from New Hampshire, Ms. Kuster, is recognized for her 5 minutes of questions.

Ms. Kuster. Thank you very much.

I was thinking we would go to Michigan first. So, my apologies.

Thank you, Madam Chair. And I am delighted to be here with all of you today. I wanted to focus in on the Dairy Pride Act. I served for 6 years on the Agriculture Committee. And I think I am in the first panel. I am sorry.

I am sorry, let me skip to the Orphan Drug Act. I apologize.

By monopolizing the market, how many have been unable to access lifesaving medication? And I am wondering how many have been deterred from evidence-based treatment out of fear for the current formulation?

These are questions that we need to address. And I want to turn to Dr. Chua if I could. In 1994, the FDA granted Subutex, commonly known as buprenorphine, orphan drug status even though opioid use disorder is not a rare disease.

Your testimony described Sublocade's orphan approval as an abuse of orphan drug policy, but also a catastrophe in the treatment of opioid use disorder. Can you detail how the cost of buprenorphine is a barrier to opioid use disorder treatment and how the gaming of the Orphan Drug Act has contributed to that prohibitive cost?

Dr. Chua. Thank you for that question.

So, the current list price for Sublocade for each shot

of monthly shot is $2,000. What that does is two things. One is that it makes insurers reticent to cover it, or at least more willing to put up barriers such as prior authorization.

The other thing that it does is that it exposes patients to out-of-pocket costs, particularly those who are privately insured and who have to pay a portion of a drug's price due to deductibles or co-insurance.

So, absolutely the price of buprenorphine products and of opioid use disorder medications more generally can be a deterrent to receipt of safe and effective care.

Ms. Kuster. And one of the greatest challenges associated with medication-assisted treatment in the criminal justice setting has been the fear of diversion. Subutex and Suboxone were tablets placed under the tongue, while newer, extended release formulations by another company could not enter the market due to this monopoly established by the gaming of the Orphan Drug Act.

How might the entrance of new formulations of buprenorphine improve treatment in vulnerable populations?

Dr. Chua. Right. That is a really good question, too.

So, these extended release once-monthly injections have a couple of advantages. One of them is that you don't have to remember to take your buprenorphine every day, so it is

going to promote adherence.

The other in this particular instance is that if you substitute a monthly injection for a prescription, for example Suboxone film, there is less potential for that film to be diverted on the black market because the buprenorphine is being controlled essentially in that sense by a monthly injection.

Ms. Kuster. Thank you. And how is the legislation before us today effective in closing the loophole that has prevented other companies from entering the market with new formulations?

Dr. Chua. This bill, H.R. 4712, would close the loophole that allowed Sublocade to gain orphan exclusivity in the first place -- sorry, orphan drug status, that wasn't approval. And if in the event that FDA's decision to revoke Sublocade's orphan status is overturned, it would permanently bar the possibility of exclusivity for Sublocade which, as mentioned before, would block out new buprenorphine products until 2024.

Ms. Kuster. So, you think overall that would be beneficial for Americans, including vulnerable populations and those that are receiving their medically-assisted treatment, that this will improve access --

Dr. Chua. Yes.

Ms. Kuster. -- to treatment for substance use disorder?

Dr. Chua. Yes. We know that medications for opioid use disorder are extremely effective. And, yet, they are widely underused.

So, we need to do whatever we can to increase use, increase choice, increase innovation, make sure that there are products that work for patients because each one of these products has different properties, they are administered differently, they have different kind of advantages and disadvantages. And we just need to make sure that we are doing everything that we can to give people the best chance to treat opioid use disorder.

Ms. Kuster. Well, I want to thank you for being with us today. And certainly on behalf of my constituents and on behalf of our bipartisan Opioid Task Force I appreciate what you are doing. And I would urge my colleagues to support the bill.

And with that, I yield back.

Ms. Eshoo. The gentlewoman yields back.

It is a pleasure to recognize Mr. Griffith from the great state of Virginia for his 5 minutes.

Mr. Griffith. Thank you very much, Madam Chair.

Dr. Muzzio, we have all been following the coronavirus

outbreak over the last couple of weeks. Your testimony discusses the ability of the continuous manufacturing process to more quickly respond to emergency needs. In a world where continuous manufacturing was the norm, how would you foresee a response to an outbreak like the one we are currently watching play out?

Mr. Muzzio. Thank you for the question. I think it is an excellent question.

So, if we had the technologies in place so that we could implement these rapid development methods for a wide variety of product, if some of the products or the, you know, the drug substances that are known or we would want to see whether they are good and effective for treating an emerging disease were manufacturable by continuous manufacturing systems, the response would be to assign the task of creating multiple versions of a potential product to a manufacturer that is enabled and knowledgeable, that manufacturer could come back with suitable versions of a possible product in days or weeks, which is much faster than you can do today.

Mr. Griffith. Thank you very much. That is what I was looking for: much faster than what we can do today.

I am going to yield now to my good friend from Indiana, Dr. Bucshon.

Mr. Bucshon. Thank you for yielding.

Mr. Kaeser, I was interested when we were talking about deaths related to counterfeit medications or devices. And it seems to me that likely that is related to people not getting the active component of the drug they are supposed to be getting and, therefore, they will, you know, not do well and they pass away based on the fact they are not getting it.

Or, is it because of the toxicity? Do we know? Because I think when you throw out the number of a million people dying from counterfeits, I do think from a public perception standpoint it is important to understand conceptually, you know, what does that actually mean? I mean, what, is the American public, you know, you take the pill and you die, you know? Or is it just because you have -- they are getting a chemotherapeutic agent that doesn't have active component?

Do you have any breakdown on that at all?

Mr. Kaeser. A great question. And I really don't. The INTERPOL data doesn't get that deep on specific products. You know, I can speak to some of the things that we have seen. It is both. There can be toxic things in the drug or there could be lack of an API that would cause interruption in therapy. But, regardless, if it is not coming from an authorized manufacturer you are at risk.

Mr. Bucshon. Yeah, I am not implying that it is bad -- you know, that it is not bad to have counterfeit drugs or

products, right. I am just saying that I think when, you know, when we have public hearings it is important, you know, the American people are watching that, you know, a million people are dying from counterfeit drugs that it is important for people to understand why is that.

Is it because, like I said, you take the pill and, you know, you don't want people to stop taking their medicine. That is what my point is that I am getting at. Because people will do that based on these type of things; right? And so it is important to understand that most likely, in my view, it is probably because the active component is much less prominent in the counterfeit than it would be in a J&J drug or product. But, I don't know, and that would be important to understand.

So, Dr. Muzzio, why hasn't the private sector in the United States adopted continuous manufacturing? I mean, you know, it is a free market. If it -- it seems like, you know, in a lot of other industries you have this type of continuous process, why, why haven't we done it?

Mr. Muzzio. It is a really good question.

Technology-wise we could have done this 30 years ago. I think it is because it took universities to procure the funding, create the partnership, demonstrate that the technology would work, be able to work in a non-adversarial

way with the regulators. FDA played a phenomenal leadership role, very quickly promoting adoption, very quickly telling companies it was safe to do.

When I started working on this 20 years ago, pharmaceutical companies were telling me that the FDA was never going to let them do it.

Mr. Bucshon. Right. Because that --

Mr. Muzzio. When I talked to FDA, FDA said, oh, we want them to do it. And then it happened.

Mr. Bucshon. To finish up, that was the other part of the question I was going to ask. What is currently the greatest barrier and what has been the greatest barrier to the adoption, is it just the marketplace hasn't supported it? Or is there, are there government barriers? And you, I think you mentioned the FDA, but what can we do here to change that?

Mr. Muzzio. Well, so the greatest barrier to adoption by companies that are not doing it yet is what I said earlier several times is that there is a large amount of know-how that you need and they need to be able to access that know-how.

Mr. Bucshon. Okay, thank you. I yield back to Morgan.

Mr. Griffith. And I yield back to the chair. Thank you.

Ms. Eshoo. The gentleman yield back.

A pleasure to recognize the gentlewoman from Delaware, Ms. Blunt Rochester, for her 5 minutes of questions.

Oh, I am sorry. Who is it? Ms. Kelly from the great State of Illinois, recognized for 5 minutes.

Ms. Kelly. Thank you, Madam Chair. Thank you for your testimony today. And thank you, Chairwoman Eshoo, for holding this important hearing on the safety and transparency of food and drugs.

The Orphan Drug Act was a critical piece of legislation that encouraged the development of drugs for rare diseases that may otherwise not have been developed. However, as Dr. Chua mentioned in his testimony, there have been instances in which this policy has been abused.

In your testimony you mention how Sublocade's orphan drug approval is an abuse of orphan drug policy. Can you explain how this abuse impacts patient's access to affordable drugs by preventing other treatments from the market?

Dr. Chua. So, when you get orphan drug exclusivity, what that means is that FDA can't approve any other competing products that contain the same medication, which in this case is buprenorphine, to treat the same disorder, which in this case is opioid use disorder, for 7 years.

So, given the timing of Sublocade's approval, which was

November of 2017, that meant that if exclusivity had been granted to Sublocade there would be no competitors, no new, no innovation, no new buprenorphine product until December 2024. In the midst of the worst public health crisis, arguably, of this generation, that strikes me as the definition of abuse of an orphan drug policy.

Ms. Kelly. While many of us have concerns about access to affordable medicine, we all recognize the need to develop drugs to treat rare orphan diseases. We want to make sure that we have a policy that is tailored to fix this particular problem. Can you speak to the scope of the fix included in H.R. 4712? Will this bill do anything to harm the incentives we have --

Dr. Chua. That's a great question.

Ms. Kelly. -- to treat these patients of rare diseases?

Dr. Chua. This is a great question. And I want to emphasize that the scope of H.R. 4712 is limited. It would only affect the three drugs that have ever been designated through the cost recovery prong designation, which is the unprofitability kind of pathway. And, actually, only two because one of them, one of them, Subutex's has been revoked, the designation has been revoked. So, it is actually only two drugs.

And it would also affect any future approvals that occurred under a cost recovery prong designation.

So, it really does not affect a lot of drugs. But, again, I want to emphasize how important this bill is, even though it has a limited scope, which is that it is going to protect patients from the possibility of not being able to access new, innovative buprenorphine products until 2024.

Ms. Kelly. Thank you so much.

And, Madam Chair, I yield back the balance of my time.

Ms. Eshoo. The gentlewoman yields back.

The gentleman from Florida, Mr. Bilirakis, is recognized for his 5 minutes of questions.

Mr. Bilirakis. Thank you, Madam Chair, I appreciate it.

Mr. Kaeser, does the rise of e-commerce create additional challenges in monitoring for counterfeit goods? I think I know the answer to that question.

If so, in what ways do they?

Mr. Kaeser. I have been involved with brand protection, anti-counterfeiting for 7 years, and it has, I would say, been a very dark shadow in my life, and I see the world a little bit different. I see that the e-commerce space, the internet, provides the perfect playground for bad actors. Many times counterfeiters are third party sellers that are hiding behind a brand name that is very reputable. But when

you purchase, if you don't look closely you can end up with counterfeit goods.

Mr. Bilirakis. Yes. Are brands working with e-commerce businesses to crack down on counterfeit goods? If so, how?

Mr. Kaeser. I am sorry, what was the question?

Mr. Bilirakis. Okay. Are brands working with e-commerce businesses to crack down on counterfeit goods?

Mr. Kaeser. We are constantly working across the e-commerce platforms to protect ongoing illicit trade and to take them down. We at Johnson & Johnson, our illicit trade analytics, and we work with external companies to help us to constantly monitor the internet, the e-commerce space. And we take down tens of thousands of sites per year.

Mr. Bilirakis. Okay, good.

Do all products run the same risk of being counterfeited? If not, which products carry the most risk of being counterfeited?

Mr. Kaeser. Counterfeiters are very shrewd businessmen. They are looking for big brands, recognizable brands, that typically have strong market share and strong margins. So, I would say if you are a big brand and you are making money, you have a big target on your back.

Mr. Bilirakis. Okay. Do patients and consumers play a role in addressing the problem of counterfeited goods? If

so, in what way? And does Johnson & Johnson partner with consumer goods groups, consumer groups or their health care stakeholders?

Mr. Kaeser. I think that there is an opportunity for more consumer, more general awareness around the risks imposed by illicit trade and counterfeiting. But, they do play an important role that if a consumer has a bad experience or they suspect counterfeit, on all of our packaging there is a toll free number to contact us.

And we urge anybody that has a bad I will say event with a J&J product to let us know.

Mr. Bilirakis. Okay. How might Congress further support efforts to protect consumers from counterfeit goods?

What other authority should the Federal Government have to curtail the supply of counterfeit medical devices?

Mr. Kaeser. As I said multiple times, I think the support of this bill is an enormous opportunity. I think it is low-hanging fruit. And I have alluded to that I think getting this in place, and opportunities to explore other tools.

I have heard many references to the International Mailing Facilities and the resources there, that they are old or they lack resources. And I will share an example or an analogue that I got from a friend who is at Homeland

Security. And if you know anything about counterfeiting, it used to be, you know, the slow boat from China per se. It was cargoes, it was containers, they were large containers coming in.

With e-commerce it has changed. It is small parcels coming in through these mailing facilities. And the analogue that this Homeland Security agent shared with me said in the old days it was as if somebody was rolling a bowling ball across the table. You knew it was awkward, it was going to be heavy, but you could probably stop it.

Mr. Bilirakis. Right.

Mr. Kaeser. Today it is like somebody has opened up a bucket of marbles and rolled it across the table. And you can catch a few, but a lot more are going to get through.

Mr. Bilirakis. Yeah.

Mr. Kaeser. So, I think that we have a lot of opportunities to continue to improve.

Mr. Bilirakis. All right. Thank you very much.

Anyone want my time?

Ms. Eshoo. I do.

Mr. Bilirakis. Oh, okay, please. Please. I yield.

Ms. Eshoo. I thank the gentleman for yielding.

Do you believe that the most effective thing that we could do is to add to the bill that since these are -- it is

illicit --

Mr. Kaeser. Yes.

Ms. Eshoo. -- that no platform be allowed to carry them, to advertise them?

Dr. Burgess just showed me -- well, no, it was on your iPad. I opened kind of --

Mr. Burgess. It was on sale, 80 percent off.

Ms. Eshoo. Yeah, 80 percent off on fentanyl. So, why don't we just shut this -- do the strongest language just to shut this thing down?

Mr. Kaeser. If it is that blatantly obvious, I completely agree.

Ms. Eshoo. Good. Okay.

I thank the gentleman for yielding.

Mr. Burgess. Would the gentleman yield to me for one additional second?

Mr. Bilirakis. Oh, absolutely.

Mr. Burgess. And just, really, the gentleman had a good observation. One of the things I saw when I was at the International Mail Facility it wasn't a device, it was a drug. It was botox, counterfeit botox. And, man, the packaging was just superb. You could not tell any difference between regular allergen-produced botox.

The problem with botox is, well, one thing, if it is not

sterile, as you said with Surgicel, but if the potency is off, okay, if it is too mild the wrinkle is still there. If it is too potent, that is a potent neurotoxin and it could be fatal.

So, that is the reason we need to be so focused on this.

I thank the Chair, and I thank the gentleman. I will yield back to the gentleman from Florida.

Ms. Eshoo. The gentleman yields back.

I am happy to recognize the gentlewoman from California, Ms. Barragan, for her 5 minutes.

Ms. Barragan. Thank you.

Mr. Kaeser, one of your most striking parts of your testimony was the estimate that a million people, mostly in developing countries, die each year from taking counterfeit medicine. There is a real danger that is posed when the counterfeit medical devices are in the supply chain. And we must ensure that the proper resources and mechanisms are in place to eliminate these products so patients are protected.

Additionally, representing the district with the Port of Los Angeles, I know firsthand the difficulties that the ports face when it comes to inspecting and securing the large number of product that come into the country.

Can you, can you tell me about if you have any information on some of the more common counterfeited medical

products? And what are the dangers posed from these products entering the market? And if you happen to have any idea maybe how some of that comes through the ports?

Mr. Kaeser. I apologize, your question is what are some of the more counterfeited products coming into the United States?

Ms. Barragan. Do you have any information on some of the common counterfeited medical products and the dangers from those products? And if you have any information maybe as it pertains to those coming through ports?

Mr. Kaeser. Yeah, it has, I have to say, in the United States it has been a more recent surge of counterfeit products coming into the U.S. And associated with the Surgicel investigation, the more we look, the more we find. And we have also found, Dr. Burgess might appreciate, LIGACLIPs. LIGACLIPs are stainless steel clips that are used for surgical procedures.

Imagine you are having, you know, a lung removed and you need to cut the blood supply off to that, to the lung to remove it. You clip it, clip it, cut it.

These clips are also counterfeit, non-sterile. And there is also a feature on those that allows the clip to close securely. These don't have those serrations. So, post-op in recovery, with the pulsation of those vessels

those clips could potentially slide off.

Stapling devices, we are finding counterfeit stapling devices.

So, this is, it is, right now it looks like it is probably the same source, which will help us significantly. But it is a big challenge.

Ms. Barragan. Do you have any insight on what more can be done to increase resources at the ports to be able to conduct the number of inspections necessary to dramatically reduce the number of counterfeited medical devices that are coming in through our ports?

Mr. Kaeser. Yeah, I am not an expert on what we would do to necessarily upgrade the ports. Industry is doing, I think, a good job. We are doing a much better job of working with Customs officials training them on what to look for, training them on what inbound freight from a company like Johnson & Johnson where it should be coming from --

Ms. Barragan. Right.

Mr. Kaeser. -- versus where the counterfeit is coming from, to help them to identify it.

So, it is an evolution. And I have to say that I take my hat off to Homeland Security, Customs and Border Patrol, are outstanding partners in our efforts.

Ms. Barragan. Yeah, I have done a tour down at the

port. And --

Mr. Kaeser. Yeah.

Ms. Barragan. -- the collaboration is key in knowing what to look for. And they have an entire room where you can walk in and see counterfeit purses. And I am sure those are a little easier to identify maybe than some of these medical devices.

So, for Dr. Chua, rare diseases are those that affect fewer than 200,000 people. Like with many diseases, various rare disease have substantial racial disparities. This includes sickle cell disease, which occurs in about 1 out of every 365 African American births.

Like we have discussed today, medications that treat these rare disease receive orphan drug designations, such as ARU-1801, a potential gene therapy for sickle cell disease that the FDA recently gave orphan drug status.

Because of exclusivity rules it is harder for lower cost generics to come to market quickly. While the rules are beneficial to help incentivize the development of orphan drugs, we must make sure there aren't bad actors that are taking advantage of the system.

How will the Orphan Drug Exclusivity Act help reduce the overall cost of prescription drugs so that patients can afford the treatments they require?

Dr. Chua. So, I agree with all your points. I think they are very good points.

Again, this bill has a very limited scope. It would only affect orphan drug designations that occurred under the cost recovery prong, which has only happened three times in the history of the Orphan Drug Act.

To your question about cost, right now Sublocade has a 3-year period of exclusivity because it is just a standard exclusivity that is granted for a new formulation of a previously approved drug. So, right now, as I mentioned, the list price for each multi-shot is 2,000. And that is because the company Indivior can charge what it wants. It is the only medication on the market.

And again, that, there is a tradeoff for that; right? We want to be able to reward companies for innovation. But there are downsides to that as well. And so, walking that fine balance is very important.

In this situation I think the idea of extending that monopoly to 2024 is unconscionable -- I can't even say that word -- unconscionable in the context of the opioid epidemic.

Ms. Barragan. Thank you. I yield back.

Ms. Eshoo. The gentlewoman yields back.

A real pleasure to recognize the gentlewoman from Indiana, Ms. Brooks.

Ms. Brooks. Thank you, Madam Chairwoman. And thank you so much for holding this really important hearing. I think it builds on past hearings we have had, specifically as it relates to active pharmaceutical ingredients.

And I would like to talk to you, Dr. Muzzio, about continuous pharmaceutical manufacturing that you are such an expert in. I represent Indiana, one of the largest manufacturing states in the country. Purdue University has been one of the -- one of those universities that has partnered to help advance continuous manufacturing research, and then also Eli Lilly in Indianapolis I represent. And these are employers that are -- employees that are trailblazers in the field.

And I have toured their manufacturing facilities. But one of the concerns that this committee I think has learned a lot about, and we are continuing to explore, is the real threat posed by China, India, and overseas with respect to the active pharmaceutical ingredient adulteration. And now that we are so focused on, the chairwoman of this committee and I have been very focused on the biological threat. And now, with what is happening with coronavirus, how can we accelerate in this country the continuous manufacturing in this country?

Certainly we, I think, probably need to have a reduction

in many ways on foreign manufacturers, although many of our companies are international and are multinational companies. But if we want to bring back more continuous manufacturing processes here, you have connected our universities, and you have said the largest amount of know-how comes from the universities, why is it the manufacturers themselves are apparently choosing to rely on the universities?

And what do we need to do to accelerate either the expertise in both our higher ed institutions, as well as our manufacturers?

Mr. Muzzio. That is a very good question. Thank you.

So, I think historically the reason why it took the partnership is because of the ability to build a different relationship with regulators as well as to demonstrate a technology in a non-competitive, non-confrontational situation where everybody could benefit from it.

So, that was our role historically. And you are absolutely correct, Purdue was one of our most appreciated partners we worked together on this.

Going forward, now you have some companies that do know how to do this, and you have many, many companies that don't. So, one way to accelerate this is to, as I said already, make the knowledge available. But, in addition to that, create an environment where the technology can be demonstrated, where

they can come with their drug substance and we can create a process and turn it into product.

Also, I want to talk for just 1 second about the APIs that you referred to; right? We had to distinguish, finish those manufacturing from API manufacturing. Continuous manufacturing can help us well, in API manufacturing, in creating agile ways to recreate a manufacturing capacity that we have lost. It is a slightly different application but the principles are similar.

So, you asked me what you can do. To provide the support, to provide the resources so that we can create the centers that can do these jobs and can help everybody move forward.

Ms. Brooks. And what would you say with respect to the grants? The 21st Century Cures was all about really advancing continuous manufacturing. How, how widespread do we need for these grants to, you know, what amount might we say is needed to help our higher ed institutions get engaged in this process --

Mr. Muzzio. Well --

Ms. Brooks. -- and in, you know, securing these grants?

Mr. Muzzio. So, I don't have the exact number in mind right now, but I could come back to you with it. But Europe

has allocated in the order of billions of euros to this activity.

Ms. Brooks. To their higher ed institutions?

Mr. Muzzio. To their initiatives in advanced pharmaceutical manufacturing. There was a major initiative in the U.K. that was worth well over a billion euros. There has been what they call their 2020, right, which they started several years ago. They had very large amounts of funding allocated to this, specifically promoting the creation of government/academia partnerships so that they could march on quickly.

Their centers are larger than the ones that we have got funded. They also have a much more focused mandate on creating and demonstrating technology and basic research. We are behind in this area.

We greatly appreciate the resources that have been made available through 21st Century Cures and now, hopefully through the new bill. But I have to say, Europe has invested much more steadily on this.

Ms. Brooks. Okay, thank you.

And I yield back.

Ms. Eshoo. The gentlewoman yields back.

And now the gentlewoman from Delaware, Ms. Blunt Rochester.

Ms. Blunt Rochester. Thank you, Madam Chairwoman, and thank you Ranking Member Burgess for this important hearing on improving safety and transparency in America's food and drugs.

I also want to thank the panel for your testimony. And, Dr. Chua, I want to also specifically reference the fact that you really reinforced that decades ago Congress passed the Orphan Drug Act to incentivize the development of new therapies for diseases affecting less than 200,000 people, or for drugs unlikely to be profitable.

In May of last year I, too, was concerned to learn that Sublocade -- Sublocade, buprenorphine, drugs used to treat those with substance use disorder could be granted orphan drug manufacturing exclusivity, even though millions of Americans suffer from addiction, and the drug generates multi-million dollars in profits each year.

While the FDA ultimately reversed their decision, this would have potentially kept competing products off the market, artificially reduced treatment options, and potentially made a lifesaving medication more costly for those who need it.

I recently visited a small business in my state of Delaware, and it was a family-owned business, a car dealer. And we spent time talking about training. We talked about,

you know, cars, electric vehicles. But the thing that stuck out most was the impact that the opioid crisis is having on his employees and the families that he works with. Our nation is in the middle of an opioid crisis. There are an average of 130 Americans dying from an opioid overdose every single day. And in Delaware we lose someone every 22 hours to an overdose.

Simply put, extending orphan drug designation in this manner would have been inconsistent with the intention of the Orphan Drug Act.

Dr. Chua, in your testimony you state that buprenorphine is an under-used treatment, even with the severity of the opioid epidemic. Can you share with us why? And how is patient access to buprenorphine impacted by requirements that prescribing physicians obtain an X waiver?

Dr. Chua. These are all really good questions.

I think that waiver is in fact one of the major barriers to buprenorphine prescribing. So, just to put this in perspective, there are three drugs to treat, FDA approved medications to treat opioid use disorder: buprenorphine, methadone, and extended release naltrexone.

Each of them have advantages and disadvantages. An advantage of buprenorphine is that it can be prescribed in office-based settings, whereas methadone can only be

dispensed in methadone treatment centers. So, that makes it more convenient and accessible, provided that you can find somebody who actually prescribes it.

In order to find somebody who prescribes it, that somebody has to go through 8 hours of training, and has to apply for a waiver in order to prescribe buprenorphine. And data show that most of the people who might be candidates to prescribe buprenorphine, many primary care physicians for example, have not gone through that process.

So, I think the waiver is certainly a big, or exing the waiver would be something that would greatly increase access.

Ms. Blunt Rochester. I have two different sets of questions that I am trying to decide between, so I might have to follow up with you. One was going to be focused on adolescents and lack of research or data that is out there and what your thoughts are on that.

But what is really pressing to me, we saw a JAMA Network open study that found that for every three additional payments that manufacturers make to physicians per 100,000 people in the country, opioid overdose deaths increased by 18 percent. But the study suggests that it was the frequency of the marketing interaction, not individual payment amounts, that had a greater impact on physicians' opioid prescribing.

More interactions led to increased awareness of the

product, interest trust at the company, and then different prescribing practices.

And so, in the limited time that I have, time versus money, are there any limits on the number of interactions or amount of direct payments that manufacturers can make to physicians?

Dr. Chua. Not really as far as I can -- there is no, there is no, as far as I am aware, there is no cap on the amount of payments that can be made.

Ms. Blunt Rochester. And my follow-up question -- and we will follow up with you in writing -- will be about just the relationship between manufacturers and physicians and how it develops over time, and how that impacts the prescribing rate.

I thank you and I yield back. I am out of time, but I yield back. Thank you.

Ms. Eshoo. The gentlewoman yields back.

A pleasure to recognize the only pharmacist in the Congress, the gentleman from Georgia, Mr. Carter.

Mr. Carter. Thank you, Madam Chair. And thanks all of you for being here. This, all of this is important.

Dr. Chua, I want to stay with you because the opioid epidemic is something that I have had firsthand experience at as a practicing pharmacist, as a legislator as well. In

2009, during what could be arguably called the epitome of this problem, I was the lead sponsor of the legislation that created the Prescription Drug Monitoring Act in Georgia.

And this is something that is very important to me. And I am the lead sponsor on the Fairness -- the lead Republican sponsor on the Fairness in Orphan Drug Act, so I wanted, I want to thank you for your testimony here today because it is very important, extremely important.

So, let's, let's talk about it. And you talk about why the bill is so important. And under the current statute, because there is a real loophole here, and we are closing that loophole. Can you address it very quickly?

Dr. Chua. So, essentially any time anybody wants to get an orphan approval and, therefore, exclusivity under a cost recovery prong designation in the future they would have to prove at the time of approval that there was no expectation of profitability. Let me just give an example.

So, it turns out that one of the other -- I had mentioned that there were three designations in the history of the Orphan Drug Act under the cost recovery prong -- one of the other ones is Suboxone, which was also designated in 1994 also for the company Reckitt Benckiser which is now -- which Indivior spun off from in 2014.

Mr. Carter. And it is important to note that this was

pre the opioid crisis.

Dr. Chua. This is correct, yes. That is absolutely correct.

And so, with the loophole as is, in theory Indivior could develop a new formulation of Suboxone, which is I think the best selling buprenorphine drug in the world, and automatically gain orphan status for that new formulation because essentially the designation for Suboxone in 1994 would be automatically grandfathered.

So, essentially that would just be a repeat of what the company did for Sublocade.

Mr. Carter. Right.

Dr. Chua. And this bill would close that possibility.

Mr. Carter. And it is only a small change.

Dr. Chua. That is right.

Mr. Carter. It is only a small change. And it is obviously a necessary change.

So, again, I want to thank you because this is extremely important. And I just appreciate you being here and appreciate your testimony.

Dr. Allen, I want to ask you, under the Modern Labeling Act who, the updates, if there are updates to a label of a drug, who is to communicate that to the doctor and to the pharmacist? Whose responsibility is it, is it the FDA, or is

it the manufacturer, or who?

Mr. Allen. So, generally speaking that information would be first listed in the label, which would allow it to be the basis of communication. So, FDA would communicate the label that would be accessible to the prescriber. And for the information that is in the label, that could then be actively communicated by the manufacturer.

Mr. Carter. Well, with all due respect, I didn't just start reading the label to see if anything had changed. I mean, somebody needs to notify the pharmacist, somebody needs to notify the doctor that a labeling change has been made. Whose responsibility is that?

Mr. Allen. I think in instances where it is a safety concern there are more active mechanisms that that can be pushed out. For some of these others, they may be more just a reference as opposed to every modification that could occur to a drug over the life cycle.

Some of that may not even raise to the point of a label change, for example, because I think the important thing that hasn't necessarily been mentioned in our discussions today or on this bill is the standards for the information that would be put in the label here will be consistent with current law that has been in place for decades.

Mr. Carter. But, I mean, if there is a new indication

for a drug it is going to be communicated most probably by the manufacturer. I mean, they are going to want the physician and the pharmacist to know there is a new indication for this.

Mr. Allen. If it is updated in the label.

Mr. Carter. Right.

Mr. Allen. If it is supported in scientific evidence there may be limitations in terms or how they might be able to communicate that.

Mr. Carter. Okay. Mr. Kaeser, I wanted to ask you regarding counterfeit medical devices, this is obviously something that has evolved over time. And is it getting more detailed, is it getting more complex as time goes on?

Mr. Kaeser. From what I have seen, counterfeiting is evolving. I do believe that they are getting better at what they do, which is really forcing our hand to get better at what we do. So, the short answer is yes.

Mr. Carter. And, I want to just issue a warning. As we talk about prescription drug prices and how we are going to control those prices, and we open up markets outside of the United States, this is a very big concern of mine. I, in my years of practicing pharmacy I have had people bring products to me: I got this through the mail; is this the right thing?

And, you know, I mean, I don't have a laboratory there

that I can ascertain whether it is or not. So, I just think there is a big warning there that we need to all heed to.

So, thank you very much.

Mr. Kaeser. Thank you.

Mr. Carter. And I yield back.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the gentleman from New York, Mr. Engel, for his 5 minutes of questions.

Mr. Engel. Thank you, Madam Chair. And thank you very much for holding today's legislative hearing and including my bipartisan legislation, the Safeguarding Therapeutics Act, which I drafted with my friend Congressman Guthrie.

Counterfeit drugs and medical devices pose a significant health risk to the American public which can lead to serious patient harm or even death. Just last November, the DEA reported that 27 percent of the counterfeit pills it had seized contained potentially lethal doses of fentanyl.

Since 2008, the FDA has frequently participated in an international initiative known as Operation Pangea to prevent the sale of counterfeit health care products.

The Safeguarding Therapeutics Act provides the FDA with another tool to protect Americans from counterfeit medical products. Specifically, this bipartisan legislation provides the FDA with the authority to destroy counterfeit medical

devices.

Chairwoman Eshoo, I would like to ask unanimous consent to submit into the record a letter of support for H.R. 5663 from the Healthcare Supply Chain Association.

Ms. Eshoo. So ordered.

[The information follows:]

********** COMMITTEE INSERT **********

Mr. Engel. Thank you.

Mr. Kaeser, thank you for joining us today and sharing your insights on protecting the health care supply chain from unscrupulous actors I know much earlier in the testimony you mentioned to us.

In your written testimony you share a recent example of how a counterfeit version of J&J's medical device known as Surgicel, which is critical to controlling patient bleeding during and after surgery, nearly ended up in patient care. Mr. Kaeser, how did this product end up in the supply chain?

What steps can policymakers take to educate health care providers and patients about counterfeit medical products?

Mr. Kaeser. Representative Engel, first of all, thank you very much for your sponsorship of this bill. It is very important.

Going back to the example with Surgicel, the counterfeit Surgicel was manufactured in India, went through a distributor in the Middle East based in Dubai, and eventually landed in three distributors in Florida. So, best for our investigation, these distributors contact hospitals offering lower-cost Johnson & Johnson products, and they took the bait.

So, it was through an unauthorized gray market distributor is how they acquired that.

Mr. Engel. Well, thank you very much. And thanks for helping us to expose it.

Dr. Muzzio, let me say this. I am going to talk about drug shortages, which is certainly a priority for the New York hospitals. Drug shortages can hamper patient care. They delay, obviously, medical procedures, or lead to the substitution of recommended treatments with alternative therapies. And these shortages have increased in recent years, putting an unnecessary burden on safety-net hospitals in my home state of New York.

In September, I led a bipartisan letter with Congressman Guthrie, signed by over 90 House members, to the FDA which prompted the agency to release a report on approaches to reduce drug shortages. And I also want to thank Chairman Pallone for supporting us on this issue.

His bill, the National Centers for Excellence and Continuous Pharmaceutical Manufacturing Act, which I have co-sponsored, would expand federal support for promising technology that could help address drug shortages.

Dr. Muzzio, could you describe how continuous manufacturing is more expeditious in responding to drug shortages than traditional batch manufacturing?

Mr. Muzzio. Yes. Thank you very much, Congressman, for your co-sponsorship of the bill.

So, when you have to develop a product or a process in batch manufacturing, typically you have to make a full batch of product many times over to obtain the information needed to figure out what are the right parameters to make the product. You make each of those batches under different conditions, and from that you determine how to make the product going forward. So, each time in batch you end up making a full batch.

Or you make a small scale batch, and then you have to do scale-up studies to be able to then implement the process at the full scale. This takes many weeks, sometimes months.

In continuous manufacturing you are feeding your ingredients to a system that turns those ingredients into finished product in a matter of minutes. And if you want to explore many conditions, you modify your settings, and every 10 or 15 minutes you have a full new experiment. So, the entire large set of experiments that you need to do to find the right way to make the product or the process takes a day or two.

Even if you want to repeat your studies, all you end up needing is a few weeks at the most. So, the intrinsic nature of continuous processes is much faster.

One more thing that is important. As you do those experiments you are collecting information about what the

process is doing every second. So, you have much more information about how those experiments tell you how to implement the process. And, as a result, you can implement any process and find the right conditions much more quickly.

Mr. Engel. Well, thank you very much. And thanks to everybody on the panel. It has been really very enlightening and interesting.

And thank you, Madam Chair. I yield back.

Ms. Eshoo. Thank you, Mr. Engel. And I know you waited a long time to speak. And appreciate the good words that you, both your questions and the good words about the excellent witnesses.

A pleasure to recognize the gentleman, and my pal from Illinois, Mr. Shimkus, for his 5 minutes.

Mr. Shimkus. Thank you, Madam Chairman. I see my colleague from Illinois has been also waiting patiently, Ms. Schakowsky.

Ms. Eshoo. She is waiving on though.

Mr. Shimkus. Okay. I am going to yield back my time. I appreciate you all being here.

Ms. Eshoo. Okay, moving right along, we will recognize the gentlewoman from Illinois, Ms. Schakowsky, who is waiving on to the subcommittee.

Ms. Schakowsky. Thank you, Madam Chairman. And I thank

you for the opportunity once again to waive on to this, this committee.

I heard what you said to Congressman Welch about the relevance of some of the questions for this panel, which is an excellent panel. I do want to raise another issue, but I do also want to connect it to Johnson & Johnson and Mr. Kaeser's presence here today.

I do want to tell you that on December 10th, 2010, Representative Pressley and I sent a letter to the CEO at Johnson & Johnson, Alex Gorsky, about the targeted marketing and sale of your talc-based baby powder and its potential to cause harm, particularly to women and girls of color, due to asbestos contamination. I don't know if you are familiar with that letter at all, Mr. Kaeser.

Mr. Kaeser. No, ma'am.

Ms. Schakowsky. I didn't expect so.

In 2006, Johnson & Johnson's talc supplier warned the company that perineal use of talc could be possibly carcinogenic. That information actually didn't get passed on to consumers, and instead there was a multi-cultural marketing campaign for your baby powder targeted to black and Latino women.

The response letter that I got didn't come from the chairman of the company. And I actually am now seeking a

meeting.

And I would like to have permission to enter in the record, Madam Chair, the 2010 -- 2019 Reuters article that revealed that Sri Lanka halted imports of Johnson & Johnson baby powder until they can prove the product is free from cancer-causing asbestos.

[The information follows:]

********** COMMITTEE INSERT **********

Ms. Schakowsky. And this is where I get to the issue of importing and also exporting. I wonder if you are aware, Mr. Kaeser, yes or no, do Sri Lankan sales of your baby powder, have they fallen under the -- under your job? Does that fall under your job description at all?

Mr. Kaeser. That does not fall under my job description.

Ms. Schakowsky. Well, let me just say, let me just say this. We are concerned about counterfeit drugs coming into, and medical devices coming into the United States, but I think it is worth pointing out that other countries are afraid of importing a Johnson & Johnson product that may contain -- that do contain asbestos-contaminated baby powder.

But I guess you are saying this is not something under your jurisdiction.

Mr. Kaeser. That is correct.

Ms. Schakowsky. Okay. Well, I certainly hope that the company will take this seriously, even as it looks at imports that it ought to look at the question of exports and the concerns that other countries have with products that are made by Johnson & Johnson.

I would also like, Madam Chair, if I can, to enter into the record my letter to Johnson & Johnson and the response that we received from J&J's consulting firm including

documents that revealed that Johnson & Johnson partnered with a manufacturing agency that specialized in "ethnic consumers" to distribute a hundred thousand gift bags containing baby powder and other Johnson & Johnson baby products in black and Hispanic communities and neighborhoods in Chicago and that J&J launched a campaign to boost sales of baby powder to "curvy Southern women, 18 to 49, skewed African American" that increased sales by nine percent.

And so, I think that when we are talking about the problem of these kinds of drugs coming into the country it is very important. I appreciate the work that you are doing, but we also have to consider what is being marketed to Americans and exported to other countries that don't want that product. Thank you. I yield back.

Ms. Eshoo. Was the gentlewoman asking for something to be placed in the record?

Ms. Schakowsky. I am. I mentioned or said what they were, yes.

Ms. Eshoo. The letters?

Ms. Schakowsky. Yes.

Ms. Eshoo. Yes.

Ms. Schakowsky. Letters and some other article.

Ms. Eshoo. And the newspaper article.

Ms. Schakowsky. A newspaper article and other --

Ms. Eshoo. Without objection.

Ms. Schakowsky. Thank you.

Ms. Eshoo. Without objection.

[The information follows:]

********** COMMITTEE INSERT **********

Ms. Eshoo. I want to be clear about something that I said earlier, and this committee has always, I think, really conducted itself with a great deal of respect to our witnesses whether we agree or disagree with maybe the company's policy, what we want to do in the Congress, et cetera, et cetera, but we don't badger witnesses and that was my point this morning.

So I appreciate the gentlewoman coming and raising what she wished to raise, but I want it to be very clear why I spoke up relative to Mr. Kaeser, and I think what I said earlier stands and I stand by it. We don't badger witnesses. So, thank you.

So I think this concludes the work of this panel and its witnesses. I think you have been outstanding answering the questions and helping us to understand different parts of the policies that are being advanced how they will really benefit the American people.

Dr. Muzzio, I want to particularly follow up with you relative to the continuous manufacturing, because we have a big job to do to what I think is a necessity and that is overhaul our country's drug supply. So thank you to each one of you for giving your time, your professionalism, your expertise, your considerable intellect on each of the bills that we were considering and we will ask -- you can now be

excused.

And I would ask the staff to prepare the witness table for the next panel, panel 2. Thank you again. You have been absolutely terrific.

Ms. Eshoo. All right, so we have the majority of witnesses seated. We are now going to hear from the second panel of witnesses on the important issues that we are taking up today. The bills that we are dealing with now center in and around food and FDA, and so welcome to each one of you. I think I recognize you because most of you have been sitting and waiting patiently, but I am sure you enjoyed the testimony from the first panel too because we are all learning together. So welcome.

We have Ms. Talia Day, a patient -- where am I?

Am I not -- there you are. Someone's hair down there is in the way. Who is that? There you are. Why are you on the floor like that? Oh, you have a camera. I see.

Ms. Talia Day, welcome to you. She is a patient advocate with the Food Allergy Research & Education group, sometimes known by the word FARE, F-A-R-E. Our next witness, I can't see because we have the water jug there. I think it is Sara. Is it Sara? Sara Sorscher, Deputy Director -- oh, I am sorry -- of Regulatory Affairs Center for Science in the Public Interest. I skipped over Mr. Carlin. I apologize.

Mr. David Carlin, Senior Vice President of Legislative Affairs and Economic Policy with the International Dairy Foods Association, welcome to you this afternoon. Ms. Nancy Perry, welcome to you. She is Senior Vice President

Government Relations, American Society for the Prevention of Cruelty to Animals. Welcome to you, thank you for the work of your organization. Dr. Douglas Corey, welcome to you, past President, American Association of Equine Practitioners.

Mr. Tom Balmer, welcome to you, Executive Vice President, National Milk Producers Federation. I want you to know I love milk, I really do. I love that ad, you know, with the -- mmm. Ms. Melanie Benesh, Legislative Attorney, Environmental Working Group, thank you, welcome to you. Dr. Paul DeLeo, Principal at Integral Consulting, Inc.

And where is -- Ms. Mountford is not here. Anyone know about Ms. Mountford? Okay, we are checking. At any rate, we hope that she will be here because she is the President of the Infant Nutrition Council of America. So thank you to each one of you. We have a very full, wonderful panel and we will begin with Ms. Day. You have 5 minutes for your testimony.

STATEMENTS OF TALIA DAY, PATIENT ADVOCATE, FOOD ALLERGY RESEARCH & EDUCATION GROUP; J. DAVID CARLIN, SENIOR VICE PRESIDENT OF LEGISLATIVE AFFAIRS AND ECONOMIC POLICY, INTERNATIONAL DAIRY FOODS ASSOCIATION; SARA SORSCHER, DEPUTY DIRECTOR OF REGULATORY AFFAIRS, CENTER FOR SCIENCE IN THE PUBLIC INTEREST; NANCY PERRY, SENIOR VICE PRESIDENT, GOVERNMENT RELATIONS, AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS; DOUGLAS COREY, D.V.M, PAST PRESIDENT, AMERICAN ASSOCIATION OF EQUINE PRACTITIONERS; TOM BALMER, EXECUTIVE VICE PRESIDENT, NATIONAL MILK PRODUCERS FEDERATION; MELANIE BENESH, LEGISLATIVE ATTORNEY, ENVIRONMENTAL WORKING GROUP; PAUL C. DELEO, PRINCIPAL, INTEGRAL CONSULTING, INC.; AND MARDI MOUNTFORD, PRESIDENT, INFANT NUTRITION COUNCIL OF AMERICA

STATEMENT OF TALIA DAY

Ms. Day. Thank you. Chairman Eshoo, Ranking Member Burgess, and members of the subcommittee, my name is Talia Day and all three of my children have severe food allergies, including to sesame. I want to thank you for the opportunity to explain why the FASTER Act will have an enormous and positive impact on 32 million Americans living with food allergies and their families. These allergies are not only life-threatening, they are life-altering.

My son Zachary was diagnosed with several severe food allergies in infancy. When he was just 3 years old, Zachary ingested dairy at school and had an anaphylactic reaction. Let me tell you in simple terms what this means. Almost instantly, his blood pressure began to drop, his throat began to close, and he struggled to breathe. His eyes and face began to swell. Luckily, epinephrine was promptly administered and Zachary recovered.

I wish I could say this only happened once and that since then we have been able to avoid his allergens, but I cannot. Since then, Zachary has had multiple anaphylactic reactions, each one landing us in the emergency room not knowing whether he would live or die, and paralyzing me with overwhelming fear and anxiety.

Just this last summer, Zachary, now 10 years old, was off to summer camp. We did everything we are supposed to do as parents of a child with life-threatening food allergies. We met with camp directors and staff; we provided detailed, written instructions around his dietary limitations; we supplied substitute foods and epinephrine auto-injectors. None of that mattered though, because due to a simple oversight, pure human error, Zachary was given the wrong food one afternoon, sending him into his worst anaphylactic episode to date. The situation was so dire, we thought the

unthinkable: his food allergies were going to cost him his life. We would lose our son to something that should be preventable. While most parents who send their child to camp or school worry about homesickness or scrapes on the playground, our reality is different. Our greatest fear is that he will be accidentally exposed to sesame or one of his other allergens and not come home at all. This is our reality every single day.

As I mentioned, 32 million Americans have food allergies with a rise of nearly 400 percent in the number of hospitalizations for food allergies from just 2007 to 2016. One in thirteen children have a life-threatening food allergy. That is roughly two children in every classroom. The trend is frightening. Imagine how many people in the next generation could be at risk. We need to do more.

Today, sesame remains the most common allergen that is not required to be written on food labels and is often hidden on labels as spices or natural flavors. How are parents, schools, and other caretakers supposed to keep children like Zachary safe if companies aren't even required to label for their allergens. Nearly 1.5 million Americans are allergic to sesame.

When you consider this combined with the rapid increase in overall food allergies, it is clear we must act now. We

are thankful for organizations like FARE, who advocate on behalf of the food allergy community, and Congresswoman Matsui for introducing this important legislation. H.R. 2117 stands to drastically improve our day-to-day lives and change our reality. If passed, it will require the federal government to gather comprehensive information about who has food allergies, the kind of food allergies they have, and what types of food allergies occur most often. Further, it will update allergen labeling laws to include sesame and it would require labeling standards for additional allergens as new scientific evidence emerges.

We need this for me, for my family, and for families all over the country in every state and district. Now is the time to pass the FASTER Act. Thank you.

[The prepared statement of Ms. Day follows:]

********** INSERT 5 **********

Ms. Eshoo. Thank you very much, Ms. Day, for your powerful testimony. It is now a pleasure to recognize Mr. Carlin. You have 5 minutes for yours.

STATEMENT OF DAVID CARLIN

Mr. Carlin. Chairwoman Eshoo, Mr. Shimkus, and members of the subcommittee, thank you for inviting me to testify at today's hearing in support of the Codifying Useful Regulatory Definitions Act, which would define the term "natural cheese" in federal statute. My name is David Carlin and I am the Senior Vice President of Legislative Affairs and Economic Policy at the International Dairy Foods Association which represents the nation's dairy manufacturing and marketing industry.

U.S. cheesemakers have used the term "natural cheese" for more than 70 years to describe a particular category of cheese and to differentiate it from processed cheese in the supermarket. Natural cheeses are made directly from milk, while processed cheese is made by combining various natural cheeses to achieve certain characteristics desired by consumers such as how well a cheese will melt. Consumers know that a natural cheese like Cheddar or Havarti would be appropriate to serve at a social function and that processed

cheese is perfect for making a grilled cheese sandwich.

The term "natural cheese" has also been used extensively over several decades by FDA, USDA, Congress, and the courts to describe a particular category of cheese. Unfortunately, the ability of U.S. cheesemakers to continue to use the term "natural cheese" on their packaging is now threatened. 4 years ago, the FDA initiated a separate process to define how the term "natural" may be used to make product claims such as 100 percent natural or all-natural. Even though the term "natural cheese" is not a product claim and is only used to define a particular category of cheese, U.S. cheesemakers find themselves caught up in an unrelated policy debate that could force them to change decades' worth of labeling practices that generations of consumers have come to rely on when choosing the right cheese for every occasion. Defining the term "natural cheese" in statute will clarify its specific meaning and narrow the scope of FDA's work so that it can focus on how the term "natural" may be used to make product claims.

I would also like to note that FDA's technical experts have reviewed the CURD Act extensively over the past 2 years and all of their substantive comments have been addressed by the bill's sponsors. On behalf of our cheesemaking members, I would like to express our sincere appreciation for FDA's

careful review and extensive input regarding this legislation. The CURD Act is strongly supported by natural and processed cheesemakers and by the National Milk Producers Federation which represents dairy farmer cooperatives.

I would also like to use the rest of my time to address some of the misconceptions regarding this legislation. First, this would not be the first time that Congress has acted to define a dairy term or a type of food in federal statute. Definitions of butter and nonfat dry milk are already included in the Federal Food, Drug, and Cosmetic Act. Congress also passed legislation in 2002 that added definitions of ginseng and catfish to the act.

Second, the CURD Act does not change in any way the ingredients that may be used to make standard and nonstandardized cheeses. In other words, if a cheesemaker was permitted to use a particular ingredient to make a standardized cheese before this bill was enacted, the cheesemaker will still be able to use that same ingredient after enactment of this bill. Conversely, if a particular ingredient was not permitted to be used before, it would not be permitted to be used after enactment.

Third, the CURD Act does not change FDA's policy on the use of the term "natural" or all-natural claims and it does not establish a product's specific definition of natural.

The bill would simply codify a definition of natural cheese as a category of cheese. It does not define the term "natural" with respect to product claims. As stated earlier, Section 3 of the bill contains language that explicitly states that any cheese that makes a product claim such as 100 percent natural or all-natural must continue to comply with FDA's current regulations regarding those terms.

Finally, the CURD Act would not in any way create an inconsistency between FDA and USDA regarding the use of natural claims on labels. As members of this subcommittee well know, FDA regulates most food products including cheese, while USDA regulates meat, poultry, and certain egg products. Therefore, USDA's definition of "natural" only applies to those meat, poultry, and egg products that fall under its jurisdiction. FDA regulates cheese and, accordingly, the only definition of "natural" that is relevant to this discussion is FDA's definition of that term.

As stated previously, even if this bill is enacted, U.S. cheesemakers will continue to be required to comply with FDA's current policy and any future regulations governing the use of the term "natural" for product claim purposes. By preserving our industry's ability to use the term "natural cheese" to describe a category of cheese, the CURD Act would ensure continued clarity in the marketplace for consumers and

codify the historical regulatory use of the term by both FDA and USDA.

Thank you for inviting me to participate in today's hearing and I look forward to answering questions from members of the subcommittee.

[The prepared statement of Mr. Carlin follows:]

********** INSERT 6 **********

Ms. Eshoo. Thank you, Mr. Carlin.

Ms. Sorscher, you are recognized for 5 minutes for your testimony.

STATEMENT OF SARA SORSCHER

Ms. Sorscher. Good afternoon. Thank you, Chairwoman Eshoo, Ranking Member Burgess, and members of the committee. I am pleased to testify today on behalf of Center for Science in the Public Interest, America's food and health watchdog.

Since 1971, CSPI has represented consumers in advocating for a safer, healthier food system and has played a major role in pushing for laws governing food labeling including the Nutrition Facts panel, menu labeling, and allergen labeling. Our work is funded by individual subscribers to our Nutrition Action Healthletter and donations from individuals and foundations. We do not accept donations from corporations or government grants, allowing us to serve as an independent voice for consumers.

I will speak today primarily on two bills that would impact food labeling, the FASTER Act and the CURD Act. CSPI supports the FASTER Act which, among other things, would update the U.S. list of major allergens to include sesame. When Congress passed FALCPA in 2004, it created an important

new requirement for labeling the so-called major food allergens which were the eight most common allergens that had been identified at the time. The law also authorized FDA to label additional non-major allergens through separate regulations.

In 2014, CSPI was the first group to urge FDA to make use of that new authority by petitioning the agency for sesame allergen labeling. Recent studies have shown that sesame allergy is similar in prevalence and greater in severity than some of the big eight major food allergens required to be labeled. Importantly, a greater fraction of adults with sesame allergy report having an ER visit in the past year than adults with any other major food allergy, illustrating how difficult it is even for adults to avoid undeclared sesame in foods.

In addition, in 2018, CSPI reported that a majority of 22 large food companies that we surveyed were already voluntarily labeling for sesame and more indicated that they could easily do so if given clear direction from regulators. FDA opened a docket to collect data on sesame labeling in 2018, but it has taken no further action since that docket closed in December of that year. Given the clear and urgent need for sesame labeling and ongoing delay by the agency, we urge Congress to add sesame to the list of major allergens

through legislation.

CSPI opposes the CURD Act as this bill would confuse consumers by defining as "natural" any cheese product that does not meet the narrow regulatory definition of processed cheese. The ostensible purpose of the bill is to draw a clear line for consumers by defining processed cheese and differentiating it from natural cheese, yet processed cheese is already clearly labeled as such and there is no evidence that manufacturers are currently representing that such products are natural.

Instead of protecting consumer interest, the bill addresses the interests of cheese manufacturers who wish to be sheltered from litigation by consumers alleging that they were misled by natural claims on cheeses that contain artificial ingredients. For example, in 2016, Kraft was sued for natural cheeses alleged to contain artificial coloring; more recently, Sargento was sued based on feeding and rearing practices for the cows that produced the milk for its line of natural cheeses. CSPI is not involved in either of these cases and has not taken a position on the litigation, but we do oppose any legislative effort to distort the meaning of natural for the purpose of denying consumers their day in court.

While traditional cheesemaking involves only a few

ingredients -- high-quality milk, salt, and cultures -- the cheese industry today employs a host of novel processes and additives that can cut the time and expense required to produce cheese. These novel ingredients are not necessarily reviewed for safety by the FDA, which permits companies to self-certify new ingredients as generally recognized as safe without even notifying the agency or making safety data available to the public.

Certain artificial ingredients are also expressly legally permitted under the standards of identify for cheese. For example, artificial coloring is expressly allowed in many standardized cheeses. While legally permitted, many American consumers would not consider these cheeses to be natural. For example, a nationally representative telephone survey conducted in May 2018 by Consumer Reports found that more than 80 percent of consumers say "natural" should mean no artificial ingredients were used. That is why the USDA permits the term "natural" only on products containing no artificial ingredients or added color and that are only minimally processed.

FDA is also currently working on a definition of "natural" that ideally will be non-misleading and apply uniformly across all FDA-regulated foods. The CURD Act would seek to short-circuit that process by carving out a special

definition for "natural" that would only apply to cheese and run counter to consumer expectations. Finally, because the CURD Act also defines milk as lacteal secretions from an animal, it could be interpreted to prohibit the use of the term "natural" on nondairy alternatives eaten by consumers who are vegan, allergic to milk, or otherwise wish to avoid dairy cheeses. Use of the term "natural" should not be prohibited on these products, provided the products otherwise meet consumer expectations for that food. So we therefore urge Congress not to act prematurely and define "natural cheese" in a way that will confuse consumers and make the rule inconsistent with other labeling.

[The prepared statement of Ms. Sorscher follows:]

********** INSERT 7 **********

Ms. Eshoo. Thank you for your testimony.

And now, pleasure to recognize Ms. Perry for your 5 minutes of questioning.

STATEMENT OF NANCY PERRY

Ms. Perry. Thank you. Chairwoman Eshoo, Congressman Shimkus, and distinguished members of the subcommittee, thank you for inviting me to offer our support for the SAFE Act to end horse slaughter. The American Society for the Prevention of Cruelty to Animals is a leading voice for animal welfare as the very first humane organization established on this continent in 1866.

We strongly support the Safeguard American Food Exports Act as a critical missing link in the existing systems vital for protecting American equines. It has 225 bipartisan House cosponsors and every major animal welfare organization, along with 80 percent of the American public who support it. The ASPCA believes horse slaughter prevents serious food safety concerns, is a primary obstacle to achieve equine welfare by interfering with and depriving horses of good homes, and is, itself, a form of serious equine cruelty.

Congress has effectively banned horse slaughter since 2007 in annual spending bills with strong bipartisan support.

Both Presidents Obama and Trump requested this ban in their budget. Unfortunately, a loophole that still allows tens of thousands of American horses to be shipped over our borders for slaughter, the SAFE Act will close this loophole to protect our horses as well as human health.

Horse meat is unsafe. Horses are not raised for food in the U.S. and those who wind up for slaughter are not unwanted, but rather unlucky during career shifts from racetracks, riding camps, show barns, and ranches. They don't come from a setting where anyone ever expected they might become food. Veterinarians, owners, and trainers regularly administer myriad therapeutic treatments during daily horse care, many of which are expressly banned by the FDA for use on animals for human consumption.

Since horses are not raised for food, we don't track any of these treatments and horses change hands on average eight times throughout their lives, so it would be nearly impossible to do. In contrast, animals raised in our food system are closely tracked, fed approved feed, and are given approved drugs from birth to death. The FDA routinely visits farms enforcing its regulations when animals are given prohibited substances or even if records are inadequate or missing.

Phenylbutazone or bute is one of the most prevalent

drugs given to horses and the most toxic to humans. This carcinogen induces blood dyscrasias as well as hypersensitivity reaction in the liver which can cause renal failure and death. Due to its idiosyncratic health risks to humans, bute is only approved for use in dogs and horses. In FDA's own words, there are currently no approved uses of bute in food-producing animals. Also, there are no safe residue levels and no withdrawal periods for bute.

We have provided the committee with a list of more than 100 banned and dangerous substances commonly given to horses including dewormers, fly sprays, hoof hardeners, tranquilizers, hormone regulators, and anesthetics that are carcinogens or cause developmental issues in children, cardiovascular illness, or hormone-dependent cancers. FDA banned these drugs for consumption because they are toxic and should not be present in any concentration in our food.

Suggesting that we should send known toxic meat to other countries and export this obvious public health risk is irresponsible. The good news is that the number of American horses shipped to slaughter is actually declining, down to under 62,000 from over a hundred thousand in recent years, and welfare organizations and re-homing programs with industry engagement are at an all-time high. However, without a ban, we actually incentivize slaughter instead of

rescue, and compromise equine welfare.

Kill buyers bid against and outbid good homes at auctions, squandering resources by predatorily driving up prices. Even more insidious, these kill buyers then hold online auctions seeking ransoms for horses they would ship to slaughter, taking advantage of the public while competing with our rescuers. The ASPCA has compelling evidence now that horse slaughter actually causes neglect. More than 70 percent of owners surrendering horses to our support centers report keeping horses past the point of good care because they so feared their horse would end up at slaughter.

Horse slaughter is equine cruelty. These animals are not suited for this purpose due to their physiology, their flight response, and the slaughterhouse equipment for stunning. We support humane euthanasia for horses when quality of life is impaired, but slaughter is not euthanasia. Americans overwhelmingly oppose the slaughter of horses. It is a public health risk that we shouldn't be exporting to our neighbors. It is time to close this loophole, and I thank Representative Schakowsky and Buchanan for leading a bipartisan effort to pass the SAFE Act. Thank you.

[The prepared statement of Ms. Perry follows:]

********** INSERT 8 **********

Ms. Eshoo. Thank you. We haven't had any lunch here, but I just lost my appetite.

Ms. Perry. Sorry.

Ms. Eshoo. Thank you, Ms. Perry.

Dr. Corey, it is a pleasure to recognize you for your 5 minutes of testimony.

STATEMENT OF DOUGLAS COREY

Dr. Corey. Thank you. Chair Eshoo and Ranking Member Burgess and distinguished members of the subcommittee, thank you for the opportunity to appear here today. My name is Dr. Douglas Corey and I have been an equine veterinarian for more than 40 years. I am here today not only as a longtime horse owner, but also as a past president of the American Association of Equine Practitioners, a professional association which represents the vast majority of equine veterinarians in the country. I have served as chair of the AAEP's Equine Welfare Committee, the American Veterinary Medical Association Animal Welfare Committee, and the Unwanted Horse Coalition. I also serve on the American Horse Council Welfare Committee.

There is little evidence that shows consuming equine meat from horses raised in the United States poses a threat

to public health. Each country accepting horse meat is responsible to ensure that the product is safe for citizens to consume. As an example, horses being transported to Canada for processing must be held in holding facilities for 6 months to ensure there are no medication residues. Additionally, the meat of horses processed in Mexico and Canada is tested for drug residues, heavy metals, bacterial contamination, exactly like what is done with beef, pork, sheep and, in addition, the European Union has its own regulations regarding drug residues in horse meat.

Our primary concern is this bill will negatively impact the health and welfare of horses across the country and offers no solution to the problem of the unwanted horse. The unwanted horse represents a group of horses within the domestic equine population that are no longer wanted, needful or useful, or their owners are no longer interested in them or are not financially able to provide the horse with appropriate care.

Our chief welfare concerns in the bill are, number one, the long-term placement of these unwanted horses. It is estimated that there are approximately eighty to a hundred thousand horses are transported to Canada and Mexico for processing annually. The proponents of the legislation suggest that these additional horses will be absorbed by the

alternative homes, the rescues, and retirement facilities. However, these options are already under stress and overcrowded. With a life expectancy of 20 to 30 years, where will the additional facilities and funding come from to care for these animals? In addition, many of the individuals who adopt horses are often unprepared for the cost to adopt and provide proper care and feeding for a horse.

While many of these people are well-intentioned, the sad fact is that without proper resources many of these horses are headed for a much worse fate of starvation, neglect, and abandonment. It would be nice to absorb every unwanted horse into the equine society, but as history has proven there simply are not enough people with the desire, the means, the knowledge, and/or assets available to respond to the need.

Two, the bill does not address the funding required for the care of these additional horses. To provide a horse's basic needs, the funding needed for 1 year per horse is approximately $1,800. Inadequate funding often leads to inadequate care. Third, in regards to the bill itself, it will not stop the transportation of horses for other reasons such as sporting events, sales, recreation. Once they cross the border, this language would not stop horses from being processed.

The AAEP partners with a number of equine welfare

organizations that have enhanced efforts and outreach to improve rescue, retirement, and re-homing facilities, promoted more adoptions, and offer a safety net of programs for owners in need including stallion castrations, euthanasia, and disposal assistance. As you can see, this industry is coming together to address the problem and we are pleased that this concerted effort is reducing the number of unwanted horses. The AAEP believes that processing is not the ideal solution for addressing the large number of unwanted horses. However, if a horse owner is unable or unwilling to provide humane care and no one can assume that responsibility, humane euthanasia at a processing facility in accordance with AVMA's euthanasia guidelines is an acceptable alternative to a life of starvation, neglect, or abuse.

In summary, we all must work together to address the root cause of this unwanted horse. We need proactive solutions and believe that the AAEP and equine welfare advocates are developing these solutions that will continue to help decrease the number of unwanted horses. However, and most importantly, supporting this bill will not improve the welfare of the horse. Thank you for the opportunity to address you today and I would be happy to answer questions at the end.

[The prepared statement of Dr. Corey follows:]

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3246 ********** INSERT 9 **********

Ms. Eshoo. Thank you, Dr. Corey.

Mr. Balmer, you are now recognized for your 5 minutes of testimony and thank you.

STATEMENT OF TOM BALMER

Mr. Balmer. Chairwoman Eshoo, Ranking Member Burgess, members of the subcommittee, my name is Tom Balmer and I serve as Executive Vice President of the National Milk Producers Federation, the voice of America's dairy cooperatives and their farmer owners for over 100 years. I thank you for the opportunity to testify on the DAIRY PRIDE Act, a bipartisan bill intended to finally enforce or, excuse me, to finally compel FDA to enforce its existing standards of identity for dairy products.

Mr. Welch, we commend you for introducing this legislation and thank your co-author Mr. Simpson and many others for their support. We also commend Senator Baldwin and Risch for authoring this measure in the Senate.

At its core, the DAIRY PRIDE Act would ensure the accurate and appropriate labeling of nondairy foods that use standardized dairy terms, an issue with significant implications for consumers. Federal standards of identity were established to promote honesty and fair dealing in the

interest of consumers by promulgating reasonable definitions for food products. These defined terms have come to carry distinct meanings in the minds of consumers.

Dairy farmers work hard to make products that are wholesome, nutritious, and in compliance with these standards. However, for decades the FDA has been negligent in their enforcement, particularly with respect to the clear requirement that a product labeled as milk or yogurt, for example, originates from cows and other lactating food animals. Unfortunately, grocery stores today are filled with copycat products that flout these long-established standards of identity and mislead consumers about their nutritional equivalents with real dairy products.

Real milk is a nutritional powerhouse. It is full of numerous vitamins, minerals, and other nutrients essential to human health. Milk is the number one source of nine nutrients in children's diets including potassium, calcium, and Vitamin D. According to the 2015 Dietary Guidelines for Americans, these are three of the four nutrients for public health concern.

These guidelines also recognize that most plant-based imitation milk products are not nutritionally equivalent to milk. Plant-based food processors like to use terms such as "milk" on their products in a blatant attempt to trade on the

health halo and other positive attributes of the real thing. The widespread marketing of these imitation products has created an abundance of consumer confusion. Evidence shows that consumers think that plant-based products are nutritionally equal to or better than those from cow's milk. An Ipsos survey conducted in 2018, found that 73 percent of consumers surveyed believed that almond-based beverages have as much or more protein than a serving of milk. In reality, milk has up to eight times as much protein per serving.

The 2015 Dietary Guidelines also found that most Americans don't meet the recommended intake for dairy. The upshot of this is that there are real consequences to a drop in the intake of nutrients that dairy provides. Recognizing this, four leading health groups, the American Academy of Pediatrics, the American Heart Association, the Academy of Nutrition and Dietetics, and the American Academy of Pediatric Dentistry issued a report last fall urging that young children not be fed most plant-based imitation products in place of cow's milk as their nutrition profiles are largely not equivalent to real milk.

My organization has repeatedly raised concerns with FDA regarding its failure to enforce the law. We were encouraged when former Commissioner Gottlieb announced in 2018 that FDA would finally look at this issue. During the FDA's review

process, multiple health stakeholders voiced concerns about consumers not grasping the nutritional differences between real dairy products and imitators. Although we were hopeful that FDA would finally act, their timeline has continually shifted with no endpoint in sight. Unless Congress acts, FDA's follow-through remains uncertain.

That is why we are encouraged that the DAIRY PRIDE Act is included in today's hearing. The bill is not complicated. It simply directs FDA to promptly explain how it will enforce existing standards of identity for milk and other dairy foods. It would require foods that use standardized dairy terms inappropriately to be considered misbranded on under the law and subject to enforcement.

Speaking of misbranded, I would be remiss if I did not point out that imitation dairy products labeled as plant butter are currently in the marketplace and are in violation of the statutory definition of butter established by the Butter Act of 1923. In past years, FDA has stated that any product that used the term "butter" and does not meet the enacted definition is misbranded. Nonetheless, the word "butter" is now being used to market imitation products nationwide.

FDA's decision not to enforce the definition amounts, in effect, to an agency rewriting an act of Congress. I point

this out to underscore a widespread pattern of deception that can cause consumers to make well-intentioned but misguided purchasing decisions for themselves and their families.

Madam Chair, I want to thank you once again and the ranking member for holding today's hearing. We appreciate the opportunity to testify and look forward to answering any questions members may have.

[The prepared statement of Mr. Balmer follows:]

********** INSERT 10 **********

Ms. Eshoo. Thank you, Mr. Balmer.

I love hearings. I just learn so much from what everyone has to say.

I now have the pleasure of recognizing Ms. -- is it Benesh or?

Ms. Benesh. Benesh.

Ms. Eshoo. Benesh -- for your testimony. You have 5 minutes, and you can proceed.

STATEMENT OF MELANIE BENESH

Ms. Benesh. Thank you for the opportunity to testify.

Ms. Eshoo. Welcome.

Ms. Benesh. PFAS chemicals are in the blood of virtually every living being and have been linked to serious health threats including kidney and testicular cancer, reproductive harms like lower sperm counts and lower birth weights, developmental harms like altered mammary gland development, and even immunotoxic effects like reduced effectiveness of vaccines. When released into the environment, PFAS chemicals stay there forever.

The Environmental Working Group has identified nearly 1,400 communities with contaminated water, but unless you live in one of those highly contaminated communities your primary source of PFAS exposure is actually from your food. PFAS gets into food in many ways, one of which is through migration from food packaging like pizza boxes, sandwich wrappers, and microwave popcorn bags, but PFAS also gets into food from PFAS in irrigation water or biosolids that are applied to farm fields that then build up in livestock, plants, and even in milk.

Many PFAS chemicals were allowed for use in food

packaging before FDA understood the risks, but chemical companies have also hidden the risks of PFAS from FDA. Dupont and 3M have a long history of hiding the risks, of hiding information about the toxic effects of PFAS from regulators like EPA and FDA, and some companies continue to hide the risks from FDA. More recently, between 2008 and 2016, Daikin, a Japanese company that makes PFAS chemicals, submitted applications to FDA for the use of a PFAS chemical in food packaging, but withheld information from two of their own internal company studies that showed toxic effects to the liver and kidney, and FDA did approve those food contact notifications. And companies also take advantage of a legal loophole in the law that allows them to use PFAS chemicals without any FDA review at all and without even notifying FDA.

But FDA has also failed to protect us. FDA has known at least since 2005 that PFAS chemicals migrate from food packaging into food, but failed to take action until 2016 and only then after response from a petition from NGOs. When companies do submit a chemical to FDA for approval either for use in food or food packaging, the law requires that industry show with reasonable certainty that that chemical is safe. But for PFAS chemicals industry has consistently failed to meet that legal burden, like failing to provide FDA with studies about the reproductive harms or immunotoxic effects

from PFAS chemicals even though we know that those health effects are associated with PFAS chemicals even at low doses.

In turn, when FDA reviews those submissions, the law explicitly requires that FDA take into consideration the cumulative risks from chemicals like PFAS; that is not only the PFAS that is in the food wrapper, but also your other exposures from PFAS in food, water, air, or other household products, and yet FDA has consistently failed to provide that cumulative risk analysis. And, in fact, FDA has not even established safety values to calculate what it considers to be a safe amount of PFAS in food.

And yet, despite these glaring data gaps and the lack of scientific information, FDA has continued to authorize PFAS food contact substances and these decisions were made through a process that involves no public involvement or oversight, minimal transparency, and no clear way for consumers to challenge FDA's decisions. We cannot afford to wait and see if FDA will finally follow the law and properly review PFAS in food packaging. Given the risks posed by PFAS, Congress should take action to end nonessential uses like PFAS in food packaging.

Cleaning up the legacy of PFAS pollution from polluters like Dupont, 3M, the Department of Defense, and other bad actors who have been emitting PFAS and dumping PFAS into

waterways for more than 50 years is a complex problem and it will take decades to clean up that legacy pollution. But by contrast, eliminating a nonessential use like PFAS in food packaging is relatively simple. Congress can simply ban it and remove that source of exposure.

This is an emergency. States and local governments have not been waiting for FDA to take action. Washington State banned PFAS in food packaging in 2018 and that ban will take effect in 2022. The City of San Francisco has already implemented a ban on PFAS in food service ware. Retailers like Giant, Food Lion, Stop & Shop, Panera, Taco Bell, McDonald's, Burger King, are also not waiting for FDA to take action and have indicated that they are moving to alternatives.

And Congress should not wait for FDA to take action either. We urge you to support H.R. 2827, the Keep Food Containers Safe from PFAS Act, and thank you for the opportunity to testify and I look forward to your questions.

[The prepared statement of Ms. Benesh follows:]

********** INSERT 11 **********

Ms. Eshoo. Thank you very much.

Dr. DeLeo, it is a pleasure to welcome you. You have 5 minutes for your testimony.

STATEMENT OF PAUL C. DELEO

Mr. DeLeo. Good afternoon, Chairwoman Eshoo, Representative Shimkus, and members of the subcommittee. Thank you for the invitation to speak before the subcommittee today. My name is Paul DeLeo and I am a principal at Integral Consulting, an international science and engineering consulting firm of 150 employees nationwide. I am based in Annapolis, Maryland.

I am pleased to be here today to express my scientific opinion on H.R. 2827, the Keep Food Containers Safe from PFAS Act of 2019. However, I would like to note that no client or any other entity has retained me to offer this position. I am here today based on my firm's expertise of PFAS and my firsthand knowledge of the regulatory process for the safety assessment of food contact substances, having worked for 6-1/2 years at the Food and Drug Administration in the office with those responsibilities.

I testify here today in opposition of H.R. 2827 as unnecessary, overly broad, and contrary to the well-

established scientific processes for the premarket evaluation of the safety of chemicals in the United States. FDA has had the responsibility for the regulation of food additives since 1938. FDA has well-trained and highly dedicated staff who are fully capable of evaluating PFAS chemistries in food packaging. Prior to 2000, FDA authorized uses of food contact substances through the food additive petition process. However, since 2000, FDA authorizes the use of food contact substances through the food contact notification program.

According to FDA online databases, the current universe of regulated PFAS food contact substances is approximately 100 substances. This is a modest number of substances, all of which have been evaluated by FDA staff prior to being permitted to come to market as a food contact substance. There are substantial data requirements associated with the food contact notification program and the agency has the authority to object to any notification if it does not believe the proposed use of a food contact substance is safe.

In addition, the Federal Food, Drug, and Cosmetic Act gives the agency authority to require or accept submission of a food additive petition for the food contact substance in cases where it is necessary to provide adequate assurance of safety of that substance. Once a food contact substance is

on the market, FDA has the ability to track the safety of these chemicals and has a record of doing so for PFAS. For at least 15 years, scientists at FDA have been publishing peer-reviewed scientific papers regarding the potential for PFAS to migrate from food contact substances and the safety of those exposures. Moreover, FDA can revoke food contact authorizations when scientific data demonstrate that the authorized uses of a food contact substance are no longer safe, or remove food contact substances from the market through voluntary agreements.

Recently, FDA revoked several food contact authorizations based on their abandonment by the manufacturer. H.R. 2827 is overly broad because it would apply to any PFAS used in food contact substances without consideration for its safety. For example, polymeric PFAS, also known as fluoropolymers, are not bioavailable or bioaccumulative and they satisfy the widely accepted assessment criteria to be considered polymers of low concern around the globe. Therefore, they are considered to be of low hazard to human health in the environment.

More importantly, the impacts of H.R. 2827 would be very broad because although the number of individual PFAS food contact substances may be modest, PFAS have been safely used throughout the food supply in a variety of applications for

decades. Therefore, it is not possible to predict the implications for food safety and the potential unintended consequences such legislation might precipitate. The rapid and broad changes would lead to disruption and confusion in the food industry and potentially compromise the safety of the U.S. food supply.

Consumers in the U.S. benefit from a robust regulatory regime that requires new chemicals and new chemical applications to be evaluated for safety before they are permitted to be brought to the market. These programs have a long track record of success and Congress has a long track record of successful oversight and reform when it is necessary to adapt those programs. The hallmark of safety regulation in the U.S. is a transparent, scientifically rigorous, risk-based process. The arbitrary declaration of an indeterminate number of PFAS applications as unsafe flies in the face of the track record of success of U.S. regulatory agencies and programs with unpredictable, potentially wide-reaching, disruptive consequences.

In conclusion, by recommendation to Congress would be to the extent there is concern regarding PFAS that it work closely with FDA to understand the safety of currently permitted uses of PFAS as food contact substances, to retrospectively analyze the assessment process, and to make

sure that the agency has the tools and resources necessary to fully address PFAS's food contact substances.

Thank you again for this opportunity to share my perspective. I look forward to your questions.

[The prepared statement of Mr. DeLeo follows:]

********** INSERT 12 **********

Ms. Eshoo. Thank you very much for your testimony.

Welcome to the table, Ms. Mountford. Glad you made it. You have 5 minutes to present your testimony to us, and thank you again for being with us.

STATEMENT OF MARDI MOUNTFORD

Ms. Mountford. I am on? Okay. Good afternoon.

Ms. Eshoo. Move it closer, so --

Ms. Mountford. Okay, there we go.

Ms. Eshoo. -- we don't miss a word.

Ms. Mountford. Good afternoon. I am Mardi Mountford, president of the Infant Nutrition Council of America, or INCA, and I appreciate the opportunity to address H.R. 2267, the Infant Formula Protection Act of 2019. INCA is an association representing manufacturers of infant formula who make over 95 percent of the formula fed in the United States.

The primary focus of INCA and its member companies is and will always remain the health and welfare of infants and young children. That is why we share Congresswoman Meng's goal of preventing the purchase of infant formula that is past its use-by date and we support the intent of H.R. 2267. Most babies in the United States receive infant formula, which is the only safe and medically recommended alternative

to human breast milk, at some point during their first year of life. Most new moms initiate breastfeeding when their baby is born, but may supplement or switch to infant formula during the first year. For this reason, ensuring the quality of infant formula is very important to manufacturers as well as millions of parents, caregivers, and infants.

Infant formula is one of the most highly regulated foods in the world because it may be fed as a sole source of nutrition at a critical time of infant growth and development. This makes quality a key factor for regulatory oversight. U.S. infant formulas are manufactured with high quality ingredients and with strict adherence to the U.S. Infant Formula Act and to FDA's Good Manufacturing Practices.

All infant formulas are required by law to include a use-by date on the container which ensures that throughout the product's shelf life it provides the 30 essential nutrients listed on the label. Infant formula fed past the use-by date may not deliver all the nutrients at the exact levels that are listed on the label because some of the nutrients degrade over time. Thus, the use-by date is primarily an indicator of product quality, not safety.

By contrast, the term "adulterated" as defined by FDA generally means a product that is harmful or injurious to human health because it contains a poisonous or deleterious

substance. And although the definition of adulterated includes specific infant formula provisions, they refer to manufacturer activities rather than retailers. Accordingly, calling an infant formula that is past its use-by date adulterated would be inconsistent with existing definitions in the law and would not address the issue of concern that is selling expired formula.

Therefore, INCA suggests alternative language that would instead more clearly prohibit the retail sale of infant formula past its use-by date. Indeed, Congress took a similar approach in 2011 with the passage of the Food Safety Modernization Act when it implemented preventive controls and created a new "prohibited act." We suggest the Infant Formula Protection Act of 2019 be implemented in a similar manner.

INCA and its member companies consistently work with stakeholders to ensure infant formula is safe and nutritious. INCA meets regularly with the FDA's Office of Nutrition and Food Labeling to share information on infant feeding issues of mutual importance. INCA is working with the retail industry to develop a joint resource guide outlining best practices for handling infant formula returns and ensuring returned or expired product is never reshelved. INCA is also engaged with USDA regarding strengthening recommendations

that state WIC agencies do not accept expired or returned infant formula or allow it to be given to area food banks or distributed through any other channels due to potential safety and quality concerns.

In summary, INCA supports the intent of the Infant Formula Protection Act of 2019, but believes the best way to accomplish the goal of legislatively precluding the retail sale of expired infant formula is to amend Section 301 of the Federal Food, Drug, and Cosmetic Act. Failure to abide by this restriction would constitute a prohibited act. We believe this would be the most effective way of supporting the collective goal of establishing statutory measures that ensure formula-fed infants receive safe, nutritious products while continuing to reassure parents and caregivers about the high quality of that formula.

INCA and its members look forward to working with the bill sponsor, the committee, and all interested stakeholders to determine a workable solution to this issue. Thank you for the opportunity to testify today and I am happy to answer any questions.

[The prepared statement of Ms. Mountford follows:]

********** INSERT 13 **********

Ms. Eshoo. Thank you very much for your testimony and that of all of the witnesses. I think you all have done a superb job. So now we have concluded your opening statements. We are going to move to member questions now, and I will recognize myself for 5 minutes kicking that off.

The FDA regulates about 77 percent of the U.S. food supply. That is a lot, 77 percent. This includes, and this was mentioned earlier, I don't know, by testimony or maybe one of the opening statements of a member that it includes everything we eat except meat, poultry, and some egg products.

I am concerned that the FDA may not have the adequate staff and the resources to carry out -- it has extraordinary responsibilities, but there is also, just as there is here, political will, I think sometimes that may be missing at the FDA as well to make the hard choices about food regulation and safety because they are controversial. I mean we hear the differences right here on the panel. But, very importantly, it shows up in delays in FDA regulatory or enforcement action and I think that is where we come in on this.

So let me start with, you can just answer this really very quickly starting with Ms. Day, how long have you been waiting for the FDA to take action on sesame allergen

labeling? You know, it has never been done. I don't know. How old is your son now?

Ms. Day. My son is 10 years old.

Ms. Eshoo. Okay. Well, and you gave the example of when he was 3?

Ms. Day. Yes.

Ms. Eshoo. Okay. That says something.

Ms. Day. And I will say I would like to add in that sesame is labeled in Canada, in the European Union, in many places in Asia already, so America is behind.

Ms. Eshoo. Yes, I am on this. I called over to the FDA and spoke to the lovely person that heads up the division or the department on this to see if it was better if we just get this done administratively or should we go the legislative route. Administratively it was going to take 5 to 7 years; 5 to 7 years, I mean, you know, that is a long time. So, thank you for your answer.

Ms. Benesh, how long has the Environmental Working Group been petitioning the FDA on the issue of PFAS contamination in food?

Ms. Benesh. Environmental Working Group has been working on PFAS chemicals for 20 years no, and the first action that we took on food packaging was in 2003.

Ms. Eshoo. But petitioning the FDA?

Ms. Benesh. We have only -- we were part of the NGO petition that was filed in 2015, but we have been raising concerns about this issue for the last 15 years.

Ms. Eshoo. Okay, so it has been a long time.

Ms. Sorscher, how long have you been waiting for the FDA to define "natural" in food products?

Ms. Sorscher. I would say it has been a while, yes.

Ms. Eshoo. Well, what does that mean though, because we need that for the testimony for the record.

Ms. Sorscher. Yes, so FDA had this issue in its unified agenda for some time. I have the --

Ms. Eshoo. I think in your testimony you said 4 years?

Ms. Sorscher. So we have been waiting on sesame labeling since 2014.

Ms. Eshoo. Dr. Balmer, how long have you been petitioning the FDA to make a decision on the use of "dairy" to describe certain foods?

Mr. Balmer. We submitted our first complaint to FDA on this subject in 1979.

Ms. Eshoo. Holy moly. And I remember 1979, so I have been around for a while.

Ms. Sorscher, should the FDA -- this is a broad question, but it is something that I have thought for many years. And going back to when Senator Kennedy was still with

us, we did legislation, myself in the House, he obviously in the Senate, to make the FDA an independent agency with a 6-year term for a commissioner so there wouldn't be any political entanglements with the agency. And we can see from your testimony there are really some split decisions between FDA and other agencies.

Do you have a view on that, both Ms. Sorscher and Ms. Benesh? If you don't, it is okay. You look floored by my comment, but.

Ms. Benesh. Particularly about the --

Ms. Eshoo. About FDA. About FDA. As public health advocates, do you think that if the FDA were an independent agency that that would, A) that it would be able to make decisions that were more timely on any of the issues that are before us at the table -- we have two, four, six, eight witnesses.

Ms. Benesh. We think what is clear is that FDA has been slow to act on this particular issue and --

Ms. Eshoo. Got it.

Ms. Benesh. -- we are one of many organizations that are frustrated by that.

Ms. Eshoo. Anyone else? Anyone else have -- my time is expired, so did you want -- does anyone else want to comment?

Ms. Sorscher. I would say it is very important for FDA

to be able to preserve that independence. I don't know if I can comment on the particular legislation.

Ms. Eshoo. Right. Thank you.

All right, my time is expired. I am pleased to call on -- and it is not Dr. --

Mr. Shimkus. Burgess.

Ms. Eshoo. -- Burgess. It is Mr. Shimkus from the state of Illinois, recognized for 5 minutes of questioning.

Mr. Shimkus. Thank you, Madam Chairman.

Dr. DeLeo, anyone else a scientist on this panel? So timing is an interesting thing and, you know, I am on the toxic chemical committee. The scientific process, just going through the deliberations of how long it takes to prove something is safe or not, Dr. DeLeo, just how long does it take for a scientific process to go through the multiple generations, would you say?

Mr. DeLeo. With regard to this issue it is an activity that the agency FDA can do in a manner of months. Now the issue becomes if there are questions and new data what happens then, and there are time constraints around the food contact notification process where the agency can stop the clock and get the data it needs.

Mr. Shimkus. Well, let me go in this route then. Per- and polyfluorinated compounds, commonly known as PFAS, there

is a list of about 7,866 at least through the EPA. To make things -- so that is a lot. So I had -- my total always, my concern is throwing all 7,866 under a bright line of this is bad and it is really doing great damage to society is not fair nor is it correct without doing the due diligence of the scientific community. It is easy for us emotionally to do this, but it is not scientific in the application. So we can briefly break up this 7,866 into long chain and short chain, and you, I think, in this world of packaging, you mentioned a hundred of the 7,866 --

Mr. DeLeo. Right.

Mr. Shimkus. -- that are commonly used. In the U.S., are older long-chain fluorinated chemistries such as PFOA and PFOS still used for grease-resistant and moisture coatings on food packaging?

Mr. DeLeo. It is my understanding that they are no longer used.

Mr. Shimkus. And that for my colleagues, those two were the real big debate in the bill that went to the floor. Following up on that question, is there specific short-chain PFAS chemistry currently used in food packaging subject to careful review and approval by the FDA?

Mr. DeLeo. Yes, they all would have been gone through the approval process at FDA.

Mr. Shimkus. So that means careful review?

Mr. DeLeo. Absolutely.

Mr. Shimkus. And approval?

Mr. DeLeo. Correct.

Mr. Shimkus. Part of the debate that we have had too on the other bill was that this stuff has been vetted by the FDA.

Mr. DeLeo. Yes, and they have opportunities again to ask for more data, to stop the clock, to object if they don't believe in the safety of those applications.

Mr. Shimkus. Do you have confidence that the FDA has highly dedicated and capable staff to conduct these evaluations and ensure the safety of food packaging and public health?

Mr. DeLeo. Yes. Having worked with those staff personally, they are excellent, well-trained, highly-trained national, if not global, experts in this area.

Mr. Shimkus. Does FDA have sufficient staff resources to review complex chemistries such as per- and polyfluorinated compounds?

Mr. DeLeo. I believe they have the resources they need for the day-to-day review of applications. The question of, you know, a retrospective look at, you know, what has occurred, I don't know the extent to which that might require

additional resources. That is probably something you would want to check with the agency about.

Mr. Shimkus. Should Congress circumvent FDA's expertise and authority to regulate PFAS chemistries in food packaging?

Mr. DeLeo. I think FDA is the best agency to regulate these chemistries in food contact applications.

Mr. Shimkus. So if this bill were to pass what would be the real-world implications of this ban?

Mr. DeLeo. I think you would have a lot of disruption because you have a lot of uses, and I think the food industry that would be impacted wouldn't know about it and would suddenly be faced with the question of, do I have something to replace it. As was discussed previously, Washington State is implementing a ban on PFAS in food packaging, but that only goes into place if there are alternatives available.

So that question of, is there an alternative available for what would be banned is not considered in this legislation and you could have broad-reaching implications. We have, you know, folks from the dairy industry here who could be impacted and much of the other industries in the food supply.

Mr. Shimkus. Yes, and so I think the other concern is, what do they replace it with and going through the vetting process and the like. This fight will continue. And I would

just end on we need to do the scientific process. We don't need to move and regulate based upon emotion, but let science lead the debate and discussion and then move forward. So with that, I thank you for your time and I yield back.

Ms. Eshoo. The gentleman yields back. Pleasure to recognize the gentlewoman from California, Ms. Matsui.

Ms. Matsui. Thank you, Madam Chair.

Ms. Day, welcome to the Energy and Commerce Committee and thank you for sharing your personal story on parenting a child with life-threatening food allergies. I can relate to this, your story about Zachary and camp. And I have a grandson who has a peanut and nut tree allergy and he is begging to go to camp and, finally, this year we are going to let him do that. But what you said about talking to the camp counselors and packing an encyclopedia of dos and don'ts and packing the EpiPens, that is what we are facing. So this is a real thing that we have to deal with every single day and I applaud you for coming here today.

And I also want to thank the Center for Science in the Public Interest for supporting my bill, the FASTER Act. We know that 32 million Americans have food allergies, including one out of every thirteen children. Their daily lives center around avoiding certain foods and taking precautions against accidental exposure to allergens. Given the dramatic

increase in the prevalence and severity of food allergies over the past few decades, it is likely that many people in this room have a friend or a family member impacted by food allergies. I myself have a crab and lobster allergy which, I guess, is crustacean/shellfish.

In order to advance treatment and improve the lives of people with food allergies, we must do more to recognize and study food allergies as a public health issue. That is why I have introduced the FASTER Act, legislation that updates allergen labeling laws, increases research, expands patient experience data to include food allergies, and studies the economic cost of food allergies. By improving the ways in which we monitor and manage these complex and multifaceted diseases, we can better understand, treat, and maybe one day prevent food allergies.

I want to spend some time talking about sesame, as the FASTER Act has a provision requiring that foods containing sesame disclose its ingredient on the food label. When discussing my bill, I often find there is some confusion around whether food manufacturers must list all their ingredients on labels.

Ms. Sorscher, under current law, what major food allergens must be disclosed on food labels?

Ms. Sorscher. So, currently, the eight most prevalent

allergens have to be disclosed on food labels and sesame is number 9 so it is not required to be disclosed.

Ms. Matsui. Number 9, okay. And it is clear that the FDA can act on its own to update the list of major allergens. Why do we need legislation to achieve this goal?

Ms. Sorscher. So we have urged FDA to update the list and as I said we submitted a petition in 2014 and we have just been waiting a very long time. They did open a docket in 2018 and received comments. They have more than adequate data to make this decision and it has just been delay, delay, delay.

Ms. Matsui. Okay.

Ms. Day, without an explicit requirement in some cases sesame is listed in nonspecific terms like tahini and spices, correct?

Ms. Day. Correct, yes.

Ms. Matsui. Okay, then. Tell me, how do you manage to avoid exposing Zachary to sesame when it isn't labeled?

Ms. Day. So I will say it is quite difficult. The onus is very much on the caretaker or the parent to read every label which already takes a lot of time and resources. And then when you also need to look for terms like spices, natural flavors, when you see that you know it can be hidden and so you have to then call the company and see if they will

tell you if sesame is included in that term.

Ms. Matsui. Right, right.

Ms. Day. So there are often products out there that I imagine he could eat if it were labeled, but I can't give it to him and take that chance.

Ms. Matsui. Oh, exactly. I read labels all the time and it is just endless. It is terrible, and they are very small too.

Ms. Day. Yes.

Ms. Matsui. You also mentioned the number of hospitalizations for food allergies has increased by 400 percent in the last decade. A 400 percent jump is an astounding increase and it is certainly a public health problem especially when we are talking about the kinds of very serious, life-threatening reactions many children are experiencing. Do we know why we are seeing such a rapid increase?

Ms. Day. So the answer is we don't. I wish we knew. All we can say is --

Ms. Matsui. We need more research.

Ms. Day. -- there is proof that there is this rapid increase, the reason why still needs more research.

Ms. Matsui. Right. So that is what this bill is all about too, increasing the research so that we can understand

why we have the allergens, what people react to on that nature too. But in the meantime, you know, the only way that we can actually avoid this is really know what is in the food we have, so that is why this labeling is so important.

I have had experience of reading these labels and I have to read them twice and then I also have to call too. I mean we are very much concerned about, especially with Robby going to camp and you never know because you are in an accidental type situation there too. So, anyway, this is something that people really have read about and have to understand when you have a family member or friend who is exposed to some sort of allergen, it is serious. So anyway, I yield back. Thank you.

Ms. Eshoo. I thank the gentlewoman and thank you for your important work on this legislation. Pleasure to recognize the patient Dr. Bucshon from Illinois for his 5 minutes of questions.

Mr. Bucshon. Thank you very much. I mean, I am intrigued by this hearing because it is, you know, if the American public are listening, I don't think there is anything safe left in food in America. It is just striking.

A couple of questions, Ms. Mountford. You stated that the use date is an indicator of product quality not safety, so infant formula consumed past the use date is not unsafe?

Ms. Mountford. No.

Mr. Bucshon. It just doesn't provide the nutrients that are --

Ms. Mountford. At the level that they are listed on the label, correct.

Mr. Bucshon. Correct. So what are the health implications, potentially, of using it after the use date then? I mean other than the specific things that are in there, there is no negative health implication, per se, of using it, it is just there is a negative health implication because you are not getting the nutrients there.

Ms. Mountford. That is correct.

Mr. Bucshon. Okay.

Ms. Mountford. And not getting the nutrients like for 1 day would obviously not be a problem.

Mr. Bucshon. Probably not do anything.

Ms. Mountford. You would have to not get the nutrients for a long time, so.

Mr. Bucshon. Right, so the term "adulterated" could be misleading; that was your testimony.

Ms. Mountford. Absolutely.

Mr. Bucshon. Because reading about what that means, that means it wasn't even processed or developed based on the criteria that would be safe, potentially.

Ms. Mountford. Adulterated means that it has something harmful in it.

Mr. Bucshon. There is potential, so adulterated would mean that there actually is a safety concern, not a quality concern.

Ms. Mountford. Absolutely.

Mr. Bucshon. Right.

Ms. Mountford. Yes.

Mr. Bucshon. So I think that was kind of my concern with what we are maybe putting that language in, in the way it is described.

I am interested in the milk situation, Mr. Balmer. I mean, I have children who are in their 20s and they drink, you know, almond milk-milk, so to speak and all that and we have actually had this conversation in my household and asked them to actually look at what is labeled on the product.

And honestly, just personally, I do have a problem labeling things incorrectly. Not just this, but anything, because fundamentally I think it is a marketing, deceptive marketing practice to grab market share which is -- and so, in general, as a member of Congress, anything that companies, no matter what industry they are in that purposefully, deceptively, try to gain market share by mislabeling things is an issue.

And I guess I am struggling to find out why, you said 1979 you voiced this complaint, why the FDA in this particular instance has refused to do it. Is the industry out there that is producing these? And, honestly, some of it is probably going to be cultural and social pressure right now not to enforce it, I would say. I mean why do you think the FDA is not doing anything when it is pretty clear that -- and I am not criticizing the other companies. I am just saying in general I don't like it when people try to market things to people when they know, they know that it is a marketing tool and not really has no -- and the product is not labeled properly. Why is the FDA not doing anything about it?

Mr. Balmer. We appreciate your comments and obviously would concur. For years, we were told by FDA that it wasn't a priority because it was a labeling issue and it wasn't of public health concern and their first order of business is always public health maybe as it should be. But we have experienced now this growth of these imitation dairy products not meeting nutritional equivalents.

Mr. Bucshon. Right so -- yeah.

Mr. Balmer. There are episodes now where there are malnourished children out there because well-meaning parents are feeding the substitute products and assuming because they

carry the standardized dairy term that they are being adequately nourished. So we believe now FDA should be aware that there is a public health concern and that this should be brought to the fore.

Mr. Bucshon. Sounds kind of similar to the past date baby formula, right?

Mr. Balmer. Perhaps.

Mr. Bucshon. I mean because you are assuming based on it saying "milk" that it has the same nutritional value as milk as defined and that may not be true, so it is deceptive and people may not be getting the product that they want.

Mr. Balmer. Yes. I highlighted an example of the almond product having only two grams of protein versus eight.

Mr. Bucshon. Yes.

Mr. Balmer. That type of thing.

Mr. Bucshon. My objection to some of these things, like I said I am not criticizing any one specific company. We are seeing more and more and more of deceptive labeling especially as it relates to genetically-engineered food products and other things to maintain market share, to get market share. It has nothing to do with nutrition and it has nothing to do with you are getting a better product. It is purely marketing and market share.

And I think that as a society, you know, we need to be

careful because it is ultimately going to be found out that people have now a massive market share and their product doesn't provide what people are thinking it provides. I yield back.

Ms. Eshoo. The gentleman yields back. Pleasure to recognize the gentleman from Oregon, Mr. Schrader.

Mr. Schrader. Thank you, Madam Chair.

I would first like to just take a couple minutes to talk about the CURD Act of which I am a proud sponsor and feel it is time to put to rest, you know, a controversy that has been around a long, long time. For 80 years "natural cheese" has been used to distinguish from processed cheese. I think that is extremely important for the industry that men and women that are in the industry it will preserve the cheesemakers' ability to use the term "natural cheese" to help provide consistency for the consumer as they have for decades, and I think that is really important getting to the comments about truth in labeling.

And until the 2014 lawsuit, I was unaware that anyone viewed this as an issue. I have had zero comments at my office in D.C., my office back home in Oregon, so just wonder why, you know, they are trying to change things. We have had four rounds of technical assistance on this bill with the FDA. They have indicated their opinion. The passage of this

bill would not lead to consumer confusion as some people would have. The Senate actually passed this bill by unanimous consent. That does not happen every day in the United States Congress, so I think we should act on this bill and move forward.

Mr. Balmer, switching gears to the PRIDE Act a little bit, it is my understanding that other countries more consistently enforce dairy terms than we do. You alluded to the butter issue in your opening remarks. Could you expand a little bit, please?

Mr. Balmer. Sure. You won't be able to see this graphic, but I have an illustration here of three products, excuse me, the same product in three different containers sold in three different countries. So other countries are doing a better job on enforcing labeling provisions of their standards. Same product, it is an almond-based beverage product sold in the United States, sold in the United Kingdom, and sold in Canada; sold under three different names of the food presentations. In the United Kingdom it is sold as a dairy-free milk alternative. In Canada it is sold as a nondairy beverage. We hear this complaint often, "It is a necessity that we call this product -- blank -- milk." We beg to differ because we see its success for marketing in other countries.

Mr. Schrader. Very good. Thank you.

Switching gears to the horse bill, as an equine veterinarian for 30-plus years I appreciate the intent behind the bill, but I am a little concerned about the welfare of the horse itself in this country. There was some testimony about horses being injected on a daily basis or fed things on a daily basis, medications that could be toxic to humans. Is that your experience, Dr. Corey?

Dr. Corey. Well, I think to be an equine veterinarian and you are going to take care of horses, you are going to inject, you know, some with different products over the life of a horse. But as these --

Mr. Schrader. But how many do you do on a daily basis? I mean there is one horse, the implication is that these horses that you see or I see on a regular basis, we are out there daily injecting them with medication or feeding them pharmaceutical products. Is that your experience?

Dr. Corey. Well, I would say that probably -- that is a difficult question not knowing the practice types you are in. But if you are in a busy practice, you know, most horses will probably end up with an injection of some sort for something, probably. Does that answer your question?

Mr. Schrader. Yes. Well, at some point in time. I totally agree.

Dr. Corey. Oh, yes.

Mr. Schrader. There are withdrawal periods, I know that we have those in our livestock industry. And you testified that Mexico, Canada, the EU also have withdrawal periods that they require before an animal is allowed for consumption.

Dr. Corey. Yes. Canada and Mexico have the 6-month withdrawal and any of the meat that -- Canada has a zero tolerance and once this meat is processed after 6 months or more, these horses have been in a large area, they are testing. A rigorous testing is done for drug residues, and I think anything, any meat that has, horse meat that has been found to have drug residues then it is tossed. It is thrown out. So I think they are very serious about it.

Mr. Schrader. I think we have the same standards here in this country, you know, with cattle, sheep, hogs, pigs, chicken, you know, we withdraw them.

Dr. Corey. I hope so.

Mr. Schrader. So I guess I am just concerned that, you know, the idea that the medications are all dark and evil and meant to contaminate the food supply is wrong. They are done for the health of the horse in necessary situations.

Dr. Corey. Oh, absolutely. I mean that is what veterinarians do every day.

Mr. Schrader. Right, okay. Thank you.

Ms. Perry. Can I respond, Dr. Schrader?

Mr. Schrader. Well, my time is expired.

Ms. Perry. Okay.

Ms. Eshoo. The gentleman yields back. Pleasure to recognize the ranking member of our subcommittee, Dr. Burgess.

Mr. Burgess. I will yield to Mr. Carter first.

Ms. Eshoo. Okay.

Mr. Burgess. -- our ranking pharmacist first.

Ms. Eshoo. All right. We will go to, as I said at the first panel, the only pharmacist in the Congress --

Mr. Carter. Thank you.

Ms. Eshoo. Mr. Carter from Georgia.

Mr. Carter. Thank you, Madam Chair.

Did somebody want to respond to that last question?

Ms. Perry. Yes, I was hoping to just add that there really are no safe residue level or withdrawal periods per the FDA for phenylbutazone, which I am sure you are familiar with bute for horses. It is a common pain relief analgesic. I give it to my three rescue horses on a regular basis when they are sore. And the FDA has been very clear that there is absolutely no appropriate use for a horse that has received bute in the food supply.

I brought from my barn this morning, Dormosedan gel

which is a sedative that I use for my mini-horse because he is afraid of the veterinarian and it says do not use in horses intended for human consumption. Ivermectin, a dewormer regularly provided to horses, same label. So I think it is proper and we want horses to receive these drugs and treatments and therapies. In the summer, my horses are sprayed for flies every single day, so they are definitely not candidates for slaughter. And I think it is really important to realize that we know this already here in the U.S. per the FDA, so that is what we lean on is that expertise.

Mr. Carter. Okay, thank you. Thank you.

Okay, enough horsing around, let's -- argh. Thank all of you for being here. This is extremely important.

I wanted to ask you, Mrs. Mountford, "adulterated," and I am following along the same lines as Dr. Bucshon's questioning, but it is defined by the FDA to mean a product that is harmful or injurious to human health. And, you know, well know, how parents are especially with the first or second child, you know, by the time you get to the third or fourth, it doesn't matter. But the first and second you are very, very -- well, I mean you are very, very careful and we know how they are. How do you think that or what are your concerns with parents reacting to this classification of

"adulterated?" I mean is that going to, do you think that could possibly lead them to switch to nonregulated alternatives?

Ms. Mountford. Well, it is a very frightening term and I think if there were any concern that something was adulterated, absolutely yes. They turn to homemade formula which obviously is of concern and is not recommended, or some other alternative.

Mr. Carter. Well, what about the use of nonregulated formula alternatives that might be past the use-by date; is that ever a concern?

Ms. Mountford. I am sorry. Could you --

Mr. Carter. The nonregulated alternatives that are not adulterated, not labeled as that but they are nonregulated, and if they are past their use-by date is that a concern for people?

Ms. Mountford. It would probably depend on the product that you are talking about.

Mr. Carter. Okay. Okay. Well, let me ask you this. You mentioned in your testimony that you would support taking steps to ensure that expired infant formula wasn't being sold at retail, and I was surprised to learn that this was a problem to be quite frankly with you. Is it that common?

Ms. Mountford. It isn't extremely common. Safety is a

top priority, so of course we support any measures that could eliminate this issue. It seems to occur not often but sometimes in smaller stores, convenience stores, not -- it is less common in the bigger retail chains.

Mr. Carter. Whose responsibility is it? Is it the retailer to make sure that doesn't happen or?

Ms. Mountford. Retailer, yes.

Mr. Carter. Okay. Are there any kind of fines or anything associated with that? Is it different state by state or what?

Ms. Mountford. It is the retailer's responsibility, and to be honest I am not sure state to state how it is.

Mr. Carter. Right, right. You know, it is hard to believe that that is happening in our current system. You know, as a pharmacist I know that we have an expiration date and we certainly have the responsibility to make sure that we are not using a product past its expiration date. But in our case, a lot of times it is based on the efficacy of the product and not necessarily other things, so.

Ms. Mountford. This is different though. This is a use-by date, not an expiration date. So use-by again is a quality issue.

Mr. Carter. Use-by is a quality issue as opposed to a expiration date being --

Ms. Mountford. You should not use it.

Mr. Carter. -- you should not use it past this date.

Ms. Mountford. It is my understanding, yes.

Mr. Carter. Okay, fair enough. Okay, well, thank you very much for that information.

Madam Chair, I yield back.

Ms. Eshoo. The gentleman yields back. Pleasure to recognize the gentleman from Vermont, Mr. Welch, for his 5 minutes of questions.

Mr. Welch. Thank you, Madam Chair. Before I begin, I would like to ask unanimous consent to submit for the record two documents from public health organizations. One is a consensus statement last fall from four public health groups which notes that plant-based beverages are not nutritionally equivalent to cow's milk and voices agreement with the Dietary Guidelines for Americans that these products are generally not good substitutes for meeting recommendations for dairy intake.

And the second is a letter from the American Academy of Pediatrics which notes that pediatricians have noted that using the term "milk" on imitation products has caused parental confusion and led to parents buying imitation products for their children under the mistaken belief that they contain similar nutritional components to real dairy.

So with your permission?

Ms. Eshoo. So ordered.

[The information follows:]

********** COMMITTEE INSERT **********

Mr. Welch. And I am glad to see the DAIRY PRIDE Act is being considered. Mr. Schrader was just speaking about that and it is a big deal for our dairy farmers. And some of the pushback comes from folks that say it is not really a big deal, but here is what just ought to be the rule: a label is a label. And as Scott Gottlieb said when he was still in that position, if it is not lactation, then a nut, a seed, these other products that can be good, do not meet the definition of a dairy product.

So it is really just a simple question of having accuracy in labeling. And there were some folks who were pushing back saying there really isn't consumer confusion. We are not going to go out and test it, but why don't we have labeling accuracy? And if we are -- all we are asking the FDA to do in this bill, Madam Chair, is to enforce the labeling rules that already exist and they may need a nudge with legislation saying that we need them to do their job.

Mr. Balmer, I heard your statement and appreciate it, but I have heard some claims that the DAIRY PRIDE Act in enforcing standards of identity somehow violates the First Amendment and interferes with marketing of other common foods. Do you want to take a shot at addressing those claims?

Mr. Balmer. Likewise, Mr. Welch, we have heard the same

issue being raised and we are not in agreement. There is enforced government speech on food labels all the time and the issue, for instance, of the Nutrition Facts panel required on every package. And so, we see that the government does have the ability to impose certain labeling on food products, so we would -- we think there are many examples of this.

Mr. Welch. And, thank you. And can you elaborate on the so-called "health halo" effect of real milk and why nondairy alternative beverages may want to associate themselves with dairy milk?

Mr. Balmer. Yes. As I mentioned earlier, milk being the source of nine essential nutrients and obviously an attractive target to hitch one's wagon to, if I can mix my metaphors there, but, you know, with the accepted knowledge of milk's importance in the nutrition of children and adults, it is very easy for marketers of imitation products to glom on to the halo.

Mr. Welch. Thank you very much. I hope we can move forward on this just so that we give integrity to whatever the label is. And I thank the panel for your testimony in other matters as well. Being from Vermont, dairy being under siege and wanting to do everything we can for our farmers, I focused obviously on the DAIRY PRIDE Act. But I will yield

back, Madam Chair. Thank you.

Ms. Eshoo. The gentleman yields back with our gratitude for the important work that he is doing on this bill and so many other matters. Does the -- I want to recognize the ranking member --

Mr. Burgess. Thank you, Madam Chair.

Ms. Eshoo. -- for your 5 minutes.

Mr. Burgess. Ms. Mountford, I just wanted to kind of close the loop on this issue that we have talked about on adulteration. This committee, this subcommittee, heard extensive testimony back in 2007, 2008 on the issue of melamine contaminating, first, pet food, and then fortunately not in this country but melamine contaminating infant formula, melamine being the substance that basically countertops are made of. And if melamine is ground up and added to a product it significantly increases the qualitative test for nitrogen, and the inference is that hey, the protein potency of this product is good, it is way up there, so pet food was affected in this country.

I don't know, after talking to veterinarians in my district after the revelation no one could give me figures, but there was a significant increase of pets that were lost to kidney failure that was one of the consequences of ingesting this stuff. And then, Mr. Stupak is still with us

here in the audience, he will remember the reports coming out of China where there was Chinese infant formula that was contaminated with melamine, and yes, it was a scandal and the Chinese head of the food and drug administration was dealt with very, very harshly.

But to me that is adulterated formula, not something that is past its use-by date. So I appreciate your comments and I appreciate your delineation of that. Sure, if the folic acid content has diminished by the use-by date, we should be aware of that but at the same time it is not truly an adulterated product. We have seen adulterated products and this is not that.

Ms. Mountford. Correct. And we would be happy, as I said, to support the intent of this bill because we certainly want good quality products out there, nutritious products, and this would help to avoid having products that are less nutritious sold.

Mr. Burgess. You know, Chair, this seems like it is China's impact on the health of America day. I have got a coronavirus hearing that I am trying to get to, we just had on the floor the extension of the scheduling for fentanyl analogues that are coming into this country from China, and then, of course, I was reminded of the Chinese melamine issue. So yes, we can't be too careful.

I would like to yield the rest of my time to Mr. Griffith from Virginia, please.

Mr. Griffith. Thank you very much, Dr. Burgess.

Dr. Corey, domestic horse slaughter effectively ceased around 2007. Given Congress's prohibition on the use of federal funds to inspect horses intended for human consumption, what was the result of this de facto ban on domestic horse slaughter?

Dr. Corey. I think that the GAO had a report out in 2011. Let me --

Mr. Griffith. Well, time is a-ticking.

Dr. Corey. Yes.

Mr. Griffith. You can get that to us at a later date. What is your recollection of what it --

Dr. Corey. It is actually highlighted as action needed to address the unintended consequences of cessation of domestic slaughter. The bottom line is that there were a rise in investigations of horse neglect and more abandoned horses since 2007 and up more than 60 percent in Colorado and California, so I think that that is what has happened.

Mr. Griffith. So what you are saying is, is that it actually had a negative impact on the horse welfare.

Dr. Corey. Negative, yes.

Mr. Griffith. All right. Now given your experience in

the field, how will H.R. 961 place additional burdens on efforts to re-home unwanted horses?

Dr. Corey. Well, it is going to place burdens because we have that many more horses to deal with and we just don't have the facilities. And I think we are going to see these burdens via our state, local municipalities having to deal with these horses that owners can't take care of; they don't have the funds to take care of them. So, yes.

Mr. Griffith. And, in fact, in our area where they don't really -- I live in southwest Virginia so it is not really, doesn't make sense to market them north or south. We are just kind of in the middle. And what happened in the past, it hasn't happened recently, but you had to lock up your fields and your horse or your cattle haulers when you went to market because you would come back after selling your cows and find somebody had left you some unwanted horses and then you had to deal with them either in your field or otherwise.

So people were not worried about horse thieves, they were worried about people dumping horses and that is probably --

Dr. Corey. Well, actually, in the West we have found that to be true. And I have talked to several state veterinarians that have indicated that horses were abandoned

and turned out, out in the wild with the wild roaming horses, and that is fact, yes.

Mr. Griffith. All right, I appreciate it and I yield back.

Ms. Perry. Could I comment on that?

Ms. Eshoo. You have time, yes. Well, it is a little over time, but go ahead.

Ms. Perry. I just wanted to mention that the only science that tries to make any correlation between abandonment and neglect of horses can tie it to economic downturns. And in 2007 when GAO based its conclusion on purely anecdotal information, no data whatsoever, we have since then seen economists come out tying that to the economic downturn and not at all to the cessation of slaughter. And I think the data today would bear that out.

Unfortunately, no state actually accurately tracks equine neglect or abandonment. We don't have that kind of data to help us see, but we are data-driven on this issue and it does matter. I really appreciate your question. Thank you.

Ms. Eshoo. The gentleman yields back.

Did you say that the GAO gave anecdotal information? Was it a survey?

Ms. Perry. No, they --

Ms. Eshoo. The first time I have ever heard anyone say GAO has given anecdotal information.

Ms. Perry. I know. It was an anomaly. And they had a lot of good data in that report, but they did receive information from state vets who reported horses being abandoned and neglected. And our sense in looking back at that and economic experts who have looked back at that say it was tied to the recession which started exactly at the same time that the domestic horse slaughter; that we haven't continued to see that.

Ms. Eshoo. Okay, thank you. I appreciate it. All right. I would now like to recognize the gentlewoman from Michigan, Ms. Dingell.

Mrs. Dingell. Thank you, Madam Chair. Thank you for holding this hearing. In my bill, the Keep Food Containers Safe from PFAS Act is one of the bills that we are considering or having hearings on today. With the passage of the -- with the PFAS Action Act earlier this month, the committee has taken big strides needed to kickstart the cleanup of legacy PFAS contamination, limit discharges of PFAS waste into air and water, help community water systems upgrade their infrastructure to filter out PFAS, and much more, though we need the Senate to act for it to really happen.

4473 However, one of the more troublesome exposures to PFAS
4474 that often goes unnoticed is the use of these chemicals in
4475 food packaging. Last year, Congress took an important first
4476 step in the NDAA bill to ban the use of PFAS in food
4477 packaging for MREs. My bill, the Keep Food Containers Safe
4478 from PFAS Act, would build on this success to provide FDA to
4479 deem PFAS substances in any food containers or cookware
4480 unsafe.
4481 So I am going to direct these questions to Ms. Benesh.
4482 Ms. Benesh, what do we know about the health effects PFAS in
4483 food packaging? Does FDA have a safety threshold for PFAS
4484 that it uses to calculate how much PFAS in food is safe?
4485 Ms. Benesh. So we do know that PFAS migrates from food
4486 packaging into food, and we know that some of the health
4487 effects broadly associated with PFAS chemicals includes some
4488 kinds of cancers and then at much lower doses reproductive
4489 harms, developmental harms, and reduced effectiveness of
4490 vaccine. What is really concerning to me is FDA has said it
4491 is using EPA's reference dose for drinking water for PFOA and
4492 PFOS, which are two of the food packaging chemicals that are
4493 no longer being used.
4494 But for all the PFAS that are still in food packaging,
4495 they have not calculated a reference dose and so they are
4496 using the kinds of assumptions that they apply to other

chemicals that don't operate in the body the same way that PFAS do. And so, I am a bit at a loss of how FDA has determined that these chemicals are safe without determining what their safety threshold is first.

Mrs. Dingell. So if Americans currently have concerns about PFAS, which I think they should, and food packaging, can they shop around this problem if they are looking in PFAS food packaging?

Ms. Benesh. Unfortunately not. Unlike the ingredients in food that do have to be on the label or the ingredients in a cosmetic product that have to be on the label, there is no requirement that the ingredients in a food packaging material have to be on the label. So it is very difficult to avoid if consumers do want to shop around it.

Mrs. Dingell. Has FDA even withdrawn a food contact notification for PFAS chemical on its own?

Ms. Benesh. No, only in response to industry abandonment, but never on its own because of a health concern.

Mrs. Dingell. Is that why we need Congress to do something?

Ms. Benesh. We do think that Congress needs to step in because FDA hasn't appreciated the urgency of this issue. No one knows better than Michigan how urgent this problem is and

how overburdened many communities already are.

Mrs. Dingell. You know, it is not just Michigan though, just as you say that. We have tested for it. Flint water taught us something. As other states start to test, they are going to be as bad as Michigan which is what is so scary. And food isn't just marketed to Michigan, it is marketed in every state.

Are industry safety data backing up new approvals of food contact substances made public by the FDA?

Ms. Benesh. They are only through the food contact notification system, which is the way that FDA has approved food contact substances since 1997. You can only get that underlying scientific information through a public records request. It is not easy for the public to access.

Mrs. Dingell. I am going to ask you one more question because I am going to run out of time, but I don't think people understand this. I want to put something to bed that often gets raised. If we designate PFAS as hazardous substances under CERCLA, which we need to do and haven't, or Superfund, would food companies no longer be allowed to use PFAS in food packaging?

Ms. Benesh. Thank you for the question and thank you for your leadership on this issue. We couldn't agree more that PFOA, PFOS and other PFAS chemicals urgently need to be

designated as Superfund chemicals under our hazardous substances law. But Superfund is a clean-up law. It has no bearing on the use, other uses of PFAS in commerce. And we have looked at this issue and found that 80 percent of the roughly 800 hazardous substances under Superfund are still in commerce and many of them continue to be in very wide production. So the only way to ban PFAS in food packaging is to ban PFAS in food packaging as you have proposed.

Mrs. Dingell. Which is why we need the bill. And it is in the blood, for everybody here, of 99 percent of the people in this country and they don't know it. Thank you very much and I yield back.

Ms. Eshoo. The gentlewoman yields back. I now recognize the gentleman from Virginia, Mr. Griffith, for his 5 minutes of questioning.

Mr. Griffith. Thank you very much.

Ms. Day, I know that it is a struggle and my question to you is, you have three children all of whom have severe allergies, if I remember your testimony correctly. Do they have the same allergies?

Ms. Day. Ah, unfortunately, no. There are some overlaps, but I mean if I told you, my oldest daughter is allergic to tree nuts; my middle is allergic to dairy, eggs, sesame, mustard, and fish; and my youngest is allergic to

peanuts, eggs, flax seed, sesame, and mustard.

Mr. Griffith. Yes. I come from an allergy family. We don't have the same allergies, thus the question, so my wife has to make three sets of a number of foods that we eat. If we order pizza, even if it is just me and the two boys, we get three pizzas because each one of us has a different dietary concern.

Ms. Day. Yes.

Mr. Griffith. So that raises a question where I think we can get the language straightened out and I don't think you would object to it. In the bill it talks about doing a study. In one of the studies it says a study of the economic cost of food allergies in the United States both individually and the food allergy population, and the problem is every family is going to be different. I don't know how you study it individually without having a hundred thousand different studies, so I think we need to tighten that language up.

You would not have any problem with tightening that language up and looking at the costs overall, and maybe it means medical costs, but when you are looking at the cost of food, everything costs more when you have food allergies, doesn't it?

Ms. Day. Yes.

Mr. Griffith. Because you are doing three or four types

of the same thing and the ingredients cost more sometimes, or most of the time.

Ms. Day. So that is certainly an issue in my family and it sounds like in your family.

Mr. Griffith. Yes, ma'am.

Ms. Day. Sesame though has come to the top of the list. We already --

Mr. Griffith. Absolutely in favor of that. I am just talking about the study where it talks about the economic cost of food allergies, and I just don't know how you do that individually without studying hundreds of thousands of different scenarios.

Ms. Day. So I am not a research expert in that so I can't --

Mr. Griffith. Okay. We will work on that. All right.

Slightly shifting gears, Ms. Benesh, at one time, and I haven't had this issue lately, but they had boiling bags and I would have a reaction to foods that were processed or boiled in a boiling bag. Is that PFAS or is that something else?

Ms. Benesh. PFAS chemicals are usually, typically, used as anti-grease proofing agents, so in pizza boxes, sandwich wrappers or used to line a popcorn bag.

Mr. Griffith. So probably not.

Ms. Benesh. It is possible that they have been used in plastic bag lining, but I am not aware of that particular use.

Mr. Griffith. And I am trying to get to the facts and figure this stuff out.

So, Dr. DeLeo, and I don't -- we may end up with a little spat going here and that is okay. I want to get the information. And, Ms. Benesh, polymeric PFAS versus non-polymeric PFAS, explain that and why is it scientifically different and is there some way that -- is there a need to distinguish between the two, or Ms. Benesh, do you see them as being identical where Dr. DeLeo in his testimony indicated that there is differences?

Ms. Benesh. Well, there are lots of different uses of PFAS, and the use in PFAS typically --

Mr. Griffith. Well, I think he was talking about different types of PFAS.

Ms. Benesh. Yes. So one use of PFAS is to create these long polymers that are then applied to food packaging. The real concern is that particularly if you apply a hot food, those long polymers can then break down and then the PFAS chemical gets into the body, is my lawyer's understanding of the science.

Mr. Griffith. Okay, understand.

Dr. DeLeo, do you want to respond?

Mr. DeLeo. So PFAS is a chemistry, as was mentioned is thousands of chemicals and they are very diverse. There are some that are hazardous and there are some that are not hazardous. There are polymers; there are non-polymers. H.R. 2827 is a pretty blunt instrument taking a broad brush at all PFAS chemistries and I think that is not a good way to approach policy. And so I think you really need to look at all the differences and applications of these chemicals rather than painting everything with the same broad brush.

Mr. Griffith. I appreciate that.

Ms. Perry, Dr. Corey, you all are obviously on opposite sides of the horse issue. Both of you have raised good points. I did think it was interesting, Dr. Corey, you mentioned retirement homes for horses. That is a term I have often used. We are spending more than 80 million dollars a year on retirement homes for horses. There are not enough families out there who want to adopt or enough facilities that want to adopt horses, which is why we have approximately 50,000 horses from federal lands that are now in what I call retirement homes. Is that fairly accurate according to the information that you have as well?

Dr. Corey. I think the retirement and the re-homing is, we are doing a good job.

Mr. Griffith. Well, I am talking about putting them on farms where we are paying to subsidize their life after they are removed from federal lands because there are too many of them on federal lands.

Dr. Corey. Oh, you are referring to the wild horse and burro.

Mr. Griffith. I am.

Dr. Corey. Well, that is a whole other issue. So we have got a hundred thousand horses there, and now with this legislation we are going to create another additional potential eighty to a hundred thousand horses.

Mr. Griffith. My time is up. I would love to discuss this further, but my time is up and I yield back.

Dr. Corey. I would also.

Ms. Perry. Me too.

Ms. Eshoo. The gentleman yields back. I am more accustomed in the Health Subcommittee to talking about nursing homes, convalescent homes when it comes to the people in our country, so now it is very interesting to me to hear the same words used being applied to horses. So thank you. I keep learning.

I don't think there is anyone left except Ms. Schakowsky is waiving on and -- or Mr. Long.

Mr. Long. Thank you, Madam --

Ms. Eshoo. The gentleman from Missouri, Mr. Long.

Mr. Long. Thank you.

Ms. Eshoo. Who, in addition to his legislative skills, is a great, great auctioneer in case anyone, maybe some of these people who have the horses can make use of his talents. You are recognized for 5 minutes.

Mr. Long. I thought you were going to say poodle wrangler, since I broke my shoulder before Christmas wrangling my daughter's 5-month-old poodle. That didn't work out too well.

Mr. Carlin, we have heard several examples showing that the term "natural cheese" has a long history. The term even appears in the FDA regulations as you know. Shouldn't cheese products be permitted to be labeled with a term that has been in use for more 70 years?

Mr. Carlin. Yes.

Mr. Long. Can you speak to why there is a need to define natural cheese in statute and why this is different than changing the FDA's policy on the use of natural or all-natural for product claims?

Mr. Carlin. Yes. As you know, processed cheese is reflected in the current standards of identity, but for whatever reason natural cheese has never been officially defined. As FDA looks at the term "natural," since 1992 by

the way is when they started looking at how a product claim with natural would be defined, FDA has said that that is something that they are going to try to do, but it has obviously been pending for quite some time.

This legislation would not affect the cheesemakers' ability to use the term "natural" for product claim purposes. They would have to continue to comply with FDA's rules and regulations on that front. So this just provides consumers with information in the grocery store that they already have and they have had for a long time. It doesn't create anything new. It just preserves the ability to use that label going forward.

Mr. Long. You say in your testimony that the FDA's technical experts have reviewed the bill extensively. Can you elaborate on the FDA's input?

Mr. Carlin. Yes. So over the past 2 years we have had three rounds of technical assistance from FDA. We have also consulted with them informally as have the bill's sponsors on other occasions. They helped us define the term "natural cheese" in a more enforceable way from their standpoint, referencing the international codex standard, for example. They also made the suggestion that we particularly call out in the bill that natural claims, natural product claims would not be covered by this legislation to make it very clear so

that there would be no misunderstanding.

This is just a simple, a label for "natural cheese," those two words in quotes, nothing else about all-natural or a hundred percent natural. So that was another FDA suggestion.

Mr. Long. Yes, okay. And there is also a question of whether or not the CURD Act will create confusion between the FDA and the USDA regarding the use of natural claims on labels. Can you talk about whether there will be inconsistencies between the FDA and the USDA on this?

Mr. Carlin. Well, as I said in my testimony, Congressman, the only definition of natural that is relevant here is the FDA definition because that is the only definition that applies to cheese. So the USDA has used the term "natural cheese" just has FDA has for many, many decades to talk about a category of cheese. That won't change and that is perfectly consistent across these two agencies.

Mr. Long. Okay, and I am going to move down the line to Mr. Balmer, a question for you. I have heard claims that the DAIRY PRIDE Act would somehow disrupt the consumer market. It seems to me that clearer transparent labeling actually should help the market by making sure shoppers have accurate information about products on the shelves. What is your take?

Mr. Balmer. Well, we are not quite of the opinion that this would be disruptive to the marketing of these imitation products because as I showed a little while ago, we have the same product produced in the same plant called by three different names in three different countries. Only in the United States is the term "milk" involved. In Canada, a different term; in the U.K., a different term.

So we don't see how this legislation which simply is asking for FDA to do its job and enforce what is on the books now, we don't see how it would interfere with continued growth in that category. And we have no problem as long as those products are labeled correctly.

Mr. Long. Okay, thank you. And thank you all for being here today. And I will go on the record as saying when I go to the Capitol Hill Club over here across the street, I walk in, you know, everybody knows what everybody's favorite drink is, and as soon as I walk in they always put down a big glass of milk for me and everyone laughs at me. But I have done that my whole life. I yield back.

Ms. Sorscher. Could I clarify a point on the CURD Act? There is nothing that would --

Ms. Eshoo. You can proceed, go ahead.

Ms. Sorscher. Were the FDA to define natural, there would be nothing stopping a company from putting "natural

cheese" on their product provided they also met the FDA requirements, which would likely include no artificial ingredients. And I think even though cheesemakers have used this term for many years as a term of art, what goes on the label has to make sense to consumers as well, and we don't distinguish between a product name and a claim.

Ms. Eshoo. Thank you very much.

The gentleman has yielded back. On milk, I think that there are two things that the senators are allowed to have as the trial is taking place: one is water, the other, Mr. Balmer, is milk. How is that? I just hope it is not warm milk because it will put them all to sleep.

Mr. Griffith. They don't need that.

Ms. Eshoo. Yes, they don't need that. They could do that naturally.

A pleasure to recognize the gentlewoman from Illinois, Ms. Schakowksy, for 5 minutes of questions.

Ms. Schakowsky. Thank you, Madam Chair. Thank you not only for letting me waive on to this subcommittee, but also for including my legislation in there, which is the SAFE Act, Safeguarding America's Food Supply, food exports, and it now has 224 cosponsors. I also want to thank Nancy Perry from the ASPCA for being here to testify in favor of this legislation.

So the Food and Drug Administration is responsible for protecting public health through protecting our food supply, and I think it is doing generally working very hard, but horse meat has definitely fallen through the cracks. We know that my bill addresses the danger of consuming horse meat. So I want to talk not just about nursing homes or whatever for horses, but I want to talk about the dangers of allowing prohibited ingredients to be in the horse meat that is still not prohibited for eating in the United States of America.

So we know also that horses are legally being exported for the purpose of slaughter for consumption. Kill buyers purchase these horses at auction, ship them mostly to Canada and Mexico to be slaughtered for food, and even Ferdinand, the winner of the 1986 Kentucky Derby, fell victim to the horse slaughter industry. The consumption of horse meat poses a grave threat to public health. Horses are routinely treated with phenylbutazone and other extremely potent bans -- - products that are banned.

And so, Ms. Perry, has the FDA banned the use of these drugs in animals that we eat?

Ms. Perry. Yes, they have. There is no legal use of phenylbutazone and many of the hundred substances that we provided in our written testimony for provision to food-producing animals, so there is no food use for most of those

chemicals.

Ms. Schakowsky. And, Ms. Perry, are there any animals, any equine, raised for food in the United States?

Ms. Perry. There are not. There are not.

Ms. Schakowsky. And can you explain why horse meat poses a food safety hazard?

Ms. Perry. Well, I rely on the Food and Chemical Toxicology Journal peer-reviewed piece from Dr. Nick Dodman that was published in 2010 that reviews and tracks horses that were funneled into the slaughter pipeline from the U.S. and looks at the phenylbutazone content in their tissues after they were slaughtered, and that article is frightening. It really demonstrates that those residues are there.

Again, no level of residue is appropriate or legal or safe and there is no phase-out period for that particular drug and again many of the more than hundred substances that we have provided to the committee. But that article indicates and documents how the FDA determined the health impacts of just phenylbutazone alone, if we just look at that one drug which is probably the one that has been under the microscope the most.

Most of this has flown directly under the radar because nobody even knows this is happening it is such a shadowy industry. But I will just list that aplastic anemia,

leukopenia, agranulocytosis, thrombocytopenia are just some of the serious illnesses that can lead to death. They are basically blood platelet and bone marrow immunity diseases.

Ms. Schakowsky. So these are the horses that are being purchased --

Ms. Perry. American horses.

Ms. Schakowsky. -- and exported for the purpose of being eaten.

Ms. Perry. That is correct.

Ms. Schakowsky. So could you please describe some circumstances for which the FDA has issued warnings --

Ms. Perry. Sure. Ms. Schakowsky. -- to take action against food products in the United States for violating FDA standards?

Ms. Perry. I don't think it is common knowledge, but the FDA actually has a ready availability of this information on their website. You can look at their enforcement records, and we have been stunned to see the number of times they have taken action when phenylbutazone has been given to food-producing animals and often dairy cows.

Ms. Schakowsky. Let me just --

Ms. Perry. Sure.

Ms. Schakowsky. -- end because my time is running out. So what this legislation does, what the SAFE Act would do

would explicitly ban consumption of horse meat in the United States and the import and export --

Ms. Perry. Correct.

Ms. Schakowsky. -- of horses and equine parts. I think it is really important that we take action and that the FDA finally enter the picture to protect our food supply and that of what we are exporting. Thank you.

Ms. Perry. Thank you.

Ms. Eshoo. The gentlewoman yields back. I want to thank each one of you. You have spent a long time here today and we appreciate it. But we also appreciate the knowledge that you have shared with us, firsthand knowledge -- Ms. Day, about your children -- and each one of you on the bills that were part of this discussion and your comments on the bills that deal with food and FDA.

I want to thank -- they are not in the room, but I want to acknowledge and I did earlier, but I want to acknowledge again the authors of the legislation for the work that they have done. A lot goes into bills before they ever come into this room and have expert witnesses come in and comment on it which is a very important part of our process. But I think we took up how many bills today? Ten bills.

And as long as I am around we are going to keep rolling on taking up as many bipartisan bills, bills that members

sponsor and have cosponsorship not only from this committee but from outside the committee. I think it is an important thing to do. I don't think the American people really ask for that much, but these are all things that they can't do for themselves. We are the ones that have to make the decision, so thank you --

Ms. Schakowsky. Madam Chair?

Ms. Eshoo. -- for everything that you have done to assist us.

Yes?

Ms. Schakowsky. I am wondering if at this point I could ask to add into the record a letter from the AWA in favor of the SAFE Act. Thank you.

Ms. Eshoo. Certainly. So ordered.

[The information follows:]

********** COMMITTEE INSERT **********

Ms. Eshoo. And I am requesting unanimous consent to enter into the record the following documents: A statement from Representative Meng in support of her bill, H.R. 2267; a statement from the Consumer Federation, Kid's in Danger, and Public Citizen, in support of 2267; a letter from the United States Harness Racing Alumni Association in support of 961; a letter from Animal Protection of New Mexico in support of 961; the testimony of Hilary Wood, president of the Front Range Equine Rescue in support of 961; a letter from the Plant Based Foods Association opposing 1769; a statement from the American Forest and Paper Association opposing H.R. 2827; a letter from the American Pharmacists Association.

Where is Mr. Carter? I will have to tell him -- in support of 5663; a letter from Return to Freedom in support of 961; a letter from the Professional Rodeo Cowboys Association opposing 961; a letter from -- isn't it marvelous all the associations and organizations we have in the United States of America? It never ceases to amaze me -- a letter from Diane Dorman in support of 4712; a letter from the Humane Society of the United States and the Humane Society Legislative Fund in support of 961; a letter from the Humane Society Veterinary Medical Association in support of 961; a letter from five livestock groups opposing 961; a letter from the National Black Farmers Association in support of 961; a

letter from R-CALF, c-a-l-f, opposing 961; a one-pager on 961 developed by Protect the Harvest Action Fund; a letter from the Texas State Horse Council in support of 961; a letter to Vice President Pence from the United States Cattlemen's Association opposing 961 -- they could write to us too; a letter from the American Chemistry Council opposing 2827; a letter from FluoroCouncil opposing 2827; a letter from the Animal Welfare Institute in support of 961; a statement from the American Society of Health-System Pharmacists, but it doesn't say whether they oppose or support, but it is a statement so we will have to read it; a statement from 15 healthcare organizations in support of 5668; a letter from the Jockey Club in support of H.R. 961 -- I doubt that is the restaurant though, do you? I don't think so.

So without objection?

Mr. Griffith. No objection.

Ms. Eshoo. So ordered.

[The information follows:]

********** COMMITTEE INSERT **********

Ms. Eshoo. So at this time, the subcommittee is adjourned. Thank you, everyone.

[Whereupon, at 2:27 p.m., the subcommittee was adjourned.]