

IMPROVING SAFETY AND TRANSPARENCY IN AMERICA'S FOOD AND DRUGS

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

JANUARY 29, 2020

Serial No. 116-93



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² Nancy Perry, did not answer the question by the time of publication.

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³The information has been retained in committee files and also is available at <https://docs.house.gov/meetings/IF/IF14/20200129/110423/HHRG-116-IF14-20200129-SD024.pdf>.

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⁴The information has been retained in committee files and also is available at <https://docs.house.gov/meetings/IF/IF14/20200129/110423/HHRG-116-IF14-20200129-SD029.pdf>.

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WEDNESDAY, JANUARY 29, 2020

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

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, Cárdenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Rush, Burgess (subcommittee ranking member), Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Hudson, Carter, and Walden (ex officio).

Also present: Representative Schakowsky.

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 and 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 if you can do both, but I am not going to stop the 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.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

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 ten 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 eight percent of American children are affected by food 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 face. 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 the 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 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 prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

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Today, we will examine ten mostly bipartisan bills to support the FDA's immense mission.

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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 labelling is important for children and their families. An estimated eight percent of American children are affected by food allergies, and the NIH recently found that sesame allergy is common among children with other food allergies, occurring about 17% of the time.

But those parents and children can't easily avoid sesame since it's often not listed as an ingredient. Anyone who's 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 face. The FASTER Act will help the FDA do just that.

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

PFAS chemicals have been found to easily accumulate in the environment or 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 the PFAS approved for use on paper or cardboard to prevent grease stains can potentially migrate to food. The Environmental Working Group found that as much as 40 percent of fast food wrappers tested positive for perfluorinated chemicals, 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, the 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.

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

**OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

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 kinds of devices into the marketplace.

H.R. 4712, the Fairness in Orphan Drug Exclusivity Act, seems to seek 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 is 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.

Mr. BURGESS. I yield back.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Thank you, Madame Chair. The Food and Drug Administration is the oldest comprehensive consumer protection agency in The Federal Government. Dating back to the 1906 Pure Food and Drugs Act, the FDA has been the administrative body tasked with protecting Americans from adulterated and misbranded drugs and food. Since 1906, the FDA's authority and 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 the Secretary of HHS to destroy certain counterfeit medical devices. Counterfeit devices pose a risk to Americans. I saw this firsthand when I visited the JFK International Mail Facility with Former FDA Commissioner Scott Gottlieb and was taken aback. Many counterfeit devices come in through facilities like the one I saw, and this bill would allow for such devices to be destroyed at the point of entry. Granting authority to the Secretary to ensure that these counterfeit devices will be destroyed will help protect patients from bad actors who distribute counterfeit devices into the marketplace.

H.R. 4712, the Fairness in Orphan Drug Exclusivity Act, 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 innovators of 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 to inhibit competition. We must make sure to walk that fine line of competition and encourage new cures.

Another bill aimed at innovation is H.R. 4866. This bill would designate certain qualifying higher education institutions as National Centers of Excellence in Continuous Pharmaceutical Manufacturing to support the advancement and development of continuous manufacturing. Continuous manufacturing has many benefits, including allowing for more flexible tracking and tracing in the event of product failure and eliminating hold times between steps of production. This is important technology because the ability to track and trace during a product failure could minimize the risk of a drug shortage. Additionally, a fast and efficient production of pharmaceuticals is beneficial to patients.

Less often has the Health Subcommittee held hearings on the food jurisdiction of the FDA. The FDA is the authoritative agency on labeling and nutrition, ingredients and packaging, and food defense. It is important for Americans to be aware of what's in their food—from the nutritional value, to what additives and allergens may be present.

Some bills before us today are aimed at these issues. H.R. 2117, the Food Allergy Safety, Treatment, Education, and Research Act of 2019, would require sesame to be a major allergen for the purposes of labeling. H.R. 2269, the Infant Formula Protection Act of 2019, would require infant formula to be considered adulterated by the FDA if it is passed the use-by date.

Some of the other bills before us today dealing with food requirements overstep into the authority of the FDA. The FDA is 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.

Unfortunately, the FDA is not a witness today; however, I look forward to hearing from our witnesses on these pieces of legislation.

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.

OPENING STATEMENT OF HON. DEBBIE DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

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 for 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.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

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 I know his valued expertise for bringing important perspective to our discussions about animals.

I am pleased we will be considering 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 products.

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 Excellence 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 have already 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 legislative 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.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

At today's hearing, we will have the opportunity to review legislation 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 a special thanks to Dr. Doug Corey from Oregon's Second Congressional District for being here today. While it may seem tamer here in Congress than what he's used to seeing at the Pendleton Round-up back in Oregon, I can assure you we have our fair share of excitement here at these hearings. I appreciate Dr. Corey taking the time to testify and know his valued expertise will bring an important perspective to our discussions.

I am pleased that we will be considering 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 protection against the threat of counterfeit products.

H.R. 5663, the Safeguarding Therapeutics Act, would extend FDA's administrative destruction authority to medical devices. Under current law, FDA is authorized to destroy certain imported drugs that may pose a threat to the public health; however, this authority does not extend to medical devices, including some combination products. This legislation, introduced by Mr. Guthrie and Mr. Engel, would provide the Agency with an additional tool to protect American consumers against potentially dangerous, unapproved products.

Furthering our efforts to protect the country's medical product supply chain, we will also be considering H.R. 4866, the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act. H.R. 4866, introduced by Chairman Pallone, would direct FDA to designate higher education institutions as National Centers of Excellence, allowing 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.

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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 cost-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 block competition.

I appreciate the majority's attention to these bipartisan proposals and hope that 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 this

fiscal year. One of these programs is the rare pediatric priority review voucher program. Several members of this committee have already worked together, in a bipartisan manner, to introduce the Creating Hope Reauthorization Act, which would extend this program, and I would ask that the Chairman consider its inclusion in a future hearing.

Finally, we will be considering several legislative initiatives intended to address FDA's regulation of foods. I have heard concerns from dairy and beef producers in my district related to standards of identity, and I welcome the discussion on these matters today. However, I also have concerns that some of the bills being considered today may have unintended consequences and ignore the science-based approach FDA takes when regulating products under their jurisdiction.

I look forward to hearing from our witnesses and appreciate your time in being here today. I yield back.

Ms. ESHOO. We know that you bounce well.

The gentleman 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 to 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. OK?

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 DR. KAO-PING CHUA

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 policymakers 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 seven 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 in 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:]

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 the two companies.

Dr. CHUA. OK.

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, and 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 the 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 the 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:]

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**STATEMENT
OF
FERNANDO J. MUZZIO, PH.D.
DISTINGUISHED PROFESSOR OF CHEMICAL AND BIOCHEMICAL
ENGINEERING
DIRECTOR, NSF ENGINEERING RESEARCH CENTER ON STRUCTURED
ORGANIC PARTICULATE SYSTEMS
RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY

BEFORE THE SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

HEARING ON
“IMPROVING SAFETY AND TRANSPARENCY IN AMERICA’S FOOD AND DRUGS”**

JANUARY 29, 2020

Dear Chairman Pallone, Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, by way of introduction, my name is Fernando Muzzio and I am a Distinguished Professor of Chemical and Biochemical Engineering at Rutgers, The State University of New Jersey. I am also the Director of the NSF Center on Structured Organic Particulate Systems, an NSF Engineering Research Center dedicated to the design of pharmaceutical products and their manufacturing processes.

I greatly appreciate the opportunity to appear before you at the hearing on improving the safety and transparency of America's food and drugs, and to share my views on H.R. 4866, the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2019. I strongly believe that this bill is critical to maintain the viability of drug product manufacturing in the United States.

Continuous Pharmaceutical Manufacturing – an Ongoing Transformation in the Pharmaceutical Manufacturing Paradigm

After decades of near stagnation, pharmaceutical manufacturing is experiencing unprecedented innovation. In the last decade, the pharmaceutical industry and its technology and ingredient suppliers have embraced a world-wide transformation from traditional, inefficient batch methods, to Continuous Manufacturing, which is an emerging technology that has been shown to greatly reduce both the time and the cost of developing and manufacturing new medicines, while enabling significant improvements in the quality of the final product and the reliability of the manufacturing process.

As defined in H.R. 4866,

The term 'continuous manufacturing'— '(A) means a process where the input materials are continuously fed into and transformed within the process, and the processed output materials are continuously removed from the system; and '(B) consists of an integrated process that consists of a series of two or more unit operations.

In traditional batch manufacturing, the entire amount of raw materials (e.g., 500 Kg) to be transformed into products are first loaded into equipment, and then this large amount of material undergoes a series of processing steps to transform it into a large number of finished product units (e.g., 1,000,000 tablets) with desired quality attributes. In this manufacturing modality, since the process is intrinsically time-dependent (i.e. the different manufacturing steps take place in a temporal sequence), and because large amounts of material are processed all at once, there is limited opportunity to control the process and to ensure product quality. Moreover, this approach to manufacturing is slow, labor intensive, and very difficult to optimize.

In contrast, Continuous Manufacturing is a modality where the ingredients are fed continuously at controlled rates, and travel non-stop from one manufacturing step to the next, until the process

is completed. Only a small amount of material is in residence in an equipment item at any time, and the process is operated at, or near, steady state in a condition of closed loop process control. The continuous state of control enables the continuous monitoring and assurance of product quality. This modality enables a high level of automation and optimization and can minimize quality failures, decrease manufacturing cost, and improve quality. While this description is given in terms of powders and tablets, continuous pharmaceutical manufacturing is also feasible for products in fluid, suspension, and semi solid form, including injectable solutions, ophthalmic suspensions, creams, ointments, and a myriad other product forms.

Current State of Implementation of Continuous Manufacturing

As a result of its numerous demonstrated advantages, Continuous Manufacturing of both small molecules and biologics has become a priority for biopharmaceutical companies, its technology suppliers, the FDA, BARDA, and the United States Pharmacopeia, an organization dedicated to quality standards. Dozens of pharmaceutical manufacturers, equipment and instrumentation suppliers, and ingredient vendors are actively engaged in this major reinvention of their pharmaceutical manufacturing platform. Companies such as Johnson and Johnson, Vertex, Pfizer, Eli Lilly, Glaxo SmithKline, Merck, Sanofi Aventis, Bayer, and Novartis, have all made corporate goals of converting a large fraction of their total production volume to Continuous Manufacturing in the next few years. Other brand-based manufacturing companies are also following suit.

We must also consider that the biopharmaceutical market has already exceeded a trillion dollars in annual worldwide sales. Within the next decade, we are likely to witness a worldwide conversion to Continuous Manufacturing of a significant fraction of the brand-based sector, which would mean that just a few years from now, pharmaceutical products worth hundreds of billions per year, spanning many drug product forms, including tablets, capsules, vaccines and injectables, could be manufactured using the new continuous methods.

Countries that are able to implement these methods effectively will capture much of this activity. This represents a large opportunity for the United States. Selection of manufacturing venues for traditional batch manufacturing activities has been driven in substantial part by labor costs and perceived regulatory burdens¹. As a result, the US has lost a significant fraction of its manufacturing activities, in particular in labor-intensive industries. Implementation of continuous manufacturing processes, on the other hand, are less labor intensive, but they require access to a significant amount of specific knowledge that is not generally available in the public

¹ Dr. Janet Woodcock's testimony in front of this subcommittee, October 30, 2019.

domain, as well as a suitably trained workforce. It is therefore likely that Continuous Manufacturing activities will concentrate in countries and locations where this knowledge and highly trained workforce are available, because these activities cannot be carried out without access to such knowledge and training.

The Rutgers-led Engineering Research Center for Structured Organic Particulate Systems (C-SOPS), which was one of the origins of this technology revolution, is also one of the largest repositories of relevant knowledge. Funded by the NSF in 2006, C-SOPS formed a coalition of six universities (Rutgers, Purdue, NJIT, UPR, Hawaii, and Rowan) to create a long-term strategic plan seeking to transform pharmaceutical manufacturing. C-SOPS implemented one of the first working Continuous Manufacturing systems in 2008, and subsequently worked closely with more than 50 member companies to create a functioning ecosystem devoted to developing, demonstrating, and facilitating the implementation of Continuous Manufacturing systems for solid oral dosage products.

Critical to C-SOPS' success was the active participation of the FDA, which joined the center shortly after its inception and has provided critical input and additional funding for research and educational activities. After the NSF funding period for C-SOPS concluded in 2016, the FDA became C-SOPS main federal sponsor, providing support for research and educational activities that continue to this day, which in turn helped FDA to acquire and maintain clear intellectual leadership among worldwide regulatory agencies.

In the 14 years since C-SOPS was established, our academic-industrial-regulatory partnership has attracted research funding in excess of \$100 million, published over 500 peer-reviewed papers, and enabled implementation of advanced manufacturing methods at numerous companies. Among many examples of successful interaction, C-SOPS undertook a significant partnership with Johnson and Johnson in 2010, which remains active to this day, and led to the implementation of the first FDA-approved conversion from batch to Continuous Manufacturing for the HIV drug, Prezista.

Implementation of Continuous Manufacturing systems is accelerating. The FDA has already approved six finished dosage forms (FDF) to be manufactured by four companies (Vertex, Johnson and Johnson, Eli Lilly, and Pfizer) using integrated Continuous Manufacturing processes. Many other brand-based pharmaceutical companies are also actively engaged in exploring, developing, and implementing continuous manufacturing processes, not only for small molecule prescription products, but also for biologicals and over-the-counter products, and many more products are currently at various stages of submission.

It is important to highlight the enlightened and highly positive role the FDA has played in enabling this ongoing technology transformation. The FDA embraced Continuous Manufacturing

early on, funding academic research and strongly encouraging industry to pursue its implementation. Moreover, FDA hired people from other industries with relevant expertise, invested in the education and training of its personnel, and created a separate vehicle to encourage companies to engage in a productive dialogue. In these and other actions, the FDA made the ongoing technology revolution possible, and set an example for regulators worldwide.

Potential Advantages of Continuous Manufacturing

Reducing Drug Prices

Continuous Manufacturing can help reduce the cost of both prescription and OTC drugs in multiple ways. Some of the impact is direct: Continuous Manufacturing processes have smaller footprint, achieve higher yields, and require less direct labor than their batch counterparts, so they are able to directly impact the cost of making pharmaceutical products. Some of the impact is indirect: because Continuous Manufacturing processes also enable the manufacture of products with superior quality, and because they enable real-time quality control, they reduce the cost of assuring product quality. While Continuous Manufacturing processes require up-front investments in both physical and human infrastructure, they can return this investment rapidly. Moreover, Continuous Manufacturing products and their required manufacturing processes can be developed faster than their batch-based counterparts. As a result, products developed and manufactured using Continuous Manufacturing technology can reach the market place faster, extending profitability periods for the companies making them. These factors could contribute to lower drug prices to the US consumer, if Continuous Manufacturing technologies could be adopted in the highly price-competitive generic and the over-the-counter sectors of the pharmaceutical industry.

Improving Product Quality

Continuous Manufacturing processes can enable superior product quality. Our collaborations with the FDA and with industry, and our partnership with organizations like the United States Pharmacopoeia, help to ensure this outcome. There are three main reasons for this. First, the near-steady nature of the process enables all portions of material to be processed under equivalent conditions at a constant state of control. Second, because only a small amount of material is processed at any given time, quality attributes of every portion of the process stream can be rigorously monitored to assure quality. Any defective product units can be tracked and scrapped, while retaining only quality-compliant product units. Third, and again because the system is nearly-steady and continuous, real time monitoring, active control and advanced optimization can be used to ensure that the process remains within operational specifications at all times. In addition, Continuous Manufacturing enables detailed and accurate computer modeling, assuring a much deeper scientific understanding. This improvement in quality can

translate directly into health benefits, since defective product may fail to provide its therapeutic benefit, or in extreme cases, cause harm to patients.

Faster Product and Process Development

For solid dose products such as tablets and capsules, which comprise the great majority of drugs taken by patients, Continuous Manufacturing has been shown to greatly reduce both the time and cost of developing new medicines. A typical Continuous Manufacturing line for solid dose product reaches an operational state of control in a matter of minutes. Therefore, extensive studies examining alternative product formulations and multiple process conditions can be performed in just a few days, using only a small amount of raw materials. Moreover, because such development studies are performed using the same equipment that will be subsequently used for manufacturing, no scale up studies of the process are needed, and process development is further accelerated. As mentioned, this ability to develop products and processes faster and with less waste can have a major impact on the profitability of both brand-based products (which are protected by patents with finite life) and generic products (where the first company to file an approvable application often accrues a larger share of profits). In my opinion, an even more important benefit is the ability of accelerating access to life-saving new medicines to patients that literally cannot wait, providing the strongest incentive for implementing technologies that enable rapid product and process development.

Faster Responses to Shortages and Emergencies

By enabling faster product and process development, Continuous Manufacturing can allow manufacturers to develop products quickly to respond to emergencies, to address shortages, and to bring break-through therapies to market. The current state of knowledge often enables a skilled practitioner to create a formulation and a process for a given product in just a few weeks. Under emergency conditions, such processes need not be optimum, just adequate, which further enables rapid development. As mentioned, such processes can be developed at the full manufacturing scale and using only a small amount of materials, which is often critical early in the life cycle of a product, or when quality issues are detected, because under such conditions suitable raw materials can be scarce. Moreover, the intrinsically higher reliability of continuous processes should make them safer and easier to approve by regulatory authorities, further enabling rapid response during emergencies.

Growing US-based Manufacturing and Related Employment

Due to its many advantages, Continuous Manufacturing is likely to become a dominant drug manufacturing mode in the future, spanning most drug product types. Its development and deployment is an opportunity to bring drug development and manufacturing operations back to

the United States and grow output and domestic employment in one of the largest consumer goods producing industries of the US economy.

While, as mentioned, Continuous Manufacturing processes allow substantial automation and require less direct labor to be operated --which is a key reason why lower labor cost destinations provide less of an incentive-- they do require highly skilled scientists and engineers to support their specification, implementation, and optimization and well-trained operating personnel to run these modern plants. These jobs typically command high salaries, further growing the US economy and its tax base.

The pharmaceutical industry's transition to manufacturing a large fraction of its output using knowledge-intensive continuous technologies will take place not only in the US, but in all advanced economies, and in many emerging economies with large populations that require access to low cost medications. Designing and implementing the technology platforms to enable this transformation will likely create tens of billions of dollars in economic activity. Importantly, a strategic initiative in continuous pharmaceutical manufacturing would trigger significant activity in many other industries up and down the supply chain, including (1) raw materials suppliers, which are already indicating an interest in developing ingredients in grades optimized for continuous processing; (2) equipment and instrumentation companies, many of which are actively commercializing specialized manufacturing equipment, sensors and process analyzers; (3) companies that commercialize closed-loop control systems, and many others. Moreover, effective implementation of continuous manufacturing for pharmaceuticals will also provide an opportunity for enhancing other industries that rely on powder processing, including cosmetics, food, consumer products, dietary supplements, etc. These industries utilize manufacturing processes that are very similar to those used by the pharmaceutical industry and in many cases the technology is directly portable. The US is at an ideal position to capture -- or to lose -- much of this activity.

Reshoring pharmaceutical development and manufacturing operations would also facilitate more effective regulation. When those activities are carried out within our country's borders, they are easier and less expensive to inspect, facilitating compliance and enforcement of regulations. On-shoring pharmaceutical manufacturing will also increase the security of the drug supply, reducing the current high level of dependence of US patients on foreign suppliers. Moreover, by increasing its knowledge base, the proposed centers will also help consolidate and preserve FDA's intellectual leadership in this area.

The Need for Centers of Excellence in Continuous Manufacturing

More than 14 years of experience at the Rutgers' C-SOPS has taught our team a key lesson:

Continuous Manufacturing platforms are highly integrated systems that are best developed by

highly integrative programs where all necessary technical skills interact and synergize efficiently to create and capture all the required knowledge, including: (1) understanding of the properties of raw and intermediate materials and their effect on process and product performance, (2) effective design, accurate performance characterization, and optimal integration and operation of equipment, (3) accurate modeling of system dynamics, (4) effective sensors and data analytics, measuring meaningful material and process variables, and (5) effective control methodologies. This integration of relevant technical components was essential to the success of C-SOPS and its partner member companies (Janssen, Eli Lilly, Vertex, and Pfizer), which to-date developed and operate all of the solid dose Continuous Manufacturing processes approved by the FDA and by the EMA.

This level of complexity currently makes it difficult for smaller branded and generic pharmaceutical manufacturers to implement Continuous Manufacturing. Currently, such integrated development capabilities for solid dose products reside only at a few universities in the US and Europe, and at a small number of leading brand-based pharmaceutical companies that have gained this experience through many years of sustained collaborative efforts and substantial investments. Such companies have created in-house expertise pools to enable them to implement these technologies. However, smaller pharmaceutical companies, and the generic sector, as well as adjacent industries such as supplements and cosmetics manufacturers, do not have effective in-house access to such expertise.

Moreover, while we have been able to demonstrate effective implementation of Continuous Manufacturing methods for solid dose manufacturing of small molecule products, Continuous Manufacturing of medium size and large molecular entities, such as peptides or monoclonal antibodies, is at an earlier technology readiness level. However, although complete integration of all relevant unit operations in a state of closed loop control has yet to be achieved for these product families, significant development of component technologies is in progress.

In brief, until the knowledge required to integrate Continuous Manufacturing systems is made broadly available and accessible, full implementation of Continuous Manufacturing across the entire field of applications (small, medium, and large molecules, drug substances, and drug products), will remain a difficult task and adoption will remain a slow process in the US. Meanwhile, international companies in Europe and China are actively investing in Continuous Manufacturing platforms as one of their key strategies for growth, placing US leadership at risk.

The recent past provides perhaps the best perspective on how to overcome this situation. The Continuous Manufacturing initiative in its present form is the result of a collaboration between government, industry, and academia, which joined forces to create, implement, and demonstrate this technology. The combination of all of these stakeholders made the effort affordable, relevant, and practical. Each player had a critical role. Universities, initially supported by NSF,

provided the scientific strength and the long-term research perspective required to create something new, and also provided critically needed training and education to industry and FDA employees. Industry provided the critical input needed to make sure the technology was developed in a relevant and practical matter. The engagement and support by FDA support made it feasible.

The best way forward is to re-energize the original US-based partnership of universities, industry, and government, with participation of all relevant expertise, and charter it with the mission to make the required knowledge accessible and easy to implement. Key mission elements of such Centers should include:

1. Supporting US companies and US regulatory agencies in implementing continuous manufacturing methods;
2. Organizing and conducting R&D activities needed to create new and more effective technology, capture and disseminate know-how, create IP, and maintain technological leadership in Continuous Manufacturing methods that will enable industry to develop and manufacture products faster, less expensively, and more reliably;
3. Creating and maintaining a vibrant technological ecosystem, providing the ideal environment for entrepreneurial activities, collaborative research and development, and continuing innovation; and
4. Facilitating the creation of a highly skilled workforce in Continuous Manufacturing, ranging from specialized design engineers to capable plant operators.

As described by H.R. 4866, centers of excellence in continuous pharmaceutical manufacturing will nucleate and organize industry efforts to develop, implement, approve, and operate continuous manufacturing technologies, growing the number of companies capable of using these technologies from the current group of about ten companies, to an estimated 100+ end users. The resulting infrastructure will attract significant private sector involvement, serving as leverage to magnify investment from all stake-holders to maximize the benefit to all contributors. Moreover, centers will facilitate and de-risk adoption so that adopters can deploy these technologies across their entire organizations (new products, established products, OTC products, consumer products, animal health products, etc.). This would lead to the design, acquisition, and implementation of hundreds of manufacturing lines, to be housed in dozens of facilities across the country. Incentives, proximity to know-how and access to highly trained personnel, and other means of keeping those facilities in the US would help to maximize the overall impact on our nation's economy. This will provide all participants with a role in addressing the country's needs, including:

- The need to reduce the cost of developing and manufacturing medicines,
- The need to improve product quality and manufacturing processes reliability,
- The need to respond rapidly and effectively to medical emergencies, shortages, new technologies, and rapidly evolving market conditions,

- The need to reduce dependence of US patients on foreign suppliers, especially for critical medicines such as antibiotics,
- The desire to create supply chains that are robust, flexible, and highly efficient
- The desire to grow the country's manufacturing infrastructure, create high paying jobs, and strengthen our country's economy.

Continuous Manufacturing technologies, if supported by long term funding and enabled in the right forum, like those envisioned in H.R. 4866, can deliver these benefits.

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 healthcare.

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 healthcare 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 to 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 consumers and patients.

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

We learned that counterfeit products 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. Healthcare 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:]



**Prepared Testimony of Rich Kaeser,
Vice President of Global Brand Protection
Johnson & Johnson**

**Submitted to the U.S. House Committee on Energy and Commerce
Subcommittee on Health
Hearing on “Improving Safety and Transparency in America’s Food and Drugs”**

January 29, 2020

Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee, good morning and thank you for the opportunity to discuss how we can strengthen patient safety by granting the Food and Drug Administration (FDA) the same authority for dealing with certain counterfeit medical 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, responsible for combatting illicit trade, including counterfeiting, illegal diversion and tampering, across all Johnson & Johnson business segments – pharmaceuticals, medical devices and consumer health.

I am here today because illicit trade has increased dramatically in recent years, impacting nearly every industry. According to one estimate, global trade in counterfeit goods will hit \$1.9 trillion by 2023.¹ The problem is obviously a serious concern in the 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, of the \$1.9 trillion in illicit trade, counterfeit drugs are the biggest market at \$200 billion per year.² Given that figure, it’s no surprise that INTERPOL estimates that 1 million people, mostly in developing economies, die each year from taking counterfeit medicines.³

Commitment to the Safety of Products for Patients and Consumers

At Johnson & Johnson, our response to illicit trade is guided by Our Credo. The opening line reads, “We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services.” That means all who use our products 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, more importantly, protect patients and consumers from potential harm.⁴ We take a holistic view of potential risks across our

¹ [Frontier Economics \(2017\). *The Economic Impacts of Counterfeiting and Piracy*.](#)

² [Havocscope \(2016\). *Global Black-Market Information*.](#)

³ [OECD \(2016\). *Illicit Trade: Converging Criminal Networks*. OECD Reviews of Risk Management Policies.](#)

⁴ [Johnson & Johnson Health for Humanity Report \(2018\).](#)

end to end value chain and deploy a wide variety of controls to enhance the integrity of our products and supply chain, while also employing tactics to disrupt the illicit supply chain. Controls include, for example, a range of product and packaging security measures that enable us to distinguish genuine product from fake and minimize the risk of product tampering. We also conduct extensive market monitoring, both online and offline, to identify the presence of illicit products and remove them from the supply chain.

Protection Requires Multi-Stakeholder Collaboration

Our Global Brand Protection (GBP) team, which I lead, is responsible for these efforts across the company. While my team is 100% dedicated to this mission, effective brand protection also requires significant teamwork across our entire business. Internally, GBP works closely with Johnson & Johnson Global Security to maintain supply chain security and undertake investigations and enforcement actions; with Quality & Compliance to capture and respond to suspect incident reports; and with the Law Department to handle issues related to trademarks and intellectual property. GBP also works with other functional and commercial business partners to advise on illicit trade risks and embed brand protection best practices and processes in ongoing operations.

Externally, GBP collaborates with industry partners, suppliers, academic institutions, law enforcement and government agencies, including the U.S. Department of Homeland Security, U. S. Customs and Border Protection, and the National Intellectual Property Rights Center.

Lawmakers play a critical role in promoting international collaboration and strengthening our nation's laws to increase penalties for illicit traders and reduce incentives for engaging in illegal trade, and we appreciate the leadership of Representative Guthrie (R-KY) and Representative Engel (D-NY) 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, devices, and combination products valued at \$2500 or less. We believe this authority is important to protect consumers, patients, and the integrity of the supply chain by preventing counterfeit products from reaching end users.

Critical Examples and Efforts to Address Illicit Trade

I would like to share a recent example of counterfeiting that impacted our medical devices business involving a product known as SURGICEL® Absorbable Hemostats, a blood-clot-inducing material used to control bleeding during and after surgeries. We learned that counterfeit products labelled and sold as SURGICEL® were entering the supply chain in the United States and other markets through unauthorized gray market distributors - smaller distributors that buy from the secondary market.

The case began when a neurosurgeon in the United States flagged a SURGICEL® product that did not look or feel right to him, based on his experience using the product. He contacted J&J and we immediately acted to understand if there was an issue with the product. Subsequent testing by an independent laboratory showed that the product was, in fact, counterfeit. It did not have the same safety and efficacy as an authentic product and, due to its lack of sterility and performance, it posed a serious risk to patients.

The incident was escalated to senior leadership and the Johnson & Johnson Global Brand Protection Team. The counterfeit products were removed, and no patients were harmed. A timely investigation identified and shut down an international counterfeiting scheme and we are now pursuing global civil and criminal remedies against the illicit manufacturer and traders. We engaged our customers to notify them about the counterfeit issue and to explain that buying our products only from authorized distributors is vital to protect both patients and providers. Importantly, we also involved the FDA and are cooperating with their criminal investigation teams as they consider taking enforcement action against the parties involved.

While cases like this put illicit traders on notice and have a deterrent effect, unfortunately in today's global marketplace, we are likely to continue to see illicit medical devices, drugs and personal care products entering legitimate supply chains. This is a problem that impacts not only the U.S., but the broader global market as well. Illicit traders target a variety of products, including contact lenses. Late last year we worked with enforcement authorities in Dhaka, Bangladesh who raided a wholesaler and seized over 600 packets of counterfeit Acuvue® Clear contact lenses before they could reach the public. Healthcare products will continue to be one of the most commonly targeted industries for counterfeiters.

Solutions to Address the Challenges We Face

These situations demonstrate why businesses must partner with one another and with government, so collectively we can be a greater force to deter the growing threat of counterfeit. As the world's largest and most broadly-based healthcare company with more than 130,000 employees worldwide, we recognize the vital roles played by various members of the healthcare and supply chain system. It is important for Johnson & Johnson to be a strong partner in the healthcare industry's response to this problem. Our ultimate aim is to keep patients and consumers safe, but we cannot do it alone.

We look forward to continuing to work with lawmakers and regulators to advocate for solutions to illicit trade. We support solutions that seek to:

- Strengthen government authority to protect the public when counterfeits are detected, for example ensuring FDA can destroy medical products they have determined to be counterfeit
- Better understand the impact of counterfeit health and personal care products here in the U.S. and increase awareness among patients and consumers
- Address the supply of illicit products via online marketplaces, social media platforms and the dark web
- Organize key stakeholders, including industry, academia, law enforcement and our government to develop solutions to deter counterfeiting and take enforcement action; and
- Prohibit the importation of unauthorized products—and potential counterfeits— into the U.S.

Conclusion

Illicit trade and counterfeit products present growing risks to patients and consumers. We have the opportunity to make our world safer by ensuring that 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.

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 healthcare 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 ten 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 I look forward to answering your questions.

[The prepared statement of Mr. Allen follows:]



Improving Safety and Transparency in America's Food and Drugs

Testimony Before Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

January 29, 2020

Jeff Allen, PhD
President and CEO
Friends of Cancer Research

MODERN Labeling Act

Testimony of Jeff Allen, PhD, President and CEO, Friends of Cancer Research

Good morning, Chairman Pallone, Chairwoman Eshoo, Ranking Members Walden and Burgess, and Members of the committee. I am Dr. Jeff Allen, President and CEO of Friends of Cancer Research, a cancer research advocacy organization dedicated to accelerating science & technology from bench to bedside. I would like to thank all Members and the staff of this committee for putting together this important hearing. It is an honor to testify before you today and provide our perspective regarding outdated prescription drug labels and the proposal to help the FDA ensure that all drug labels contain the most accurate and up-to-date information possible.

Each time a new drug is approved for marketing in the United States, an accompanying collection of drug-related information, called “labeling” (also known as the “professional labeling” or “package insert”), is made available to health care practitioners to inform safe and effective prescribing.¹ Federal regulations state that labeling must contain “a summary of the essential scientific information needed for the safe and effective use of the drug,” and that it must be “informative and accurate.”² The content of labeling is written by drug manufacturers but must be approved by the Food and Drug Administration (FDA) to ensure that it meets standards laid out in regulations.³ Labeling is a crucial source of trusted information about prescription drugs. The package insert is the FDA’s primary means of communicating information about approved drugs, which confers to it a special status: labeling is meant to contain the “essential” information about a drug.

When it is 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, but the drug’s manufacturer does not file a supplemental application requesting a modified use be added to the drug’s labeling. This may occur because the manufacturer did not sponsor the research investigating the new use, or because the manufacturer lacked sufficient incentives to pursue a labeling expansion. Drug manufacturers are not required by law to update their products’ labeling with new uses, though they may choose to do so voluntarily when they wish to market their products in new settings.⁴

Uses of drugs in patient populations or for indications that differ from those prescribed in accordance with the product label are referred to as “off-label” uses. Off-label use in oncology is common: it has been estimated that more than half of all uses of cancer drugs are beyond the scope of approved

¹ Federal Register Notice. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products and Draft Guidances and Two Guidances for Industry on the Content and Format of Labeling for Human Prescription Drug and Biological Products; Final Rule and Notices 71 F.R. 3922, 2006.

² US Department of Health and Human Services. Requirements on content and format of labeling for human prescription drug and biological products. 21 CFR §201.56. <https://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol4/CFR-2012-title21-vol4-sec20156>. Effective April 1, 2012. Accessed February 20, 2018.

³ Lindstrom J. Sources of drug information: FDA-approved labeling and other official FDA sources. *Dermatol Ther*. 2009;22: 246-256.

⁴ Greene SM, Noah L. Debate: Off-label drug promotion and the first amendment. *Univ PA Law Rev*. 2015;62:239-267.

labeling.^{5,6} The fact that a particular use is off-label does not preclude it from being incorporated into routine practice and covered by insurers. A policy dating back to 1993 requires Medicare to cover off-label cancer drug uses that have been deemed medically accepted by at least one federally designated drug compendium.⁷ The National Comprehensive Cancer Network Drugs & Biologics Compendium (NCCN Compendium) is the most widely used compendium of oncology drugs and is used not just by Medicare but by most private insurers to guide coverage decisions.⁸ The NCCN Compendium contains a collection of drug uses that have been identified based on an evaluation of the scientific literature and expert judgment and includes both on- and off-label uses.⁹ We believe that actively managed guidelines, like NCCN and those of other expert organizations, are a valuable tool for healthcare practitioners and should remain the basis of evidence used by insurers for coverage decisions given their robust and rapidly iterative processes that actively involve the advice of leading experts in specific fields. However, this does not mean that they should serve as a replacement for maintaining accuracy of individual drug labels following the initial approval of a drug. As previously noted, drug labels serve as an unbiased and factual basis from which the communications about a drug's use is derived.

In a recent study my organization published in the peer-reviewed journal *Therapeutic Innovation and Regulatory Science*, we investigated the extent to which the recommendations of medical experts who crafted the NCCN Compendium align with approved uses of drugs on FDA labeling.¹⁰ The complete findings of our study are included as Appendix 1. To summarize, our analysis of the NCCN Compendium and FDA drug labels included the 43 cancer drugs approved between 1999 and 2011 and identified hundreds of off-label uses, most of which were strongly supported by NCCN expert panels. More specifically:

- In almost every case (34 of 43; 79%), the NCCN compendium had more recommended uses than those described in the FDA label for the drugs analyzed in this study,
- Of the 450 NCCN-recommended uses associated with all drugs included in the study, 253 (56.3%) were outside the scope of the FDA label,
- 65% of the off-label uses in the NCCN Compendium represented new disease indications, meaning these uses were in disease settings not currently represented on FDA-approved labels, and

⁵ Pfister DG. Off-label use of oncology drugs: the need for more data and then some. *J Clin Oncol*. 2012;30:584-586.

⁶ Soares M. "Off-label" indications for oncology drug use and drug compendia: history and current status. *J Oncol Pract*. 2005;1: 102-105.

⁷ Abernethy AP, Raman G, Balk EM, et al. Systematic review: reliability of compendia methods for off-label oncology indications. *Ann Intern Med*. 2009;150:336-343.

⁸ Abernethy AP, Raman G, Balk EM, et al. Systematic review: reliability of compendia methods for off-label oncology indications. *Ann Intern Med*. 2009;150:336-343.

⁹ National Comprehensive Cancer Network. About the NCCN Drugs & Biologics Compendium (NCCN Compendium®). Accessed December 5, 2017.

¹⁰ Shea MB, Stewart M, Van Dyke H, et al. Outdated Prescription Drug Labeling: How FDA-Approved Prescribing Information Lags Behind Real-World Clinical Practice. *Therapeutic Innovation and Regulatory Science*. 2018;52(6):771-777.

- 91% of off-label uses were graded as NCCN Category 1 or 2A, indicating they are based on strong existing evidence and backed by uniform consensus from NCCN advisory committees

From these findings, we can conclude that the labeling of many cancer drugs is out of date, and this is especially true for older, generic products. A review of commercial payer coverage policies further illustrates the divergence between labeling and high-quality clinical practice. We found that 4 of the 5 largest private payers, as well as Medicare, cover over 90% of uses listed on the NCCN Compendium (uses graded 1 and 2A), suggesting widespread acceptance of these uses by diverse stakeholders. While standards for FDA approval differ from standards for coverage determinations, these findings indicate that the gulf between labeled uses and covered uses may be needlessly wide. The absence from approved labeling of many well-accepted drug uses presents a significant public health concern.

When sections of FDA-approved labeling become outdated they may lose value for prescribers and fail to communicate essential information about drugs to patients and healthcare providers. In such cases, and even if labeling is kept up to date, prescribers routinely use other information such as peer-reviewed treatment guidelines in making decisions for patients. In the past, physicians have been found to have limited knowledge of FDA-approved indications of drugs vs. unapproved uses, suggesting low levels of use of labeling.¹¹ A Friends of Cancer Research online questionnaire, developed in collaboration with the Deerfield Institute, to survey physician use and perceptions of drug labeling, indicated that oncologists use multiple sources, in addition to FDA product labeling, when making decisions including clinical practice guidelines, drug compendia, and UpToDate.¹² However, while physicians report generally favorable perceptions of the major prescribing resources in their field, “timeliness” of the source information was a particularly important consideration for prescribers.

Inattention to labeling can cause patient harm, as was seen in the case of cisapride, when a revised label warning of life-threatening adverse events did not change prescribing behavior.¹³ By the same token, overreliance on sources other than labeling, such as compendia, may result in misplaced confidence in some off-label uses. While compendia recommend many strongly supported uses of drugs, they have also been shown to recommend uses that are supported by far less rigorous evidence.¹⁴ Therefore, unforeseen consequences for patients may arise from both the disregard of labeling and the overreliance on other sources, such as compendia alone. Given that the prevalence of off-label use in oncology is well known, the existence of outdated labeling will likely not come as a surprise to many observers. In the case of the drug oxaliplatin, the disparity between the uses recommended by NCCN and those approved by the FDA is especially stark (Appendix 2).

¹¹ Chen DT, Wynia MK, Moloney RM, et al. U.S. physician knowledge of the FDA-approved indications and evidence base for commonly prescribed drugs: results of a national survey. *Pharmacoepidemiol Drug Saf.* 2009;18:1094-1100.

¹² Stewart M, Shea M, Audibert C. Data Driven: How oncologists perceive FDA-approved drug labeling compared to major prescribing resources. 2019. Friends of Cancer Research. Available at <https://www.focr.org/blog/engaging-innovation/data-driven-how-oncologists-perceive-drug-labeling>. Accessed January 22, 2020.

¹³ Smalley W, Shatin D, Wysowski DK, et al. Contraindicated use of Cisapride: impact of food and drug administration regulatory action. *JAMA.* 2000;284:3036-3039.

¹⁴ Green AK, Wood WA, Basch EM. Time to reassess the cancer compendia for off-label drug coverage in oncology. *JAMA.* 2016; 316:1541-1542.

Oxaliplatin was initially approved in 2002 for relapsed metastatic colorectal cancer, and an additional use was added in 2004 for adjuvant treatment of stage III colon cancer. Since then, no new indications were added to the drug's labeling. In contrast, as of 2017, the NCCN Compendium included 38 off-label uses of the drug, representing 10 additional disease settings beyond those that are approved by the FDA. This is not just true of oxaliplatin: over half of the drugs approved between 1999 and 2011 had well-accepted off-label uses in disease settings not currently represented on labeling.

Older drugs may be particularly susceptible to outdated product labeling, especially regarding the “effectiveness” portions of labeling, including information relating to dosage and clinical studies. In the case of oncology, the ongoing evolution of information may be particularly important for identifying appropriate uses in different populations, such as pediatrics, or for use of drugs in combination, which is the case for numerous of these older drugs.

Both brand name and generic drug companies have an ongoing responsibility to report safety information to FDA, and the Agency has the authority to order changes relating to new safety information for both brand name and generic drugs.¹⁵ However, as is the case for new uses of a drug, manufacturers of products that will soon lose or have already lost marketing exclusivity or patent protection often lack an incentive to actively maintain up-to-date labeling, aside from signals of serious adverse events. In some cases, brand name manufacturers of older drugs will voluntarily withdraw their products from the market for reasons other than safety or efficacy, leaving only generic manufactured products on the market (if generic versions of the drug exist). This situation is often referred to as a withdrawn reference listed drug or Withdrawn RLD. In these cases, patient access to the drug typically is not a concern due to the availability of multiple generics. However, access to accurate information about the drug can essentially become frozen in time.

Under the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), generic drug labeling necessarily relies on the brand name drug labeling as a matter of product approval. The Hatch-Waxman Amendments established the modern generic drug industry and required “sameness” for generics with the brand-name drug counterpart in all material respects. The statute mandates that generic drug products have the same active ingredients, strength, dosage, indications, and safety labeling as the reference drug. In fact, the Hatch-Waxman statute's whole premise is that generic drugs are materially indistinguishable from their brand-name counterparts, and so naturally must bear labeling that “is the same as the labeling approved for the [brand-name] drug” on which the generic product's approval is based.¹⁶ In enacting the Hatch-Waxman Amendments, Congress provided that FDA cannot approve an abbreviated new drug application (ANDA) if, with certain exceptions (e.g., patent carve-outs), the labeling proposed for the generic drug is not the same as the labeling approved for the listed drug.¹⁷ Those requirements subsequently were incorporated into FDA's regulations.¹⁸

¹⁵ See, e.g., U.S. FDA, FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm>.

¹⁶ 21 U.S.C. § 355(j)(2)(A)(v) (emphasis added).

¹⁷ See 21 U.S.C. § 355(j)(4)(G); see also 21 U.S.C. § 355(j)(2)(A)(v) (requiring that ANDAs include information to show the labeling proposed for the generic drug is the same as the labeling approved for the listed drug).

¹⁸ See 21 C.F.R. § 314.94(a)(8) (providing that ANDAs must include labeling that is the same as labeling approved for listed drug and must include [a] statement that the applicant's proposed labeling ... is the same as the labeling of the reference listed drug except for differences annotated and explained under paragraph (a)(8)(iv) of this section).

The result is that most older drugs have aspects of FDA-approved labeling that need to be modernized to prevent the dissemination of incorrect information and to enable the communication of information pertinent to safe and effective prescribing. Owing to its desire to communicate effectively with prescribers through labeling, the FDA has attempted at several points in the past 20 years to maximize labels' accessibility and usability. In 1998, the FDA issued proposed regulations aimed at helping speed the incorporation of "new uses" of approved products onto labeling.¹⁹ Then in 2006, the FDA altered the structure of labeling to make it more user-friendly.²⁰ In 2013, FDA launched the Prescription Drug Labeling Improvement and Enhancement Initiative to "enhance the safe and effective use of prescription drugs by facilitating optimal communication through labeling."²¹ Most recently, the FDA Oncology Center of Excellence has launch an initiative called Project Renewal²² designed to update oncology drug labels that have fallen out of date. Thus far, the oncology experts at FDA have identified 44 candidates of older drugs that would benefit from a labeling review. However, for over a quarter of the drugs identified, the RLD has been withdrawn which prevents label updates from taking place.

Existing laws requiring that generic product labels be the "same" as brand-name reference product labels, as well as ongoing concerns over product liability, complicate the initiation of labeling changes by generic firms. Under current law, drug manufacturers can request that additional uses of their products be added to labeling by submitting supplemental new drug applications. This is a voluntary process; manufacturers are not required to update labeling with new information about drug effectiveness. Thus, manufacturers typically submit new efficacy data about previously approved drugs only if they wish to market their products for additional uses. In 2007, the Food and Drug Administration Amendments Act added new authority for FDA to require safety-related labeling changes when new safety information becomes available after approval, but no such requirement currently exists for the addition of efficacy-related information.²³

In collaboration with numerous stakeholders, Members of this Committee developed a legislative proposal to address the prevalence of outdated labels in cases where the brand name reference listed drug that a generic product relies upon has been withdrawn from the market. In such circumstances, it is essential that FDA manage the review of new clinical data and maintain the sameness requirement, whereby all generic labeling changes at once after an FDA order. The legislation would address this problem by giving the FDA the authority to require updating of labels to reflect new information relevant to the drug and its use. The legislation also determines a process through which the FDA can identify labels to be updated, notice label holders, and allows for a process for label holders to submit modifications to the notice.

Specifically, under the proposed legislation, the FDA may:

¹⁹ Dissemination of information on unapproved/new uses for marketed drugs, biologics, and devices. Fed Regist. 1998;63:31143.

²⁰ United States Food and Drug Administration. Guidance for industry: labeling for human prescription drug and biological products—implementing the PLR content and format requirements. Rockville, MD: FDA, 2013.

²¹ Prescription drug labeling improvement and enhancement initiative; request for comments and information. Fed Regist. 2013;78:8446.

²² FDA Oncology Center of Excellence Annual Report. <https://www.fda.gov/media/122837/download>

²³ US Department of Health and Human Services. Food and Drug Administration Amendments Act of 2007. Public Law 110–85. Effective September 27, 2007. <https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf>. Accessed February 20, 2018.

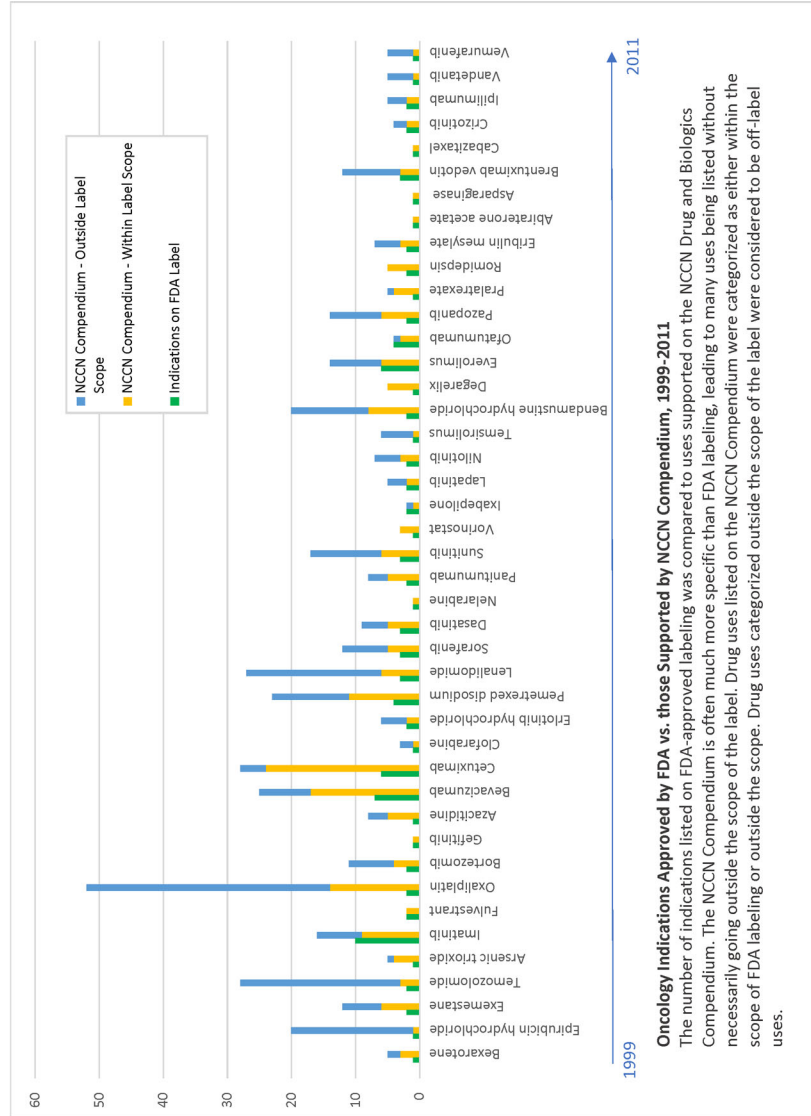
1. Identify one or more drug products for which labeling is missing critical information about drug safety or effectiveness or includes outmoded prescribing instructions and has a withdrawn RLD.
2. Notify the sponsor(s) of drugs identified and proceed if agreement to pursue revised labeling is obtained.
3. Enter into cooperative agreements or contracts with private entities to review the available evidence concerning drugs identified.
4. Seek public input concerning such evidence (including, as determined appropriate by the Secretary, holding public meetings or seeking public comments).
5. Determine, with respect to a drug identified, whether the evidence reviewed is sufficient to meet existing regulatory standards for revising the labeling of the drug.
6. Provide notice to holders of approved applications for a generic version of the drug that:
 - a. Summarizes the findings supporting the determination of the Agency that the available evidence is sufficient to meet the standards under section 505 of the FDCA for amending the labeling of the drug as an additional indication for the drug
 - b. Describes the determined modifications for the labeling
7. Allow the sponsor of a selected drug to respond to a notice; including any request for further discussion with FDA in order to modify the labeling of the drug in accordance with the statement of the FDA in the relevant notice.

It is important to note that the procedures for making the finalized updates to the generic drug label proposed in the MODERN Labeling Act would be no different than those that generic drug manufacturers use for updating their labels when an active RLD holder submits a supplement or change to their label. This process is familiar, routine, and presents little added burden to generic manufacturers at the value of having more accurate information available about the drug.

Restoring the relevance of approved labeling is an important public health goal. While other high-quality sources of clinical prescribing information exist, labeling is the sole source of information that reflects the scientific and methodological rigor of the FDA approval process. Not only does labeling contain the most trusted information about drugs, it reflects the basis for each approval decision. Patients and prescribers can have the assurance that the use of medicines in conformity with drug labeling is supported by a positive benefit-risk assessment. The inclusion of new uses in product labeling, as appropriate, will provide patients and prescribers with these assurances of safety and effectiveness on a more frequent basis. For this reason, preserving the accuracy and reliability of labeling may be viewed as tantamount to preserving trust in and the relevance of the entire drug approval system. The MODERN Labeling Act would aid in maintaining up-to-date drug labels for certain generic drugs and restore the relevance of approved labeling to 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.

Appendix 1: Oncology Indications Approved by FDA vs. those Supported by NCCN Compendium, 1999-2011



Appendix 2: Uses of Oxaliplatin Described in FDA Labeling and NCCN Compendia

	FDA	NCCN
	Disease Indications Contained on Label	Disease Indications contained on Compendium
Chronic Lymphocytic Leukemia		✓
Colon Cancer	✓	✓
Esophageal Cancer		✓
Gastric Cancer		✓
Hepatobiliary Cancers		✓
Neuroendocrine Tumors		✓
Non-Hodgkin Lymphoma		✓
Occult Primary		✓
Ovarian Cancer		✓
Pancreatic Cancer		✓
Rectal Cancer ²⁴	✓	✓
Testicular Cancer		✓

²⁴ Oxaliplatin is indicated for two colorectal cancer uses on the FDA-approved label.

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, and studying the whole issue of API, of the status of drug manufacturing in the United States, and being dependent upon a foreign country that has the API, the core ingredients for drugs, and I found it chilling.

This subcommittee had an extensive hearing on the subject, and FDA did testify on the importance and they 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. OK.

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 the finished products, 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. Yes.

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 the 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 place 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 Johnson & Johnson.

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 [continue]. 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. Yes.

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 hemostasis 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 a 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 and 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. OK. 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 than 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 a 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 on 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?

There are shortages of 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 products. It could also be further developed as a technology option for other kinds of products.

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 five or six 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. OK. OK. 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 an 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, and 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 [continue]. Ten seconds?

Dr. Muzzio, I wanted to ask you, you have talked about thename-brand drugs and continuous manufacturing. Ninety 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 [continue]. 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 ten seconds of my ten 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 ten 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 healthcare 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 the 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. OK.

Mr. ALLEN. The authority for safety—

Ms. MATSUI. Right.

Mr. ALLEN [continue]. 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. OK. 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 Web site.

Ms. MATSUI. Yes. 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.

OK. 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 Web sites 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 watching 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. Yes. 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. Yes, 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. Yes, 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 helping 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 reasons 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, an 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 have 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 [continue]. 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. Yes, OK. I am going to express my frustration here. We hear that a lot from witnesses.

Mr. KAESER. OK.

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. OK.

Dr. CHUA [continue]. 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. youtube the above statement

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

Mr. WALDEN. Yes.

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. Yes. All right. And then how would extending FDA's administrative destruction authority to medical devices com-

plement 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, it would be a great opportunity for us to extend that authority to the FDA on this inbound at these International Mail Facilities.

Mr. WALDEN. OK. 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? Are some better than others?

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

Mr. WALDEN. Yes.

Mr. KAESER [continue]. 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 year ago when 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. Yes.

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. Yes. 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. OK.

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 [continue]. 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. In some places, they lack internet access in some segments of the building. Customs and Border Protection is good about providing the FDA with 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. Yes, 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. Yes. 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 six 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 are 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 things 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 approved. 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 [continue]. 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, and they have dif-

ferent kinds 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 products, 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 a 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. Yes, 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 types 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 Johnson & Johnson 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, and 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. OK, thank you. I yield back to Morgan.

Mr. GRIFFITH. And I yield back to the Chair. Thank you.

Ms. ESHOO. The gentleman yields 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 is 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 seven 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, and 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 [continue]. 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, and anti-counterfeiting for seven 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. OK. 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. OK, 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. OK. 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 healthcare stakeholders?

Mr. KAESER. I think that there is an opportunity for more consumers, and 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 Johnson & Johnson product to let us know.

Mr. BILIRAKIS. OK. 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. Yes.

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, OK, 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 [continue]. 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. Yes, 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. OK.

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, OK, 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. Barragán, for her 5 minutes.

Ms. BARRAGÁN. 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 products 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. BARRAGÁN. 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. Yes, 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, and non-sterile. And there is also a feature on those that allow 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. BARRAGÁN. 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. Yes, I am not an expert on what we would do to necessarily upgrade the ports. The 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. BARRAGÁN. Right.

Mr. KAESER [continue]. 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. BARRAGÁN. Yes, I have done a tour down at the port. And—

Mr. KAESER. Yes.

Ms. BARRAGÁN [continue]. 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 diseases 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 diseases 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 three-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. BARRAGÁN. 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 the 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 have 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 the product.

Also, I want to talk for just one second about the APIs that you referred to; right? We had to distinguish, and 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. OK, 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 eight 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, and 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. OK. 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 hands 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 healthcare 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 appears at the conclusion of the hearing.]

Mr. ENGEL. Thank you.

Mr. Kaeser, thank you for joining us today and sharing your insights on protecting the healthcare 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 Johnson & Johnson'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 healthcare 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. OK. I am going to yield back my time. I appreciate you all being here.

Ms. ESHOO. OK, 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 appears at the conclusion of the hearing.]

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. OK. 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 Johnson & Johnson'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 Johnson & Johnson 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, these counterfeits, 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 appears at the conclusion fo the hearing.]

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 two. 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? OK, 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 mil-

lion 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 three 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 ten 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:]

House Energy and Commerce Subcommittee on Health Hearing**Chairman Anna Eshoo (CA-18)****Talia Day - Witness Testimony****January 29, 2020 – 5 mins allotted**

Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, my name is Talia Day and all three of my children have severe food allergies, two of them are allergic to sesame. I want to thank you for the opportunity to appear before you today to explain why the FASTER Act will have an enormous and positive impact on the 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 three 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 airways began to close, 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've been able to avoid his allergens. But I can't.

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 the camp directors. We provided camp staff with detailed, written instructions around his dietary limitations and needs. 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% in the number of hospitalizations for food allergies from just 2007 to 2016. 1 in 13 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 care takers 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 like Zachary. When you consider this, combined with the rapid increase in overall food allergies – it’s clear we MUST TAKE ACTION NOW.

We are thankful for organizations like FARE who work every day to 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 kinds 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 each of your states and districts.

NOW IS THE TIME TO PASS the FASTER Act.

Thank you.

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. Four 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 two 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 Cos-

metic 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:]



Statement of

J. David Carlin

Senior Vice President, Legislative Affairs
and Economic Policy

Before the

**Subcommittee on Health of the
Committee on Energy and Commerce
United States House of Representatives**

**Federal Food and Drug Administration
Efforts to Ensure Safety and Transparency in
Food and Drug Supply**

January 29, 2020

Introduction

Thank you for inviting me to testify at today's hearing in support of the Codifying Useful Regulatory Definitions Act ("CURD Act/H.R. 4487) which would establish a definition of 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.

IDFA represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate \$159 billion in wages and \$620 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy companies and cooperatives to food retailers and suppliers. Together, they represent 90 percent of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world.

Why This Legislation is Needed

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

The term "natural cheese" has been used extensively over the years by the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), Congress, and the courts to describe a particular category of cheese. For example, the FDA standard of identity for "Spiced, Flavored Standardized Cheeses" requires that product to combine one or more safe and suitable spices and/or flavorings with a "specific natural cheese variety."¹ Similarly, in January 1983, FDA amended the standards of identity for "nine natural cheeses," including Cheddar cheese and Provolone cheese.² FDA's ultrafiltered milk rulemaking also recognized natural cheese as a category.³ USDA uses the term "natural cheese" in a manner consistent with FDA. For example, USDA has published a pamphlet called "How to Buy Cheese" in which it describes "natural cheese."⁴ USDA also requires warehouses storing "natural cheese" products to report their "natural cheese" stocks but excludes "processed cheese" from this requirement.⁵

Unfortunately, the ability of U.S. cheesemakers to continue to use the term "natural cheese" on their packaging is now threatened. Four years ago, the FDA initiated a separate process to define how the term "natural" may be used to make product claims such as "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.

¹ 21 C.F.R. Section 133.193(a).

² Nine Natural Cheeses; Revision Based on International Standards of Identity, 48 Fed. Reg. 2736 (Jan. 21, 1983)

³ Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk, 70 Fed. Reg. 60751 (Oct. 19, 2005) (discussing "natural cheese" made directly from milk).

⁴ U.S. DEPT. OF AGRIC., HOW TO BUY CHEESE (1995)

⁵ 7 C.F.R. Section 1170.10.

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. In fact, the CURD Act specifically provides that any cheese that does make a product claim such as “100 percent natural” or “all natural” must continue to comply with FDA’s current policy and any future regulations governing the use of that term.

Finally, it is important to note that this would not be the first time that Congress has acted to define a dairy term or type of food in federal statute. Definitions of “butter” and “nonfat dry milk” are already included in the Federal Food, Drug, and Cosmetic Act (“the Act”). Congress has also passed legislation that added definitions of “ginseng” and “catfish” to the Act.⁶

Description of the Legislation

The CURD Act defines “natural cheese” by identifying the types of cheeses covered by the “natural cheese” definition, as well as the permitted basic ingredients and processing techniques that would be used to make a cheese that meets the definition of “natural cheese.” Consistent with longstanding governmental and industry usage of the term, there are two paths for a cheese to be labeled as “natural cheese”:

1. A cheese will be considered “natural cheese” if it is covered by existing federal standards of identity issued as regulations by FDA (e.g., Cheddar cheese, Swiss cheese, Mozzarella cheese), or
2. Certain cheeses that are not defined in FDA regulation (e.g., Feta cheese) can also qualify as “natural cheese” if they generally follow the Codex Standard for Cheese, which is an international definition that is widely accepted by industry and policymakers.

The bill then sets forth the types of cheeses that do not meet the definition of “natural cheese.” These include process cheeses, process cheese foods, process cheese spreads, cold pack cheeses and grated American cheese food as currently defined in the Code of Federal Regulations.

As stated above, the CURD Act also contains clarifying language that “natural cheese” is a factual descriptor of a category of cheese and may not be used to make a product claim that is inconsistent with regulations, guidance or policy statements issued by the Secretary of Health and Human Services. Finally, the bill expressly preempts non-federal definitions of the term “natural cheese.”

Extensive FDA Review and Consultation

FDA’s technical experts have reviewed the CURD Act extensively and the agency has provided three sets of technical assistance comments on the bill to Congress over the past two years, including the most recent set of technical comments which were provided to Committee staff last month. We believe that the bill’s sponsors have addressed each of FDA’s previous technical comments and suggestions and we

⁶ 21 U.S.C. 321d; Public Law 107-171 (January 23, 2002).

look forward to working with the Committee and FDA to address two additional technical recommendations that FDA included in its most recent technical assistance comments. On behalf of our cheesemaking members, we appreciate FDA's careful review and extensive input regarding this legislation.

The Legislation is Strongly Supported by the U.S. Dairy Industry

The CURD Act is supported by all of IDFA's cheese company members, including those that manufacture process cheese products. In addition to IDFA, which represents the U.S. dairy processing and manufacturing industry, the bill is also supported by the National Milk Producers Federation which represents cooperatives and their dairy farmer members.

State dairy organizations also strongly support this legislation, including the Dairy Institute of California, the Dairy Products Institute of Texas, the New York State Cheese Manufacturers' Association, the Northeast Dairy Foods Association, the Wisconsin Cheese Makers Association, and the Wisconsin Dairy Products Association.

Misconceptions Regarding the Legislation

The goal of the CURD Act is to support labeling transparency and consistency for consumers so that they can easily differentiate between natural and process cheeses in the grocery store. Despite this simple goal, there have been some misconceptions as to how the bill would affect current law and regulations, and IDFA appreciates the opportunity that the Subcommittee has provided us to address each of these misconceptions.

First, the CURD Act does not change in any way the ingredients that may be used to make standard and non-standardized cheeses. Specifically, the bill would not override FDA's regulatory definition for milk as it pertains to standardized cheeses. In other words, if a cheesemaker was permitted to use a particular ingredient to make a standardized cheese before this bill is enacted, the cheesemaker will still be able to use that same ingredient after enactment of the bill. Conversely, if a particular ingredient was not permitted to be used before, it would not be permitted after enactment. Moreover, how the term "cheese" would apply to plant-based foods such as a food that resembles cheese made from a plant such as soy or almonds will be considered by FDA separately. FDA has committed to address this very issue as part of its Nutrition Innovation Strategy with multiple steps to solicit input from stakeholders regarding the Use of the Names of Dairy Foods in the Labeling of Plant Based Products.

Second, the CURD Act does not change FDA's policy on the use of "natural" or "all natural" claims and it does not establish a product-specific definition for "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, Subsection (b) of Section (3) of the bill contains language that explicitly states that any cheese that makes a product claim such as "100% natural" or "all natural" must continue to comply with FDA's current regulations, guidance and policy statements regarding those terms.

Third, 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.

Conclusion

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. I look forward to answering questions from members of the Subcommittee.

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 liti-

gation 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 identity 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:]

**Hearing on “Improving Safety and Transparency in America’s Food and Drugs”
Wednesday, January 29, 2020 - 10:00am
2322 Rayburn House Office Building
Health Subcommittee**

Testimony by Sarah Sorscher, Deputy Director of Regulatory Affairs, Center for Science in the Public Interest

I am pleased to testify today on behalf of the 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. Our work is funded by individual subscribers to our Nutrition Action Healthletter and by donations from individuals and foundations. We do not accept donations from corporations, giving us the ability to provide an independent voice on behalf of consumers. CSPI has played a major role over the years in pressing for laws to require the Nutrition Facts on packaged foods, ensure clear allergen labeling, and prohibit misleading claims on foods.

I will speak today primarily on two bills that would impact food labeling in the U.S. FASTER Act (H.R. 2117)¹ the CURD Act (H.R. 4487).²

CSPI Supports the FASTER Act

CSPI also supports the FASTER Act (H.R. 2117) which among other things would update the U.S. list of major allergens to include sesame, as well as authorize the FDA to periodically review and further update the list of major allergens based on the latest science.

When Congress passed the Food Allergen Labeling and Consumer Protection Act in 2006, it created important new requirements for labeling the so called “major” food allergens, which were the eight most common allergens identified at that time. In addition to designating the so-called “Big Eight,” the law also authorized the FDA to label additional non-major allergens through separate regulations.

In 2014, CSPI urged the FDA to make use of this authority by requiring companies to label for sesame. There are than 1.5 million people in the United States with reported sesame allergy, and 1.1 million Americans have had their sesame allergy diagnosis confirmed by a physician or have a history of convincing symptoms.³ Recent studies have shown that sesame allergy is now similar in prevalence and of greater severity than some of the “Big Eight” major food allergens; and a greater fraction of adults with sesame allergy report

¹ H.R. 2117 – FASTER Act of 2019. <https://www.congress.gov/bill/116th-congress/house-bill/2117/>

² H.R. 4487 – Codifying Useful Regulatory Definitions Act. <https://www.congress.gov/bill/116th-congress/house-bill/4487/>

³ Warren C, Chadha A, Sicherer S, Jiang J, Gupta R. Prevalence and severity of sesame allergy in the United States. JAMA Network Open. 2019; 2(8): e199144. (Reported prevalence in Table 1 multiplied by current U.S. population of 327.2 million)

having an emergency room visit for food allergy in the past year than adults with any other major food allergy.⁴

A 2018 report by CSPI found that a majority of the 22 large food companies we surveyed are already voluntarily labeling for sesame,⁵ and more indicated they could easily do so if given clear direction from regulators. FDA opened a docket to collect data on prevalence and severity for sesame in 2018, but has taken no action since then.

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.

The FASTER Act would also authorize the FDA to periodically review and update the list of “major” allergens based on the latest scientific and clinical evidence, implementing a recommendation of the Committee on Food Allergies of the National Academies’ Food and Nutrition Board.⁶

While FDA is currently authorized to require labeling for new allergens, like sesame, that are not on the major food allergens list, this new provision will help streamline and simplify that process by updating the major food allergens list itself, rather than developing a separate regulatory framework for non-major allergens.

CSPI Opposes the CURD Act

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 “process cheese.”

The ostensible purpose of this bill is to draw a clear line for consumers by clearly defining “process cheese” and differentiate it from “natural cheese.” Yet “process cheese” is already clearly labeled as such and there is no evidence that manufacturers are currently misrepresenting such products as “natural.”

Instead of protecting consumer interests, the bill addresses are those of cheese manufacturers, who wish to be sheltered from litigation by consumers alleging they were misled by “natural” claims on cheese that contains artificial ingredients. For example, in 2016, Kraft was sued for “natural” cheeses alleged to contain artificial coloring. More

⁴ Center for Science in the Public Interest. The Call for Sesame Allergen Labeling. January 2020. [https://cspinet.org/sites/default/files/attachment/Sesame Allergen Labeling Fact Sheet Final updated%201.8.20.pdf](https://cspinet.org/sites/default/files/attachment/Sesame%20Allergen%20Labeling%20Fact%20Sheet%20Final%20updated%201.8.20.pdf)

⁵ Sorscher, S. Seeds of Change: While Some Companies Lead the Way in Sesame Allergen Labeling, Large Gaps Remain. Center for Science in the Public Interest. April 2018. <https://cspinet.org/sites/default/files/attachment/seeds-of-change-report.pdf>

⁶ Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy. November 30, 2016. <http://nationalacademies.org/hmd/reports/2016/finding-a-path-to-safety-in-food-allergy.aspx>

recently,⁷ Sargento was sued based on feeding and rearing practices the cows that produced milk for its line of “natural” cheeses.⁸ CSPI is not involved in either of these cases and has not taken a position on this litigation. We do, however, oppose any legislative effort to distort the meaning of “natural” for the purpose of denying consumers their day in court.

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 products that resemble cheeses made by more traditional means. 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 necessarily even notifying the agency or making safety data available to the public.⁹

Certain artificial ingredients are legally permitted under the standards of identity for cheese. For example, artificial coloring is expressly allowed as part of the standard of identity for many cheeses.¹⁰ Cheeses with no set standard of identity have even greater flexibility to add artificial ingredients.

While these artificial ingredients are legally permitted in cheeses, many Americans would not consider the resulting product 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.¹¹

That is why the U. S. Department of Agriculture (USDA) permits the term “natural” only products “containing no artificial ingredient or added color” and that are only minimally

⁷ Shook, Hardy & Bacon, LLP. Court Denies Stay for FDA “Natural” Guidance in Kraft Artificial Coloring Case. *Food and Beverage Litigation Update*. December 9, 2016. <https://foodbeveragelitigationupdate.com/court-denies-stay-for-fda-natural-guidance-in-kraft-artificial-coloring-case/>

⁸ Watson, E. Sargento defends ‘natural cheese’ claims. *Food Navigator*. September 4, 2017.

www.foodnavigator-usa.com/Article/2017/09/05/Sargento-attacks-implausible-allegations-in-natural-cheese-lawsuit#.

⁹ “Safe and suitable” is defined under 21 C.F.R. 130.3 to mean an ingredient that “(1) Performs an appropriate function in the food in which it is used, (2) Is used at a level no higher than necessary to achieve its intended purpose in that food, and (3) Is not a food additive or color additive...” However, manufacturers may determine that novel ingredients are “not a food additive or color additive under a 1997 proposal by the FDA that allows companies to self-certify novel ingredients as “Generally Recognized as Safe.” Gaynor P, How U.S. FDA’s GRAS Notification Program Works. U.S. Food and Drug Administration. December 2005/January 2006. Current as of 2/9/2018. <https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works>.

¹⁰ See 21 CFR Part 133.

¹¹ Natural and Antibiotic Labels Survey. *Consumer Reports*. May 1, 2018.

<https://advocacy.consumerreports.org/wp-content/uploads/2018/10/2018-Natural-and-Antibiotics-Labels-Survey-Public-Report-1.pdf>

processed.¹² The FDA is also currently working on a definition of “natural” that ideally will be non-misleading and apply uniformly to all FDA-regulated foods.

The CURD Act seeks to short-circuit that process, carving out a special definition for “natural” that would only apply to cheese. This definition would allow “natural cheese” to contain artificial ingredients, running counter to consumer expectations.

It would also make labeling for cheese inconsistent with U. S. Department of Agriculture (USDA) labeling requirements, which permit the term “natural” only on products that contain no artificial ingredients, leading to inconsistency and confusion across the marketplace.

Finally, because the CURD Act also defines “milk” as a lacteal secretions from an animal and requires “natural cheese” to be made from milk, it could be interpreted as prohibiting the use of the term “natural” on non-dairy alternatives eaten by consumers who are vegan, allergic to milk, or who 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 a natural food.

We urge Congress not to act prematurely to carve out a definition for “natural cheese” that will confuse consumers, and instead allow the FDA and USDA to define “natural” clearly and consistently across all foods.

We would also like to comment on two other bills included in today’s proceedings.

The Infant Formula Protection Act of 2019 (HR 2267)¹³ addresses an important gap in current FDA regulation of formula by barring the sale of expired infant formula. The nutrients in formula degrade over time, which is why the FDA requires manufacturers to prove that the formula meets minimum nutrient standards through its “use by” date, and why it recommends not consuming infant formula after that date.

However, there are no federal safeguards preventing businesses from selling the formula after the date has passed. This bill would help close that gap by ensuring that infant formula cannot be sold after its expiration date.

The Keep Food Containers Safe from PFAS Act of 2019 (HR 2827) would deem PFAS compounds as unsafe for use as food contact substances.¹⁴ The bill raises important concerns about the use of PFAS chemicals as food contact substances, including in food wrappers or packaging. We share these concerns about the use of PFAS as food chemicals in light of the known risks of long-chain PFAS and the potential for similar concerns in

¹² U.S. Department of Agriculture. Meat and Poultry Labeling Terms. August 10, 2015. <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms>

¹³ H.R. 2267 – Infant Formula Protection Act of 2019. www.congress.gov/bills/116/congress/house-bill/2267

¹⁴ H.R. 2827 – Keep Food Containers Safe from PFAS Act of 2019. www.congress.gov/bills/116/congress/house-bill/2827

short-chain PFAS. This family of compounds is very persistent in the environment and in the human body, and several long chain PFAS chemicals have been banned or phased out as hazardous.

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, hor-

mone 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:]

**Testimony of Nancy Perry, Senior Vice President of Government Relations
American Society for the Prevention of Cruelty to Animals**

**Subcommittee on Health of the Committee on Energy & Commerce
Hearing on “Improving Safety and Transparency in America’s Food and Drugs”
Wednesday, January 29, 2020 – 10:00 a.m.**

Good morning and thank you Chairwoman Eshoo, Ranking Member Burgess, and distinguished Members of the subcommittee for inviting me to provide testimony regarding an issue critical to equine welfare and public health. I would first like to recognize the leadership of Representatives Schakowsky and Buchanan as the sponsors of the SAFE Act and to thank the 224 House cosponsors, including many on this committee. My name is Nancy Perry and I am the Senior Vice President of Government Relations for the American Society for the Prevention of Cruelty to Animals. Founded in 1866, the ASPCA was the very first animal welfare organization on the continent and has long served as a leading voice for animal welfare in the United States.

The ASPCA’s history and mission are intricately tied to equine protection. Our founder was inspired to pioneer the organization after witnessing the cruelties horses endured during a time in our history when they were the primary form of transportation. In fact, the ASPCA provided medical care for these animals, inventing the first equine ambulance and operating table to care for injured equines. Then and today, our goal has been simply stated yet highly ambitious – that all equines have good welfare. To achieve this in the modern context, we have been amplifying our commitment to equine protection by establishing a new Equine Welfare department and developing a robust program that has already revolutionized the partnerships between welfare organizations and equine industry groups. We are providing directly or through grants a multitude of critical services for equines, including safety net programs that offer support to owners who have horses in need of veterinary or other care including humane euthanasia, rehoming, retraining, adoption resources for horses in transition, and open-shelter services in local communities, including rural areas, that greatly expand services for at-risk horses. We tenaciously advocate for legal protections from neglect, abuse, and cruelty.

I am here today to express our strong support for the Safeguard American Food Exports (SAFE) Act (H.R. 961), a critical missing link in the existing systems vital for protecting American equines. Our goal of good welfare for equines cannot be met while our nation’s horses are slaughtered for human consumption. Every horse, no matter how beloved, is one sale, one change of hands, one theft away from falling victim to this system. Current law allows kill buyers to attend regular auctions and bid against horse owners and rescuers to obtain race and show horses, backyard ponies, work horses, and other horses that enrich the lives of their human counterparts, then ship them over our borders for slaughter. This predatory practice jeopardizes the welfare of horses and unavoidably raises serious food safety concerns. This legislation is of the highest priority for our organization because of the extreme cruelty inherent in the commercial slaughter of horses, the hardship and interference that the practice places on equine rescues and rehoming work across the country, the negative externalities created for horse owners and the equine industry, and, most relevant to this hearing today, the significant risk that tainted and toxic horsemeat poses to the food supply and consumer confidence.

I. Legislative and Policy History on Horse Slaughter Prohibitions

Due to a groundswell of public support and bipartisan Congressional action, horse slaughter already is effectively banned within the United States. Since 2007, a provision in annual federal Appropriations bills has prevented the foreign-driven horse slaughter industry from operating in our country. Congress first enacted this provision by wide, bipartisan margins in both the U.S. House and U.S. Senate in 2005, and it has been included almost every year since. Inclusion of this provision, which prohibits USDA funding for horse slaughter inspections, legally necessary for the sale of horsemeat, has become routine. Most recently, for Fiscal Year 2020, it was included in the base U.S. House and U.S. Senate Agriculture Appropriations bills and in the President's budget request. Though consensus has been overwhelming around this issue, relying on appropriations cycles to maintain the policy is unsustainable and vulnerable to shifting political winds.

Unfortunately, the current restriction has not prevented the continued export of equines for slaughter to other countries – a practice that existed even when foreign-owned plants were operating in the United States. Each year thousands of American horses, donkeys, and mules are slaughtered in Canada and Mexico for human consumption. Government statistics show a positive downward trend in the annual number of equines exported for slaughter, dropping from more than 100,000 just a few years ago to approximately 60,000 in 2019.¹ The SAFE Act would ban the commercial slaughter of equines in the U.S. and their export for that purpose abroad, effectively closing the loophole that has existed since 2007.

For the American public, this policy reform is long overdue. A 2012 Lake Research Partners poll found that 80% of Americans opposed this practice.² In some states, such as Ohio, this figure was as high as 94%. Their opposition cuts across all socioeconomic factors and party lines. In each region examined – West, South, Northeast, and Midwest – acceptance of horse slaughter never exceeded 17%. The states of Texas, California, Mississippi, New Jersey, Arizona, Illinois, and New Mexico have already banned horse slaughter or the sale of horsemeat or horse parts for human consumption. New Mexico and Mississippi both consider horsemeat adulterated due to the ubiquitous presence of toxic substances associated with it. Unfortunately, state-level bans are difficult to enforce and do not protect horses taken across states lines and sold into the slaughter pipeline. Until the SAFE Act is law, equines will continue to be exported for slaughter, subverting the will of Congress and the American public. Each year that goes by without enactment of this law perpetuates unnecessary cruelty to animals that we hold dear and further jeopardizes human health. It is time to pass this bill and to permanently protect our nation's equines.

II. The Public Health Risk of Eating American Horses

Public antipathy toward the commercial slaughter of our nation's equines underscores how we define and value these animals – as work partners, athletes, and trusted friends – not as food. This is significant not only as a cultural norm, but to illustrate how that perception and categorization translate into the regulatory framework under which our equines are governed.

a. Regulatory Mismatch

Horses are not raised for their meat in the U.S. They live in backyards and on racetracks, in show barns and on ranches, but none live in a setting where their caretakers expect them to eventually become food.

¹ Statistics Canada "Imports By Province from the USA, by State" reports - annual subscription service - <https://www.statcan.gc.ca/eng/start>; USDA "US to Mexico Weekly Livestock Export Summary" reports - https://www.ams.usda.gov/mnreports/al_ls635.txt

² Lake Research Partners. 2012. *Memo: Research Findings on Horse Slaughter for Human Consumption*.

Therefore, these horses are regularly given a wide variety of drugs, medications, and treatments that are approved for use on equines and are necessary for the welfare of the animal. These drugs and chemicals are administered routinely, sometimes daily, and there is no system or reason to track how often or what type of treatments equines are given. Further, horses change hands an average of eight times throughout their lives, and it is extremely common for owners, along with veterinarians and trainers, to administer medications routinely.³

Many of the substances given to horses as part of daily care are expressly banned by the U.S. Food and Drug Administration (FDA) for use on animals meant for human consumption. The products found in every barn or on every ranch include fly sprays, dewormers, medicines, and pain relievers. It is commonplace for horse owners to administer pain relief and other medicines. The *Merck Veterinary Manual* indicates that "... administering medication to a horse is not difficult if you use common sense and follow good handling principles for keeping both you and your horse safe."⁴ It goes on to confirm that horse owners can routinely provide injectable medicines to their horses. "Some medications can be administered only by injection, which is usually given in the neck area or thigh. Ask your veterinarian for a demonstration and guidance to make sure you know how to give the injection properly." The most common pain relief drugs are phenylbutazone (known as 'bute') and Banamine. "Non-steroidal anti-inflammatory drugs (NSAIDs) have been the mainstay of equine analgesia for many years," Dr. Khursheed Mama, a veterinary anesthesiology professor, said, noting that phenylbutazone (Bute) and flunixin meglumine (Banamine) are the two most commonly used drugs in this category.⁵ These drugs are listed as prohibited for use in animals intended for human consumption with no exceptions or withdrawal periods.

Experts also recommend routine administration of a variety of medicines and treatments to keep horses healthy. "All horses should be on a deworming program that consists of either a periodic deworming treatment (usually by administering a paste) every 4 to 8 weeks or a daily dewormer in the feed."⁶ It goes on to confirm that "Many different insecticidal salves, lotions, sprays, and rubs are available that can be used to remove ticks and decrease insect irritation and annoyance."⁷ The most common dewormers and insecticides include labels that read: "Not for use in horses intended for human consumption."⁸ This is considered necessary, for proper equine care.

When a horse is repurposed and channeled into the pipeline for slaughter, that health history is lost as there is no tracking or regulation of equine care and treatment comparable to animals raised for food. Equines are not intended for human consumption, and their health history is not monitored or regulated throughout their lives. Their lives typically involve some form of work or performance and routine health care – all of which would lead to their ingestion or absorption of useful and helpful substances that also happen to be strictly prohibited for food animals. This treatment enhances their well-being, safety, and as a result, their performance, and it serves their true purpose.

Contrast this reality with the way food animals are raised and treated, from birth to death. They are fed approved feed and given approved drugs. Producers are required to follow regulatory guidelines

³ 91% of horse owners give their equines medications. APPA National Pet Owners Survey 2019-2020

⁴ <https://www.merckvetmanual.com/horse-owners/routine-care-and-breeding-of-horses/routine-health-care-of-horses>

⁵ <https://thehorse.com/118918/pain-management-options-for-horses/> Reporting on the presentation at the 2011 Western Veterinary Conference on Feb. 20-24 in Las Vegas, by Nev., Khursheed Mama, DVM, Dipl. ACVA, a professor of veterinary anesthesiology at Colorado State University, discussing the different analgesic (pain management) options available and how effective they generally are for treating horses' pain.

⁶ Id

⁷ Id

⁸ For example: [https://www.merck-animal-health-usa.com/product/cattle/Panacur-Suspension-\(Drench\)/1](https://www.merck-animal-health-usa.com/product/cattle/Panacur-Suspension-(Drench)/1)

determined by federal agencies working to keep our food safe. Equines exist completely outside that regulatory framework – their owners, veterinarians, and trainers do not anticipate that their flesh will be eaten by humans. The fact that horses are raised outside of the food system and the critical federal regulations controlling that system makes obvious the reasons for never allowing them to enter the food supply. Yet each year we indirectly allow thousands of pounds of toxic meat from American horses to be exported for human consumption.

b. The Toxicity of Meat from American Equines

As mentioned above, of the substances commonly administered to equines, one of the most prevalent and most toxic to humans is phenylbutazone (“bute”). The anti-inflammatory drug is used as routinely in horses as aspirin or ibuprofen is used in humans. If a horse has had human contact, it is safe to assume that the horse has had bute.⁹ In humans the drug is a potential carcinogen¹⁰ and known to induce blood dyscrasias such as aplastic anemia, leukopenia, agranulocytosis, thrombocytopenia (a hypersensitivity reaction in the liver which can cause renal failure and death), seizures, psychosis, hallucinations, etc.¹¹ Due to these often idiosyncratic health risks, phenylbutazone is currently approved for use only in dogs and horses. Per the FDA, “There are currently no approved uses of phenylbutazone in food-producing animals.”¹²

Other examples of FDA-banned substances commonly given to horses include dewormers, fly sprays, pain relievers, performance enhancers, hoof hardeners, tranquilizers, hormone regulators, antibiotics, antiseptics, and anesthetics. Many of these are carcinogens, some may cause developmental issues in children, or cardiovascular issues, or cancers, etc.¹³ The FDA banned these drugs for human use or use on animals meant for human consumption expressly because they are toxic to humans and should not be present in our food regardless of concentration levels.

c. The Need for FDA Enforcement

The FDA has jurisdiction over animals raised for food and any use of prohibited substances in those animals. Based on that agency’s unambiguous regulations, virtually all horsemeat produced in the U.S is adulterated and unfit for consumption. Since substances that are part of daily life for equines are expressly banned for use on food animals, there can be no question that these animals should be restricted from entering the global food supply. When food producers are found to have violated FDA rules on banned substances, the agency acts. FDA inspectors often visit farms and issue warnings when medicines or other substances have been administered for extra-label use or even when recordkeeping of drugs or substances administered is inadequate.¹⁴ When producers of food animals violate FDA rules, there are consequences.

⁹ Affidavits attached to letter from Bruce A. Wagman, Esq. to U.S. Food Safety & Inspection Service, February 19, 2013

¹⁰ JAVMA News. 2003. “Extralabel use of phenylbutazone banned in dairy cattle.” <https://www.avma.org/javma-news/2003-04-15/extralabel-use-phenylbutazone-banned-dairy-cattle>

¹¹ U. S. Food and Drug Administration. 2003. Final rule on PBZ. Federal Register Volume 68, Number 40.

www.gpo.gov/fdsys/pkg/FR-2003-02-28/html/03-4741.htm; Dodman, Blondeau, & Morini. 2010. “Association of phenylbutazone with horses bought for slaughter: A public health risk. *Food and Chemical Toxicology*. (48)5. <https://www.sciencedirect.com/science/article/pii/S0278691510001225>

¹² U. S. Food and Drug Administration. 2003. Final rule on PBZ. Federal Register Volume 68, Number 40. www.gpo.gov/fdsys/pkg/FR-2003-02-28/html/03-4741.htm

¹³ See Exhibit A in Appendix, “Banned and Dangerous Substances Commonly Given to Horses Sent to Slaughter.”

¹⁴ U.S. Food and Drug Administration. 2018. “Warning Letter: Welter Farms Inc.” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/welter-farms-inc-562966-11272018>; or U. S.

These rules and regulations are in place to protect the public from harmful chemicals, drugs, or other substances in food products. The recommended healthcare routine for equines involves drugs and treatments banned for use on food animals, and no records are kept of when, how much, how often, or what type of substances are administered. The SAFE Act would statutorily recognize that equines raised outside of our food system are not fit for human consumption.

d. The Dangers of Horsemeat in the Market

Countries that do eat or slaughter horses for human consumption have dealt with a host of issues related to cross-contamination of other meat products and banned substances in meat. An article published in the *Food and Chemical Toxicology Journal* estimated that 9,000 pounds of meat taken from horses with known exposure to phenylbutazone were sent abroad for human consumption over the five-year study period – the entire sample they were observing.¹⁵ Another study looking at the prevalence of comingled horsemeat in beef products in Mexico found that of the approximately 10% of samples that contained equine tissue, a disturbing figure in itself, all of them contained clenbuterol – a drug banned for use on animals meant for human consumption.¹⁶ In the UK and the EU in 2013, a scandal erupted when products labeled as beef were found to contain horsemeat. Consumer confidence in meat products dropped dramatically; frozen beef sales plummeted 43%.¹⁷ These shocking developments foreshadow the threat to American health that may result if horse slaughter resumes in the U.S.

Recognizing the dangers that American horsemeat represents, not only in terms of health risks but also in consumer confidence in federally inspected food products, the European Commission (EC) in 2015 banned all horsemeat imports from Mexico, where the majority of American horses are slaughtered. The decision followed a scathing 2014 audit of EU-certified Mexican horse slaughter plants conducted by the EC's Food and Veterinary Office (FVO). The audit report cited lack of traceability and controls on substances given to equines throughout their lives.¹⁸ In 2017 the EC acted again, in light of an FVO audit of Canadian horse slaughter facilities.¹⁹ This time, the EC implemented new regulations requiring that all American horses destined for slaughter in Canada be held for six months prior to slaughter if their meat was destined for EU member countries. While the intent is to control banned substances, many of these substances are banned *in any concentration and for use on food animals at any point in their lives*.

Americans do not eat horsemeat, so there is no domestic demand for the product. Horses have not been commercially slaughtered in the U.S. for more than a decade. However, the risk that this domestic prohibition could lapse remains, in the absence of a permanent federal prohibition. If that were to happen, and horse slaughter plants returned to the U.S., we should expect that events such as those described above would threaten U.S. consumers as well. When asked about the risk of horsemeat being comingled with other products in the U.S., the USDA responded that the risk was low so long as horses were not

Food and Drug Administration. 2011. "A Win for FDA's Food Safety Mission." <https://www.fda.gov/animal-veterinary/compliance-enforcement/win-fdas-food-safety-mission>

¹⁵ Dodman, Blondeau, & Morini. 2010. "Association of phenylbutazone with horses bought for slaughter: A public health risk. *Food and Chemical Toxicology*. (48)5. <https://www.sciencedirect.com/science/article/pii/S0278691510001225>

¹⁶ Lozano, et al. 2020. "Horse meat sold as beef and consequent clenbuterol residues in the unregulated Mexican marketplace." *Food Control*. 1:10. <https://www.sciencedirect.com/science/article/abs/pii/S0956713519306176>

¹⁷ Neville, Simon. 2013. *The Guardian*. <http://www.guardian.co.uk/uk/2013/feb/26/frozen-beefburger-sales-down-43-horsemeat>

¹⁸ Final Report of an Audit Carried Out in Mexico from 24 June to 04 July 2014:

http://ec.europa.eu/food/fvo/rep_details_2_en.cfm?rep_id=3364#

¹⁹ Final Report of an Audit Carried Out in Canada from 02 to 15 May 2014:

http://ec.europa.eu/food/fvo/rep_details_2_en.cfm?rep_id=3442

slaughtered here²⁰. The only sustainable way to protect American consumers is to permanently prevent this industry from returning to the U.S.

III. Irrefutable Cruelty

The animal welfare community, representing millions of Americans across the country, supports a ban on horse slaughter. Animal protection organizations large and small, urban and rural, equine and not, recognize the inherent cruelty of long-distance transport and commercial slaughter of these uniquely fractious and highly sensitive animals. American horses are not food animals and are not raised for this purpose. Condemning them to such intolerable suffering is a shameful betrayal of their trust.

a. Physiological Mismatch

Horses are particularly ill suited for slaughter due to their physiology and natural behavior, and to the equipment used to stun and kill them. Humane slaughter, by definition, requires that an animal be rendered unconscious prior to being dismembered. This standard is impossible to meet with equines – especially in a modern commercial slaughterhouse. Equines have long necks, a high center of gravity, and a strong flight response in the presence of danger. These qualities make them extremely difficult to immobilize and render insensible to pain. In the stunning box, horses' heads are unrestrained and may flail and flinch in a manner inconsistent with humane slaughter. Inevitably, the captive bolt misses its target multiple times, sending the injured equine into a panic.

The cruelty of this industry does not begin and end at the slaughterhouse. Horses arrive at these facilities from all over the country, often traveling up to 28 hours with no food, water, or rest. Crammed into trailers with unfamiliar animals, horses endure grueling journeys that often result in horrific injuries or death. When such facilities were operating in the U.S., the USDA documented gruesome injuries to horses arriving at the slaughterhouse, such as dislodged eyeballs, detached limbs, and downed horses who had been trampled to death.²¹ Until the SAFE Act becomes law, these horrors will continue. The 2014 audit of EU-approved slaughter plants in Mexico cited above documented persistent and extremely serious welfare concerns during transport and at the slaughter facilities. Inspectors noted that at multiple facilities handlers did not even bother to confirm that an animal had been effectively stunned before being hoisted for dismemberment. Whether in the U.S. or abroad, horse slaughter is not a humane practice.

e. Commercial Slaughter is Not Euthanasia

The ASPCA supports humane euthanasia for horses when quality of life is untenable. The entire slaughter process from start to finish flagrantly contradicts anything we would characterize as humane euthanasia. The word "euthanasia" literally means a good death. It is an act of mercy for an individual who no longer has a good quality of life. When we think of euthanasia, we imagine old, sick, or injured animals needing a peaceful and dignified end of life. Humane euthanasia would normally involve a call to the veterinarian for a peaceful, swift end. Loading an already-suffering horse into a transport vehicle and shipping her for up to 24 hours to a slaughterhouse is not euthanasia.

²⁰Weise, Elizabeth. 2013. "U.S. Officials: No horse meat in our beef." USA Today. <https://www.usatoday.com/story/news/2013/03/01/horse-meat-united-states/1957893/>

²¹ U.S. Department of Agriculture. 2005, FOIA Request #06-108.

Further, shipping sick or compromised horses across the country creates a serious public health risk to other horses. The law expressly prohibits diseased animals from being transported, slaughtered, and entering the food system. Dr. Nicholas Dodman, in his 2008 testimony before the House Judiciary Committee on behalf of Veterinarians for Equine Welfare, stated: “No ethical veterinarian, faced with a client who has a horse that is old, sick or otherwise no longer wanted, would suggest that the horse in question should be put on a truck and hauled thousands of miles to slaughter. Instead, the veterinarian would most likely suggest truly humane euthanasia via chemical injection...”²²

Slaughterhouses are not designed as sites for humane euthanasia. The USDA’s own data showed that when horse slaughter plants were operating in the U.S., 92.3% of horses at those facilities were in good condition.²³ Because kill buyers (brokers who buy and sell horses for slaughter) profit from robust, large animals, they avoid equines with poor body condition. This reality underscores the logical flaw in the suggestion that slaughter serves as an outlet for horses in poor condition or health. To increase profits, kill buyers often unload underweight horses at auction and buy healthier ones to take across the border.²⁴ The horses left behind are then at greater welfare risk, potentially suffering additional neglect if no home is found. This is not a system designed for a humane end of life option, nor is it a form of population control. It is a system designed to meet fluctuating and, in recent years, dwindling, foreign demand for horsemeat regardless of the U.S. population of horses. Over the years, the number of horses in the U.S. has hovered between seven million and nine million, while the number of horses exported for slaughter has risen and declined dramatically.²⁵ The number of horses sent to slaughter does not mirror the population, it mirrors the demand for horsemeat.

IV. Mounting Harmful Impacts and Consequences of Legal Horse Slaughter

The loophole that allows American horses to be exported for slaughter is causing havoc in the equine community. In many ways, the horse slaughter industry itself is a barrier to rehoming and adoption of horses. The industry instills fear in horse owners and inhibits good welfare for their horses. It also incentivizes predatory practices that waste resources, cause neglect, stymie efficient and effective horse rescue work, and create an image problem for the equine industry at large.

a. Theft and Fraud

The very existence of a horse slaughter industry incentivizes horse theft and fraud. Kill buyers may pose as responsible re-homers, answering sale ads and even knocking on doors. In many heartbreaking cases, distressed owners have contacted the ASPCA and the media hoping to recover their horses, to no avail. In one recent case, a veterinary student posing as a retirement facility owner took more than 50 horses, claiming she would provide them with sanctuary. Only when the owners inquired about the horses

²² Transcript of House Judiciary Committee hearing, July 31, 2008, p. 65 -

<https://www.govinfo.gov/content/pkg/CHRG-110hrg43830/pdf/CHRG-110hrg43830.pdf>

²³ Grandin, Temple, *Survey of Trucking Practices and Injury to Slaughter Horses*

<https://www.grandin.com/references/horse.transport.html>

²⁴ Horse Plus Humane, 2020. “Horse Rescue Heroes.”

https://www.youtube.com/watch?v=JJEjug7ZPeU&feature=youtu.be&fbclid=IwAR0Dw-iVRPosKbA3cZPla0Y3BOTipDKYCr7iEIDzDh4dgTn6fCOgfBZ_Zsk

²⁵ 2017 Economic Impact Study of the U.S. Horse Industry. <https://www.horsecouncil.org/resources/horsecouncil-publications/>

months later did they discover that their horses had likely been sent to slaughter.²⁶ Cases like this happen with some frequency as the current system creates an incentive for such schemes. Horses are even stolen out of their barns and paddocks. Show horses have been led from their stalls, even in secure and sophisticated facilities, and then slaughtered for their meat.²⁷ With little traceability, chances of recovering stolen horses are low. Banning the practice has demonstrably reduced the risk of theft – after California enacted a ban in 1998, horse theft cases fell by 34 %.²⁸ A federal ban would be far more effective and remove the incentive to make a quick buck off unwitting owners.

b. Neglect

Predatory and fraudulent schemes cause a ripple effect. Ever present in the mind of many horse owners is the horrifying scenario of their animal winding up on a truck to slaughter. Many owners, even those who are no longer physically or financially able to care for their animals, are not willing to take the risk of unknowingly selling them to the wrong person. As a result, they may skip veterinarian visits, or stop physically checking on the horse, or let good daily care lapse. Too often, these well-intentioned owners may allow their horses to fall ill or suffer neglect.

We are only starting to understand how broadly this fear and its negative side effects have spread. The ASPCA piloted two open admission facilities for equines in 2018 and 2019 in Dallas and Oklahoma City, respectively. In an innovative approach to addressing equine welfare on the ground, our team worked with veterinarians and rescue groups, developing a triage center to provide veterinary care, rehoming, and humane euthanasia, when needed. Almost 80% of the owners who came forward acknowledged that their fear of trusting the wrong person made them hold on to their horses longer than they should have. Clearly, the existence of horse slaughter as a legal option causes suffering to equines even outside the slaughterhouse. A permanent ban on horse slaughter would eliminate this disturbing, pervasive risk to equine welfare.

c. The Burden on Rescues and Barriers to Rehoming

The slaughter industry insidiously undermines the important work of horse rehoming and rescue. It is common practice for kill buyers to frequent regular horse auctions and actively outbid responsible horse owners and rescue groups – forcing them to overspend their limited financial resources in bidding wars. Kill buyers often focus their bids on horses that a rescue group is trying save, thereby depleting that rescue's resources and reducing competition for the other horses at the auction. Rescuers should not have to compete against a for-profit industry, and public policy should promote, not hinder, equine rescue.

In another ploy, kill buyers use the Internet to hold horses hostage online, warning well-intentioned individuals that they must pay a ransom to “save” a horse from being shipped to slaughter. They post photos of the horse and specify a “buy or they die” deadline for “bailing out” the animal. Bailouts can bring kill buyers three to four times what they would get for selling the horse directly to slaughter. The consequences of this unscrupulous fraud on the equine rescue community are enormous. Spending \$1,500 to bail out a horse that cost \$300 at auction means the loss of \$1,200 that could have been spent saving

²⁶ Berson, Scott. 2018. “Vet student promised good home for horses. She sold them for slaughter instead, cops say.” *Miami Herald*. <https://www.miamiherald.com/article208182739.html>

²⁷ Sample media coverage: <https://www.tampabay.com/news/publicsafety/crime/1300-pound-show-horse-slaughtered-on-florida-farm/2251385/>; <http://wsvn.com/news/local/several-horses-found-slaughtered-in-northwest-miami-dade/>; <https://www.mysuncoast.com/2019/12/03/deputies-search-suspects-who-stole-slaughtered-show-horse-palmetto/>

²⁸ Numbers obtained from the California Livestock and Identification Bureau, http://cdfa.ca.gov/ahfss/Livestock_ID/.

more horses. The continuation of the horse slaughter industry places onerous burdens on the equine rescue community and diminishes the good that one precious dollar can do.²⁹

The Homes for Horses Coalition, a member organization of 440 horse rescues and sanctuaries across the country, knows this all too well. That is why every member endorses the SAFE Act and supports a ban on horse slaughter. This legislation is necessary for them to do their jobs and will redirect the resources now being diverted to save horses from the grips of kill buyers.

d. Public Perception of the Equine Industry

Public participation in certain sectors of the equine industry is declining, and some have an image problem. To address this, and to protect the animals on which their businesses depend, many industry groups support a ban on horse slaughter. For example, the thoroughbred racing industry has made meaningful strides to protect the equine athletes in their care by providing funding for aftercare programs and supporting racetrack bans on selling racehorses to slaughter. Influential groups such as The National Thoroughbred Racing Association and The Jockey Club have endorsed the SAFE Act, leading the charge to protect their equine athletes both while competing and after. Many stakeholders know that public perception and trust are vital to ensuring a sustainable industry, and that meaningful reforms to ensure good welfare must be embraced. The Maryland and Texas State Horse Councils, created to promote the interests of the equine industries, have endorsed a federal ban on horse slaughter as an crucial aspect of equine welfare and a means to ensuring a sustainable future for their industry.

V. The Good News

In 2019, an estimated 61,730 equines were sent to slaughter for human consumption in Canada and Mexico. That figure represents a 24% drop from 2019, and a 63% drop from 166,572 in 2016.³⁰ Every state is home to multiple equine rescue facilities that serve large communities or even multiple states. Resources continue to build steadily, and organizations serving equines and their owners are networking more closely than ever. We believe that equine rescues, combined with vibrant and growing rehoming and shelter options coming online across the country, are equipped to take in and help care for the animals destined for slaughter. Removing the barriers that kill buyers create for horses in transition at auctions will likely have a tremendously positive and synergistic impact on these promising developments.

Even more encouraging is the estimated number of homes for horses in the U.S. when people learn of the need. Americans care deeply about horses and stand ready, willing, and able to help in large numbers. A study published in 2017 by the ASPCA and Edge Research found that 2.3 million Americans have the resources and the strong desire to adopt a horse right now.³¹ If even just half that many homes are available, we can rehome every horse sent to slaughter for the next decade through education and networking alone. This suggests that the challenge is not about creating homes, but about matching them with horses in need.

Another indicator of support for horses in need of homes is the ASPCA's development of tools, resources, and incentives for shelters and rescues to increase their capacity and rehome more horses. In 2018 and 2019, we conducted a contest aimed at increasing adoptions nationally. In 2018 participating

²⁹ Horse Rescue Group Tries to Outbid Kill Buyers: <https://www.youtube.com/watch?v=Rew4Go5yIfQ>; Kill Pen Horses: The Catch 22 of Equine Rescue: <https://www.youtube.com/watch?v=ovr-RFOogrk>; Saving Horses From the Hill Lot, One at a Time: https://www.youtube.com/watch?v=_FL7-Hf2uFk

³⁰ Statistics Canada reports and USDA reports, *ibid*.

³¹ Weiss, et al. 2017. "Estimating the Availability of Potential Homes for Unwanted Horses in the United States." *Animals*. (7)7. <https://www.mdpi.com/2076-2615/7/7/53>

groups rehomed over 1,000 equines in just two months, with many doubling and even tripling the number of horses compared to the previous year. In 2019, they rehomed over 1,500 equines in that same time frame.

The myth that horse slaughter somehow prevents suffering is an inversion of reality. The presence of horse slaughter actually magnifies suffering. We know that the horse slaughter industry poses a threat to human health as well as to equine welfare, by producing and introducing into the food supply meat laced with toxic substances. Americans want to see an end to this grisly and unnecessary practice, and they are urging Congress to enact the SAFE Act. The ASPCA and other organizations across the country are working resolutely and innovatively to solve equine welfare issues on the ground, but we cannot truly succeed while the slaughter pipeline remains open. With the strong support of the American public, and a clear FDA mandate to regulate and ban toxic substances that threaten public health, now is the time to end the slaughter of American horses for human consumption. I urge you to support the SAFE Act and open a new humane chapter in the history of our nation's equines.

Appendix

Exhibit A (See Attachment)

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 six 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 soci-

ety, 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 one 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:]

Testimony

**Douglas G. Corey, D.V.M.
Past President
American Association of Equine Practitioners
Adams, Oregon**

**Before the
House Energy and Commerce Committee
Subcommittee on Health
United States House of Representatives**

**For a Hearing Entitled
“Improving Safety and Transparency in America’s Food and
Drugs”**

**Presented
January 29, 2020**

Chair Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee, thank you for the opportunity to appear before you today. My name is Dr. Douglas Corey and I have been an equine veterinarian for more than 40 years in a five-person mixed animal practice located in Walla Walla, Washington. I am here today, not only as a long-time horse owner, but also as a Past President of the American Association of Equine Practitioners (AAEP). The AAEP is a professional association which represents the vast majority of equine veterinarians and veterinary students, many of whom are long-time horse owners as well. Our mission is dedicated to the health and welfare of the horse. Our headquarters is in Lexington, Kentucky.

I have served as the Chair of the AAEP's Equine Welfare Committee, the American Veterinary Medical Association's (AVMA) Animal Welfare Committee, and the Unwanted Horse Coalition. I currently serve as a member and past chairman of the Professional Rodeo Cowboys Association's Animal Welfare Committee and I serve on the American Horse Council's Animal Welfare Committee.

I want to make three main points today:

1. There is little evidence that meat from equines raised in the United States poses a threat to human health.
2. This bill will negatively impact the health and welfare of horses across the country and offers no solution to the problem of unwanted horses in the U.S.
3. The AAEP and industry have taken a leadership role in developing potential solutions for many of the unwanted horses.

This legislation seeks to ban the knowing sale or transport of equine or equine parts in interstate or foreign commerce for purposes of human consumption because it would deem equine meat unsafe under the Federal Food and Cosmetics Act. 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 its citizens to consume. As an example, horses being transported to

Canada for processing must be held in holding facilities for six months to ensure there are no medication residues. Additionally, the meat of horses processed in both Mexico and Canada is tested for drug residues, heavy metals and bacterial contamination exactly like what is done with beef and pork and 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 unwanted horses in the U.S.

Guided by a dedication to equine welfare, the AAEP is actively involved in the issues that surround the care of unwanted horses in the United States. The AAEP has evaluated H.R. 961 based on the legislation's ability to serve the health and welfare of the horse.

The unwanted horse represents a group of horses within the domestic equine population that are no longer wanted, needed or useful; or their owners are no longer interested in them or are not financially able to provide the horse with the appropriate care.

As written, the Safeguard American Food Exports Act will negatively impact the welfare of horses because it offers no viable solution to the problem of unwanted horses and will actually increase their numbers. The legislation does not provide

the financial resources necessary to create the infrastructure and provide veterinary care to the thousands of horses impacted by a ban on processing horses. In addition, we feel strongly that, if passed, this bill will not stop the processing or slaughter of horses. Therefore, the AAEP and its membership, based on a multiple membership surveys, vigorously oppose this legislation as it is currently written.

The AAEP's chief concerns regarding H.R. 961 are:

1. Long-term placement of affected horses. It is estimated that approximately 80,000 - 100,000 horses are transported to Canada and Mexico for processing annually. Should we remove this option for horse owners, how are we going to care for these horses? The proponents of the legislation suggest that the additional horses will be absorbed by the alternative homes and rescue and retirement facilities. However, these options are already under stress. While there may be some capacity at some facilities, simply put, there is not enough funding, volunteers or placement options for all of the current unwanted horses across this country, let alone the additional 80,000 - 100,000 horses that would be impacted by this legislation. This is exacerbated during times of recession. We applaud the many volunteers, including veterinarians, involved with these sanctuaries and facilities. The simple fact is that should this bill be enacted, the number of facilities, their capacity, funding and adoptions will have to increase significantly in order to match the demand and care for

these horses for their life expectancy of 20—30 years. Where will the additional facilities and funding come from?

In addition, many of the individuals who adopt horses are often unprepared for the costs to adopt and provide proper care and feeding for a horse. While many of these people are well-intentioned individuals, 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, means, knowledge and/or assets available to respond to the need. While efforts by the AAEP and others in the equine and animal welfare industries have improved the care of unwanted horses and promoted responsible ownership, there will always be those horses that are unwanted and are not provided with the care that they need. Some of the reasons horses become unwanted include lack of time and money, owner health issues, change in family circumstances by the owner, the horse is unsuitable, and/or it has bad behavior and can be dangerous.

2. The funding of care for unwanted horses. H.R. 961 does not address the funding required to care for or dispose of an additional 80,000 - 100,000 horses per year. Assuming an average cost of \$5 per day to provide a

horse's basic needs, the funding needed per year, per horse is approximately \$1,825. This does not include veterinary and farrier care. Inadequate funding often creates inadequate care, which is a significant welfare concern for unwanted horses. Should the horse owner decide to euthanize the horse, the disposal alone can range from \$400 for euthanasia and burial to up to \$2000 for cremation.

3. Language of the bill itself. H.R. 961 seeks to prohibit the knowing sale or transport of equines or equine parts in interstate or foreign commerce for purposes of human consumption. This bill would not stop the transportation of horses for other reasons, including sporting events, sales, recreation or transportation for medical care. Once they cross the border, this language would not stop horses from being processed.

My final point is the AAEP and equine industry are developing solutions for the issue of unwanted horses.

For more than sixty years, our association has been a renowned leader in promoting and fostering the welfare of horses. The AAEP and its members are educating horse owners and the industry about the importance of providing the appropriate care for their horses throughout their lives. We are hopeful that this concerted effort will reduce the number of unwanted horses in the United States.

The AAEP currently partners with a number of equine and animal welfare organizations that have, since the AAEP hosted the first Unwanted Horse Summit nearly 15 years ago, enhanced efforts and outreach to improve rescue, retirement and re-homing facilities, promoted more adoptions, and offered safety net programs for owners in need of assistance for obtaining care for their horse, including stallion castrations, euthanasia and even disposal assistance.

We continue to maintain and offer resources to promote horse owner responsibility, and we support equine rescue and retirement facilities with a 32-page booklet titled the *AAEP Care Guidelines for Equine Rescue and Retirement Facilities*.

As you can see, this industry is coming together to address this industry problem. Our equine veterinary members are on the front line every day helping horses and are committed to solving this problem.

The AAEP's position on processing is that horses destined for a processing facility should be:

1. Treated humanely and with dignity.
2. Transported according to guidelines approved by the U.S.D.A. in 2002 regarding the commercial transportation of equines to processing.
3. Euthanized in a humane manner in accordance with guidelines established by the AVMA.

The AAEP believes that processing is not the ideal solution for addressing the large number of unwanted horses in the U.S. However, if a horse owner is unable or unwilling to provide humane care and no one can assume the responsibility, humane euthanasia at a processing facility in accordance with the AVMA's euthanasia guidelines is an acceptable alternative to a life of suffering, inadequate care or abandonment. We believe that humane euthanasia at a processing facility is preferable to seeing an unwanted horse left to a life of starvation, neglect or abuse.

In summary, the equine industry and you, our congressional leaders, must work together to address the root cause of the unwanted horse, not just the symptom of processing. We need proactive solutions and we believe that the AAEP, veterinarians across this country, the equine industry and animal welfare advocates are developing solutions that will continue to help decrease the number of unwanted horses being processed. However, and most importantly, supporting H.R. 961 will not improve the welfare of the horse. This bill offers no solution to the problem of unwanted horses.

Thank you for the opportunity to address you today. I will be happy to answer any questions.

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 nutri-

ents 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:]



Testimony of Tom Balmer
Executive Vice President
National Milk Producers Federation

Before the House Committee on Energy & Commerce, Subcommittee on Health
January 29, 2020

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 (NMPF), the voice of America's dairy cooperatives and their farmer-owners for over 100 years. I thank you for the opportunity to testify before you today regarding the DAIRY PRIDE Act, a bipartisan bill intended to finally compel the 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, including members of this panel. We also commend Senators 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 non-dairy foods utilizing standardized dairy terms, an issue with significant implications for consumers. Standards of identity were written to promote honesty and fair dealing in the interest of consumers by promulgating regulations to establish reasonable definitions or standards for food products. These food product terms have come to carry distinct meaning in the minds of consumers, including their understanding of the nutrient values present in certain foods.

Dairy farmers nationwide work hard to ensure that their products are wholesome, nutritious, and in compliance with regulations regarding the use of standardized dairy terms. However, over many years, the Food and Drug Administration has been negligent in enforcing these established standards of identity, which clearly stipulate that a product labeled as "milk" comes from a cow or certain other lactating animals, and that other similar products – including cheese, butter, ice cream, and yogurt – are likewise made from the milk from animals – not from beans, seeds, nuts, or grains.

Unfortunately, grocery store shelves today are filled with innumerable copycat products that flout these long-established standards of identity and mislead consumers about their nutritional equivalence to real milk and milk-based products. Real milk is a nutritional powerhouse, with numerous vitamins, minerals, and nutrients essential to human health. Milk is the number-one source of nine nutrients in children's diets, and the leading food source of potassium, calcium, and vitamin D in the American diet. These are three of the four nutrients of public health concern, according to the 2015 Dietary Guidelines for Americans (DGAs). Even the DGAs

recognize that most plant-based imitation milk products are not nutritionally equivalent to milk and are therefore not included in the dairy group.

Plant-based industrial food processors typically go to great lengths to try to replicate real milk by grinding seeds, nuts or grains into a powder, adding water, whiteners, sweeteners, stabilizers and emulsifiers, possibly blending in some vitamins and minerals, and then marketing the resulting concoction using dairy terms. By calling these products “milk” they are clearly seeking to trade on the health halo of real milk. Yet these imitators engage in misleading marketing because their products don’t have the same consistent nutritional offerings as real milk, certainly not across the many types of imitation beverages on the market. Glass after glass, and even after fortification, such offerings still do not offer the same extensive nutrition profile that is found naturally in every glass of real milk. You would never know this from the labeling of many dairy imitators, which mislead people into thinking these products are comparable replacements for milk. In fact, most are nutritionally inferior, and thus not suitable substitutes.

The proliferation of these imitation products in the marketplace has created an abundance of consumer confusion. While consumers generally understand that plant-based alternatives do not contain dairy, evidence shows that consumers think that plant-based products are nutritionally equal to or better than cow’s milk. An IPSOS survey conducted in 2018 found that 73% of consumers surveyed believe that almond-based beverages have as much or more protein per serving than milk, when in reality milk has up to eight times as much protein. A follow-up survey found that roughly 50 percent of consumers mistakenly believe that the main ingredient in a plant-based beverage is the plant itself, when such drinks are mostly flavored water.

We are seeing the negative health impacts caused by a decrease in the intake of the nutrients provided by real dairy products. The 2015 DGAs found that most Americans are not meeting the recommended intake for the dairy foods group. Importantly, FDA itself has noted an increase in children who have become malnourished when fed — with benign intentions — a nutritionally inadequate, water-based slurry of nuts, seeds, or beans. Finally, four public health organizations — 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 children ages five and below 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.

NMPF has repeatedly raised concerns with FDA regarding its failure to enforce the law when nondairy products co-opt terms like “milk” and “cheese.” Therefore, we were encouraged when former Commissioner Gottlieb announced in 2018 that FDA would finally begin to look at this issue. We appreciated his interest in examining the nutrition perspective I have already outlined. During the agency’s review process, multiple stakeholders — including the American Academy of Pediatrics, North American Society for Pediatric Gastroenterology, Hepatology & Nutrition, and the School Nutrition Association — gave voice to the concern that consumers do not grasp the nutritional differences between real products and imitation products. We could not agree more.

In February 2019, NMPF filed a Citizen Petition asking FDA to enforce its existing rules against nutritionally inferior plant-based foods and to modify and refine these rules to address issues such as the consideration of protein quality when determining nutritional inferiority. While we

were encouraged that FDA would take long overdue action, it is clear that the timeline for such action is continually shifting, with no end in sight. 2019 came and went with no FDA action; this needs to be the year the job gets done. In past years the agency had repeatedly said this was a low priority issue, and it must not send that message again while labeling malpractice proliferates, consumers are being misled, and children of well-intentioned parents are at risk of getting sick as a result. Unless Congress acts, FDA's follow-through remains uncertain.

While we will continue to press for FDA to enforce its own rules to address the public health issues that have arisen from their inaction, we believe the time has come for Congress to take legislative action. That's why we are encouraged that the bipartisan, bicameral DAIRY PRIDE Act is included in today's hearing. This legislation doesn't create a new definition of milk, but rather establishes explicit conditions under which FDA must explain how and when it will enforce dairy food standards of identity. The DAIRY PRIDE Act would require foods that inappropriately use standardized dairy terms to be considered 'misbranded' under the law and subject to enforcement. It would also direct FDA to issue guidance regarding its enforcement approach within 90 days of enactment and to keep Congress informed of its work.

Let me be clear: We do not oppose the sale of imitation dairy products, but we do oppose their use of dairy terms in violation of provisions specified in the Code of Federal Regulations. Dairy farmers are not seeking to eliminate competition from these products; they just want the enforcement of existing regulations, including the frequently ignored imitation food regulation found in 21 CFR 101.3 (e), that require clear labeling of inferior copies of established food products. Many other countries take the same approach as the U.S. But the difference is, they enforce it, which is why you will not find a product labeled as "almond milk" in Canada, the United Kingdom, or the 28-nation European Union, even though almond-based beverages are sold in those nations. Many of those are manufactured in the U.S. but are required to use different labels when exported because other nations, unlike our FDA, diligently enforce dairy terms. It is worth noting that some U.S. manufacturers *do* properly label imitation products without using standardized dairy names. Unfortunately, the vast majority do not, thereby creating a "wild west" mentality in the marketplace and undermining the integrity of food labeling regulations.

The promoters of dairy alternatives claim that passing the DAIRY PRIDE Act, as well as enforcing existing dairy labeling standards, would somehow violate the First Amendment by undermining free speech. This is nothing more than a red herring argument. It is well-established that commercial speech is entitled to protection under the First Amendment, but it is equally well-established that regulations that compel factual and uncontroversial information to help consumers make informed decisions meet First Amendment requirements. We address this point at length in our Citizen Petition. Manufacturers of dairy imitators have chosen to formulate and label their products as substitutes for standardized dairy products by choosing to use standardized dairy nomenclature. These are clear attempts to deceive consumers, and for decades FDA has held that such misleading references do not align with its mission to protect consumers and public health. Unfortunately, publicly holding a position and actually enforcing the position are two separate things – thus, the need for passage of the DAIRY PRIDE Act.

We also hear claims that enforcing standards of identity will interfere with the marketing of other common foods such as coconut cream, milk of magnesia, and peanut butter. This, too, is a red herring. These other products do not market themselves as replacements for real dairy foods, and thus do not mislead the public. Peanut butter is not a functional replacement for butter made with real cream. In fact, butter makers first dealt with this issue 80 years ago, when plant-based spreads began appearing. They were not then called, nor are they today labeled, “soy butter” or “vegetable butter.” They’re called margarine or vegetable oil spreads, precisely because the federal standard dictates that butter comes from milk, not plant sources.

On the topic of butter, I would be remiss if I did not point out that imitation products like Country Crock® Plant Butter are not only in violation of regulatory standards, they are in violation of the federal *statutory* definition of butter enacted by Congress. The Butter Act of 1923 established the oldest food standard in the U.S., and the law defined butter as “the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.” FDA has repeatedly stated in the Federal Register and elsewhere that any product that uses the term butter that does not follow the enacted standard of identity for butter is misbranded and in violation of other provisions of the Federal Food, Drug, and Cosmetic Act. While this definition has not changed since 1923, the word “butter” is now being used to market imitation products nationwide. FDA’s decision not to enforce this definition amounts to an agency rewriting an act of Congress, undermining the separation of powers enshrined in the U.S. Constitution.

I point this out to underscore a widespread pattern of deception in the marketplace. Put simply, this deception presents consumers with false, misleading information that may cause them to make well-intentioned but misguided nutrition decisions for them and their families. We have repeatedly urged the FDA to enforce its own rules in the name of transparency and public health, but they have refused to act. Passage of the DAIRY PRIDE Act would fix this problem once and for all and put an end to the deception.

Madame Chair, I want to once again thank you and the Ranking Member for holding today’s hearing. We appreciate the opportunity to testify, and I look forward to answering any questions members may have.

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:]



Know your environment.
Protect your health.

Testimony of
Melanie Benesh
Legislative Attorney
Environmental Working Group
Before the
Health Subcommittee
of the
House Energy and Commerce Committee
On

H.R. 2827, the Keep Food Containers Safe From PFAS Act of 2019

January 29, 2020

Thank you for the opportunity to testify. My name is Melanie Benesh, and I am the legislative attorney for the Environmental Working Group, a national environmental health organization that has sought to address the risks posed by per- and poly- fluoroalkyl substances, or PFAS, for two decades.¹

Contamination from PFAS chemicals is a national public health and environmental emergency. PFAS contaminate the blood and organs of nearly every living being, and experts estimate that 25 percent of Americans have elevated levels of PFAS in their blood serum.²

¹ Bill Walker, *EWG and Toxic Fluorinated Chemicals: 20 Years in the Fight Against PFAS*, Environmental Working Group (July 24, 2019), <https://www.ewg.org/news-and-analysis/2019/07/ewg-and-toxic-fluorinated-chemicals-20-years-fight-against-pfas>.

² Centers for Disease Control and Prevention, National Biomonitoring Program, Per- and Polyfluorinated Substances (PFAS) Factsheet, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html. (last updated April 7, 2017). See also David Andrews, *Insight: The Case for Regulating All PFAS Chemicals as a Class*, Bloomberg Environment (May 20, 2019), <https://news.bloombergenvironment.com/environment-and-energy/insight-the-case-for-regulating-all-pfas-chemicals-as-a-class/>.

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PFAS are associated with serious health effects, even at very low doses.³ PFAS exposure has been linked to kidney and testicular cancer, preeclampsia, ulcerative colitis, thyroid disease, high cholesterol,⁴ reproductive and developmental harm,⁵ and damage to the immune system.⁶

PFAS chemicals have long half-lives, and many can stay in the human body for decades.⁷ Americans also face dozens of new exposures to PFAS every day – through our food, water, and air, from indoor dust, carpets, clothing, and cosmetics. EWG has so far confirmed the presence of PFAS at nearly 1,400 sites,⁸ and the list of contaminated sites will grow as more testing is performed.⁹ PFAS are “forever chemicals”¹⁰ – PFAS that contaminate those sites will never break down in the environment and thus will remain there unless removed.

Food is a significant source of PFAS exposure. The Environmental Protection Agency has stated that, for the general population, “the dominant source of human exposure to PFOA [and PFOS]¹¹ is expected to be from the diet.”¹² In 2018, the European Food Safety Authority, or

³ Impacts to mammary gland development have been associated with low-level doses of PFOA. See, e.g., Dierdre K. Tucker et al., *The Mammary Gland is a Sensitive Pubertal Target in CD-1 and C57Bl/6 Mice Following Perinatal Perfluorooctanoic Acid (PFOA) Exposure*, 54 *Reproductive Toxicology* 26 (2015), <https://www.ncbi.nlm.nih.gov/pubmed/25499722>; Madisa B. Macon et al., *Prenatal Perfluorooctanoic Acid Exposure in CD-1 Mice: Low Dose Developmental Effects and Internal Dosimetry*, 122 *Toxicological Sciences* 131 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3143465/>; Sally S. White et al., *Gestational and Chronic Low-Dose PFOA Exposures and Mammary Gland Growth and Differentiation in Three Generations of CD-1 mice*, 119 *Environ Health Perspectives* 1070 (2011), <https://www.ncbi.nlm.nih.gov/pubmed/21501981>.

PFOA, PFOS, PFHxS and PFDeA are also associated with reduced effectiveness of vaccines, even at low doses. See Anna Reade, Tracy Quinn, & Judith S. Schreiber, *Scientific & Policy Assessment for Per- and Polyfluoroalkyl Substances in Drinking Water*, Natural Resources Defense Council (April 12, 2019), https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf.

⁴ C8 Science Panel, C8 Probable Link Reports, http://www.c8sciencepanel.org/prob_link.html (last visited Jan. 25, 2020).

⁵ Alexis Temkin, *PFAS and Developmental and Reproductive Toxicity: An EWG Fact Sheet*, Environmental Working Group (Sept. 19, 2019), <https://www.ewg.org/news-and-analysis/2019/09/pfas-and-developmental-and-reproductive-toxicity-ewg-fact-sheet>.

⁶ Tasha Stoiber, *PFAS Chemicals Harm the Immune System, Decrease Response to Vaccines*, New EWG Review Finds, Environmental Working Group (June 21, 2019), <https://www.ewg.org/news-and-analysis/2019/06/pfas-chemicals-harm-immune-system-decrease-response-vaccines-new-ewg>.

⁷ Half-life estimates range from over two years from PFOA and PFNA to 5.4 years for PFOS to 8.5 years for PFHxS. See Reade et al., *supra* note 3, at 12.

⁸ See Environmental Working Group, *PFAS Contamination in the US*, https://www.ewg.org/interactive-maps/2019_pfas_contamination/map/ (last visited Jan. 26, 2020).

⁹ Several states are planning additional testing of tap and ground water, and ground water testing was required by H.R. 2500, the National Defense Authorization Act for FY 2020.

¹⁰ Joseph G. Allen, *These Toxic Chemicals are Everywhere – Even in Your Body. And They Won’t Ever Go Away*, Wash. Post (Jan. 2, 2018), https://www.washingtonpost.com/opinions/these-toxic-chemicals-are-everywhere-and-they-wont-ever-go-away/2018/01/02/82e7e48a-e4ee-11e7-a65d-1ac0fd7f097e_story.html

¹¹ PFOA and PFOS are two types of well-studied PFAS.

¹² See Environmental Protection Agency, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)* at 18 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf; Environmental Protection Agency, *Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS)* at 19 (May 2016); https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final_508.pdf

EFSA, recommended a dramatic reduction in daily intake levels of PFAS from food after finding that the intake of a considerable portion of the population exceed recommended levels.¹³

PFAS infiltrates our food supply through several pathways:

- Contaminated water fed to livestock can bioaccumulate in the animals, contaminating meat and milk.¹⁴
- Plants, especially leafy greens, can also take up PFAS from contaminated water and soil.¹⁵
- Fertilizer derived from sewage sludge contaminated with PFAS chemicals can in turn contaminate food and animal feed.¹⁶

PFAS also migrate into food from food packaging.¹⁷ The FDA has approved 19 distinct PFAS formulations for use in food packaging. However, there may be more unique PFAS present in food packaging and food, because the approved PFAS chemicals contain mixtures of various forms of PFAS, can break down into other PFAS, or may contain PFAS impurities.¹⁸ Independent tests have confirmed the presence of PFAS in food containers and wrappers in

¹³ EFSA Panel on Contaminants in the Food Chain, *Risk to Human Health Related to the Presence of Perfluorooctane Sulfonic Acid and Perfluorooctanoic Acid in Food*, 16 EFSA Journal 5194 (2018), <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5194>; see also International Chemical Secretariat, *Scientists Just Cut the Tolerable Intake of PFAS by 99.9%* (Jan. 30, 2019), <https://chemsec.org/scientists-just-cut-the-tolerable-intake-of-pfas-by-999/>.

¹⁴ See Environmental Protection Agency, *supra* note 12. A dairy farmer in New Mexico was forced to euthanize his entire herd as a result of PFAS-contaminated water from nearby Canon Air Force Base. Amy Linn, *'This Has Poisoned Everything' – Pollution Casts Shadow Over New Mexico's Dairy Industry*, The Guardian (Feb. 20, 2019), <https://www.theguardian.com/us-news/2019/feb/20/new-mexico-contamination-dairy-industry-pollution>.

¹⁵ See, e.g., Rosella Ghisi et al., *Accumulation of Perfluorinated Alkyl Substances (PFAS) in Agricultural Plants: A Review*, 160 *Env't'l Research* 326 (2019), <https://www.ncbi.nlm.nih.gov/pubmed/30502744>. In 2018, FDA sampling of produce taken from a farmers' market 10 miles downstream from a Chemours facility in North Carolina found most of the PFAS tested for, including one sample with 1,200 ppt of GenX. A copy of the FDA poster can be found here: <http://blogs.cdf.org/health/files/2019/06/FDA-PFAS-in-food-poster-presentation-2-5-30-19.pdf>.

¹⁶ In 2018, a Maine dairy farmer who had applied sewage to his land found high levels of PFAS in milk produced by his cows. He had to destroy that milk and is now facing bankruptcy. Pat Rizzuto, *Denied Both Sales and Aid, Face of PFAS Wonders How to Survive*, Bloomberg (Jan. 10, 2020), <https://news.bloombergenvironment.com/environment-and-energy/denied-both-sales-and-aid-face-of-pfas-wonders-how-to-survive>. Subsequent testing by the Maine Department of Environment found that every single sample of sludge tested was contaminated with at least one kind of PFAS. Sharon Lerner, *Toxic PFAS Chemicals Found in Maine Farms Fertilized with Sewage Sludge*, The Intercept (June 7, 2019), <https://theintercept.com/2019/06/07/pfas-chemicals-maine-sludge/>.

¹⁷ See, e.g., Timothy H. Begley et al., *Migration of Fluorochemical Paper Additives From Food-Contact Paper into Foods and Food Simulants*, 25 *Food Additives and Contaminants* 384 (2008), <https://www.tandfonline.com/doi/abs/10.1080/02652030701513784>; Timothy H. Begley et al., *Perfluorochemicals: Potential Sources of and Migration from Food Packaging* 22 *Food Additives and Contaminants* 1023 (2005), <https://www.ncbi.nlm.nih.gov/pubmed/16227186>.

¹⁸ Department of Toxic Substances Control, Safer Products & Workplaces Program, *Work Plan Implementation: Food Packaging with Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs)* (Oct. 24, 2019), https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/10/Food-Packaging_Perfluoroalkyl-and-Polyfluoroalkyl-Substances-PFASs.pdf.

restaurants¹⁹ and grocery chains.²⁰ In 20 fast-food wrappers collected in 2014 and 2015, 27 different PFAS were detected, including PFOA, GenX, ADONA, and PFBS.²¹

The extent to which PFAS migrate from packaging into food can vary depending on the amount, type, and chain length of the PFAS in question, and the type of food, contact time, and temperature.²² Despite brief periods of contact between PFAS food wrappers and the fast food it is used for, studies have shown that the high temperature and emulsified fat content of fast food can increase the extent to which some kinds of PFAS migrate into food.²³ Short-chain PFAS chemicals – many of which were designed to replace long-chain PFAS chemicals²⁴ – migrate more readily into food from paper bowls than their long-chain analogues.²⁵ A recent study found that eating meals from fast food and pizza restaurants and other types of restaurants was generally associated with higher levels of PFAS in blood. Eating popcorn was associated with significantly higher blood serum levels of PFOA, PFNA, PFDA, and PFOS.²⁶

The risks of PFAS exposure from fast-food packaging is of particular concern for children, because research shows that one-third of children consume fast food daily.²⁷ Studies show that children face a higher risk of multiple health impacts from PFAS, including immunity, infection, asthma, cardio-metabolic, neurodevelopmental, thyroid, renal, and puberty onset.²⁸

Grease-resistant coatings for paper food packaging was an early use of PFAS developed and commercialized by DuPont. Although DuPont and 3M have known about the health risks from PFAS since the 1960s, they did not share that information with regulators like the FDA.²⁹ In 1975, DuPont warned 3M, but not the FDA, about the “toxic effects” in food contact products

¹⁹ Laurel A. Schaidler et al., *Fluorinated Compounds in U.S. Fast Food Packaging*, 4 *Env'tl Sci. and Technology Letters* 105 (2017), <https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.6b00435>.

²⁰ Safer Chemicals Healthy Families, *Toxic-Free Future*, & Mind the Store, *Take Out Toxics: PFAS Chemicals in Food Packaging* (Dec. 11, 2018), https://saferchemicals.org/wp-content/uploads/2018/12/saferchemicals.org_take_out_toxics_pfes_chemicals_in_food_packaging.pdf?x15132.

²¹ See Schaidler et al., *supra* note 19, supporting information, https://pubs.acs.org/doi/suppl/10.1021/acs.estlett.6b00435/suppl_file/ez6b00435_si_001.pdf.

²² Schaidler et al., *supra* note 19.

²³ *Id.*

²⁴ Food & Drug Admin., *Update on Perfluorinated Grease-Proofing Agents*, <https://www.fda.gov/food/inventory-effective-food-contact-substance-fcs-notifications/update-perfluorinated-grease-proofing-agents> (last visited Jan. 25, 2020).

²⁵ Schaidler et al., *supra* note 19.

²⁶ Herbert P. Susmann, Laurel A. Schaidler, Kathryn M. Rodgers, & Ruthann A. Rudel, *Dietary Habits Related to Food Packaging and Population Exposure to PFASs*, 127 *Env'tl Health Perspectives* 107003-1 (Oct. 9, 2019), <https://ehp.niehs.nih.gov/doi/10.1289/EHP4092>.

²⁷ Sundeep Vikraman, M.D. et al., *Caloric Intake from Fast Food Among Children and Adolescents in the United States, 2011-2012*, Centers for Disease Control and Prevention, National Center for Health Statistics Data Brief No. 213 (Sept. 2015), <https://www.cdc.gov/nchs/products/databriefs/db213.htm>.

²⁸ Kristen M. Rappazzo, Evan Coffman, & Erin P. Hines, *Exposure to Perfluorinated Alkyl Substances and Health Outcomes in Children: A Systematic Review of the Epidemiological Research*, 14 *Int. J. Environ. Research and Public Health* 691 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5551129/>.

²⁹ Environmental Working Group, *For Decades, Polluters Knew PFAS Chemicals Were Dangerous But Hid Risks From Public*, <https://www.ewg.org/pfastimeline/> (last visited Jan. 25, 2020).

such as wrappers and recommended that certain kinds of PFAS not be used in food.³⁰ In 1987, DuPont found that the company's marquee paper packaging coating, Zonyl RP, could contaminate food at over three times the level agreed on between DuPont and the FDA, but it did not alert the FDA and declined to make safer alternatives.³¹ As a result, the FDA permitted the use of PFAS in food packaging without having received critical toxicity data.³²

PFAS exemplify how our food chemicals and food contact substances review system is broken. In 1958, following a lengthy select committee investigation, Congress overhauled the FDA's authority to regulate chemicals in food and food contact substances.³³ The Food Additives Amendment of 1958 created a premarket system for both direct³⁴ and indirect³⁵ food additives and a rigorous petition approval process.³⁶ The 1958 law requires the FDA to determine that the use of a food additive is safe, defined as a "reasonable certainty to cause no harm,"³⁷ before approving the use of the additive. When making a safety determination, the 1958 law requires the FDA to consider exposure, the cumulative effects of similar chemicals, and other appropriate safety factors.³⁸

³⁰ See Filed Letter from R.J. Seffl to J.D. Lazerte, detailing DuPont's concerns about potential use of a PFAS in food products (Dec. 5, 1975), https://static.ewg.org/reports/2019/pfa-timeline/1975_OralToxicity-Concerns.pdf?_ga=2.6417905.2103539113.1579796625-1525964376.1554386940.

³¹ As part of the indirect food additive application for Zonyl RP, DuPont told the agency it expected an extraction rate of only 0.2 parts per million. This 1987 internal memorandum from R.H. Goldbaum shows that Zonyl RP could contaminate food at 0.62 parts per million,

https://static.ewg.org/files/dupont3.pdf?_ga=2.221412632.1871767776.1579387823-1525964376.1554386940. See also Callie Lyons, Stain-Resistant, Nonstick, Waterproof, and Lethal: The Hidden Dangers of C8 at 76 (Praeger 2007), <https://epdf.pub/stain-resistant-nonstick-waterproof-and-lethal-the-hidden-dangers-of-c8.html>.

³² According to a former DuPont chemical engineer and whistleblower, DuPont also negotiated a weaker standard for approval for PFAS chemicals with the FDA in the mid-1960s, after FDA initially rejected its food additive petition based on liver toxicity. Although the FDA usually required a two-year study for new chemicals, it approved DuPont's food packaging chemicals based on a 90-day test and a thousand-fold safety factor. According to the whistleblower, that standard was also based on the assumption that PFAS chemicals would exit the body quickly, when in fact DuPont knew that many PFAS bioaccumulate in the body for long periods. See Press Release, Environmental Working Group, Former DuPont Top Expert: Company Knew, Covered Up Pollution of Americans' Blood for 18 years (Nov. 16, 2005), <https://www.ewg.org/news/news-releases/2005/11/16/former-dupont-top-expert-company-knew-covered-pollution-americans>. See also Environmental Working Group, *supra* note 29.

³³ The 1958 law was a response to the rapid industrialization of food production after World War II and the significant increase in the number and diversity of chemicals used in food and in the production of food with minimal oversight and significant data gaps regarding the long-term health risks from this ever-expanding universe of chemicals. Congress passed the 1958 Food Additive Amendments following a seven-year comprehensive investigation by the Select Committee to Investigate the Use of Chemicals in Food and Cosmetics, led by Representative James Delaney. See National Archives, Guide to House Records: Chapter 22: 1947-1968 Chemicals in Food and Cosmetics, Records of the Select Committees of the House of Representatives, <https://www.archives.gov/legislative/guide/house/chapter-22-select-food-and-cosmetics.html>.

³⁴ Direct additives are substances intentionally added directly to food, such as sweeteners, thickeners, emulsifiers and preservatives.

³⁵ Indirect food additives include food-packaging materials and contaminants from food-processing equipment.

³⁶ 21 U.S.C. § 348(b); see also 21 C.F.R. Part 171.

³⁷ S. Rep. No. 85-2422 at 2-3; see also 21 C.F.R. § 170.3(i).

³⁸ 21 U.S.C. § 348(c)(5). Additional safety factors can include things like accounting for consumption by vulnerable populations like children and pregnant women or lowering safety thresholds to account for uncertainty from data gaps.

The intended result of the select committee investigation and the passage of the Food Additives Amendment of 1958 was a health-protective law designed to ensure that food chemicals are allowed in food and food contact materials only after an affirmative FDA determination of safety based on robust health and safety data. However, as the current PFAS contamination crisis demonstrates, the review system Congress envisioned in 1958 is not the review system that exists today.

Although Congress clearly intended that the FDA ensure that food packaging chemicals pose a “reasonable certainty of no harm,” few if any PFAS chemicals used in food packaging have been subject to meaningful FDA review. PFAS can be authorized for use in food in three separate ways: through a formal food additive petition, the “generally recognized as safe” loophole, or, as is most common today, a food contact notification.

Nearly all of the PFAS approved by food additive petitions and still authorized for use today were approved before 1994, long before either the FDA or the EPA understood the health risks posed by PFAS chemicals or the amount of additional background exposure to PFAS Americans receive daily from drinking water, air, and other consumer products. The FDA has twice revisited the safety of PFAS that have been approved as indirect food additives and found that they do not meet the safety threshold of “reasonable certainty to cause no harm.”³⁹ However, the FDA is under no statutory obligation to reassess the safety of other PFAS used in food packaging that were authorized under the petition process.

Food chemicals rarely go through the rigorous food additive petition process originally envisioned by Congress. In fact, the FDA received fewer than 50 direct food additive petitions between 2000 and 2019.⁴⁰ The most transparent and rigorous process for authorizing new food chemicals has now become the method of last resort. Instead, industry has taken advantage of a loophole in the 1958 law that allows food chemicals to evade FDA review if deemed “generally recognized as safe,” or GRAS, by the FDA, a food or chemical company, or a food industry

³⁹ In 2010, following an agency review of the scientific literature, FDA toxicologists raised safety concerns about the safety of certain long-chain PFAS used in food packaging. See Memorandum from Penelope A. Rice, Ph.D., FDA Division of Food Contact Notifications, to Paul Honigfort, Ph.D., FDA, Re: Critical Review of Studies Conducted With ≥ C8 Perfluorinated Compounds Concerning Selected Endpoints (Sept. 30, 2010), <https://www.regulations.gov/document?D=FDA-2015-F-0714-0015>. The FDA asked three companies for additional test data and the companies opted to phase those PFAS out in 2011. See Food & Drug Admin., *supra* note 24. However, that voluntary agreement was legally unenforceable and did not ban the use of those PFAS. In 2015, several NGOs, including EWG, petitioned the FDA to revoke approval for three of those long-chain PFAS chemicals approved for use in food packaging between 1967 and 1997 on the basis that those long-chain PFAS were no longer “reasonably certain to cause no harm.” Natural Resources Defense Council et al., Filing of Food Additive Petition, 80 Fed. Reg. 13508 (March 9, 2015). After a lengthy toxicological assessment, the FDA revoked approval of those uses in response to the petition in 2016. Indirect Food Additives: Paper and Paperboard Components, 81 Fed. Reg. 5, (Jan. 4, 2016). In particular, the FDA found that those substances were no longer “reasonably certain to cause no harm” because of concerns about pre- and post-natal developmental toxicity, reproductive toxicity, and bio-persistence. See Memorandum from Penelope A. Rice, Ph.D., FDA, to Paul Honigfort, Ph.D., FDA, Re: FAP 4B4809 (July 27, 2015), <http://www.regulations.gov/#/documentDetail;D=FDA-2015-F-0714-0016>.

⁴⁰ Thomas G. Neltner et al., *Navigating the U.S. Food Additive Regulatory Program*, 10 Comprehensive Reviews in Food Science and Policy 342 (Oct. 25, 2011), <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1541-4337.2011.00166.x> (finding that only 37 food additive petitions were filed between 2000 and 2010). An EWG review found that fewer than a dozen petitions for new additives were filed between Jan. 1, 2011, and Jan. 24, 2020).

trade association.⁴¹ This exemption was written into the 1958 law to cover ingredients that were widely considered to be safe, such as flour, vinegar, and apples. Over time, industry has stretched the loophole to allow manufacturers to certify on their own behalf that a chemical is “safe” for use in food, without even notifying the FDA.⁴² For these reasons, it is possible for these so-called secret GRAS food additives to be present in the marketplace without the FDA even knowing of their existence.⁴³

Most PFAS chemicals used in food packaging today have been authorized through the food contact notification system.⁴⁴ The FDA began accepting food contact notifications in 2000 and finalized rules for the procedure in 2002. Instead of going through the more rigorous and transparent food additive petition process, the FDA reviews a notification from a manufacturer that the manufacturer has concluded that a substance is safe. Once a manufacturer submits a petition, the FDA has 120 days to object to the chemical’s use.⁴⁵ If the FDA does not act, the chemical is considered approved. If the FDA has no objections, it may choose to issue a “no objections” letter, which is also treated as an approval.

This process is markedly different from the food additive petition process originally envisioned by Congress under the Food Additives Amendment of 1958. With a food additive petition, the FDA is required to make an affirmative finding of safety based on the high safety standard of “reasonable certainty of no harm.” This involves a transparent review of the science and an opportunity for public comment. By contrast, with a food contact notification, instead of making an affirmative finding of safety, the FDA timely objects to a notification or issues a “no objections” letter, and there is no opportunity for public oversight. Instead of publication in the federal register, the basis for the FDA’s decision on a food contact notification is generally only

⁴¹ 21 USC § 321(s) (“The term ‘food additive’ means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), **if such substance is not generally recognized**, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) **to be safe** under the conditions of its intended use; except that such term does not include . . .”) (emphasis added).

⁴² Center for Science in the Public Interest et al., Comment re: Substances Generally Recognized as Safe, Docket No: FDA-1997-N-0020, https://cspinet.org/sites/default/files/attachment/GRAS%20Comment%20FINAL_0.pdf

⁴³ The FDA has received a voluntary GRAS notification for just one PFAS chemical, <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=82>. However, because the FDA currently allows for secret GRAS determinations, it is unclear how many PFAS chemicals have been “approved” for use in food or food packaging through this legal loophole.

⁴⁴ Over the past 20 years, the FDA has accepted 70 “notices” submitted by 19 different companies on uses of PFAS as food contact substances and allowed them to become “effective.” Of the 70 notices that the FDA has allowed to become “effective,” three companies have informed FDA that they would voluntarily cease uses of seven food contact notices in 2011. See Food & Drug Admin., *supra* note 24. In August 2019, Chemours reported to the FDA that it had abandoned use of three PFAS with food contact notifications and asked it to withdraw those food contact notifications. See Catherine Boudreau, *Exclusive: Maker of ‘Forever Chemicals’ Cuts Food Packaging Products*, Politico (Aug. 9, 2019), <https://www.politico.com/story/2019/08/09/exclusive-maker-of-forever-chemicals-cuts-food-packaging-products-1648303>. For these reasons, there are still 60 active food contact notifications for PFAS.

⁴⁵ 21 U.S.C. § 348(h)(2).

available through a public records request. The FDA can also tacitly approve a substance by taking no action.

Although these notices have been cast as FDA approvals, they are not subject to significant scrutiny. The FDA does not require extensive toxicology studies before allowing a food contact substance like PFAS on the market. When the Environmental Defense Fund compared a subset of approved food contact notifications to the most protective minimum risk level for PFOS proposed by the Centers for Disease Control and Prevention,⁴⁶ every one exceeded the minimum risk levels.⁴⁷ The EDF also found in its review that toxicity data was consistently poor, failed to address cumulative risks, and failed to address many of the health outcomes associated with PFAS exposure.⁴⁸ One company, Daikin, actually conducted animal studies that found toxic effects to the teeth, liver, and kidney but withheld those studies from the FDA when it submitted its food contact notification seeking authorization to use the PFAS.⁴⁹

In June 2019, the FDA announced that it was “reviewing the limited authorized uses of PFAS in food contact applications.”⁵⁰ It is critical that the FDA conduct this review in a manner that ensures that the PFAS under review meet the “reasonable certainty of no harm” standard. This includes taking into consideration the cumulative effects from mixtures of PFAS likely to be found in food contact materials and other sources of PFAS exposure, as is explicitly required under the law. When the FDA samples and tests food for PFAS, it also should test for the PFAS chemicals that have been approved as food contact substances, in addition to likely environmental contaminants.⁵¹

The FDA is already taking steps to downplay the risks from PFAS. At the same time that the FDA announced its plans to review effective PFAS food contact notices, it stated that it “does not have any indication that these substances are a human health concern, in other words a food safety risk in human food, at the levels found” in samples of food the FDA tested.⁵² That’s

⁴⁶ Agency for Toxic Substances and Disease Registry, Toxicological Profile for Perfluoroalkyls (2018) <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>.

⁴⁷ Tom Neltner & Maricel Maffini, *FDA Must Abandon its Flawed Assumptions When Reviewing Safety of Approved PFAS Uses in Food*, Environmental Defense Fund (Aug. 05, 2019), <http://blogs.edf.org/health/2019/08/05/fda-must-abandon-flawed-assumptions-reviewing-safety-pfas/>.

⁴⁸ Tom Neltner & Maricel Maffini, *Think PFAS in Food Packaging are Safe Simply Because FDA Accepted Their Use? Think Again.*, Environmental Defense Fund (Nov. 13, 2019), <http://blogs.edf.org/health/2019/11/13/think-again-pfas-food-packaging-safety/>.

⁴⁹ Tom Neltner & Maricel Maffini, *FDA-Approved PFAS: A Serious Breakdown in Assessing Food Additive Safety*, Environmental Defense Fund (Nov. 04, 2018), <http://blogs.edf.org/health/2018/11/04/fda-approved-pfas-breakdown-assessing-food-additive-safety/>.

⁵⁰ Food & Drug Admin., Per and Polyfluoroalkyl Substances (PFAS), <https://www.fda.gov/food/chemicals-and-polyfluoroalkyl-substances-pfas> (last visited Jan. 25, 2020).

⁵¹ When the FDA recently sampled and tested food for PFAS as part of its 2019 total diet study, it tested for 16 different PFAS chemicals that are not approved as food contact substances. This means the FDA was primarily concerned about PFAS in food from environmental contamination, not from sanctioned uses. As part of its review of food contact notifications, the FDA should also test food to see how much PFAS are contaminating food from use in food contact materials.

⁵² Ned E. Sharpless, FDA Statement: Statement on FDA’s Scientific Work to Understand Per- and Polyfluoroalkyl Substances (PFAS) in Food, and Findings from Recent FDA Surveys (June 11, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fdas-scientific-work-understand-and-polyfluoroalkyl-substances-pfas-food-and-findings>. Given the results of that sampling and what is known about the health impacts of PFAS at very low

surprising, given what is known about the risks from PFAS in the diet, even at low levels. The FDA's statements downplaying PFAS risks and other recent actions raise concerns that the FDA may have prejudged the outcome of this review. There are four ways in which the FDA is basing the outcome of its review on certain preconceived assumptions.

First, by using a limit of quantification instead of a detection limit, the FDA is underestimating how much PFAS get into the food supply.⁵³ A limit of quantification, or LOQ, is different from a detection limit. The LOQ indicates the amount once it has been accurately measured and is usually three to 10 times greater than the limit of detection.⁵⁴ Detection means that the chemicals are present but cannot be precisely quantified. Reporting detections based on an LOQ rather than a detection limit will lower the number of overall detections.

The FDA used an LOQ to limit detections when it validated a new method for testing 16 types of PFAS in bread, lettuce, milk, and fish, in October 2019.⁵⁵ When the FDA released the new method, it also revised its earlier test results, released in June 2019, based on the application of the new validated method. The new test method established a method detection limit, or MDL, for each food group tested. As with an LOQ, an MDL is described by the FDA as "the level at which PFAS can be reliably measured over repeated testing."⁵⁶

The results of the new test method greatly reduce the number of positive samples. That is because several of the FDA's previous test results included positive results at low levels in certain foods. Under the new validated method, those low levels were below the MDL and thus reported as non-detects. As a result, the FDA now claims that the PFAS chemicals it tested for were not detected in most of the food that was tested, even if it is possible those PFAS were present in small amounts.⁵⁷

doses, it is concerning that the FDA would downplay the risks. When FDA samples were released to the public, there were detects of all 16 PFAS tested for in produce samples from farmer's markets in North Carolina (<https://www.fda.gov/media/127848/download>), as well as in 10 milk samples from New Mexico (<https://www.fda.gov/media/127850/download>).

⁵³ For example, in its June 2019 summary of the samples tested from the mid-Atlantic region, the FDA indicated that 14 of 91 samples had detectable levels over the *Limit of Quantification*. It is unclear whether additional samples had detections under the LOQ. See Tom Neltner & Maricel Maffini, *FDA Concluded PFAS in Food are Safe. Now it has to Show how it Reached that Conclusion.*, Environmental Defense Fund (Aug. 01, 2019), <http://blogs.edf.org/health/2019/08/01/fda-pfas-food-conclusion-safety/>.

⁵⁴ *Id.*

⁵⁵ Susan Genualdi & Lowri deJager, Single-Laboratory Validation per the Guidelines for the Validation of Chemical Methods for the FDA FVM Program 2nd Ed. (Nov. 01, 2019), <https://www.fda.gov/media/131510/download>.

⁵⁶ Food & Drug Admin. Constituent Update: FDA Makes Available Testing Method for PFAS in Foods and Final Results from Recent Surveys (Oct. 31, 2019), <https://www.fda.gov/food/cfsan-constituent-updates/fda-makes-available-testing-method-pfas-foods-and-final-results-recent-surveys>

⁵⁷ Detections from the FDA's total diets study results dropped from detects in 14 out of 91 samples to just two out of 91 samples. The FDA's produce survey contained 20 samples. With the new method, detects dropped from 19 to 16 samples. An EDF analysis found that 104 of the 182 PFAS detects in samples collected from North Carolina and New Mexico were replaced with <MDL in FDA's new data tables. See Tom Neltner & Maricel Maffini, *FDA's Updated Results for PFAS in Food Suggest Progress but Raise Questions About its Method*, Environmental Defense Fund (Nov. 20, 2019), <http://blogs.edf.org/health/2019/11/20/fdas-updated-results-for-pfas-in-food-suggest-progress-but-raise-questions-about-its-method/>.

Some states, such as Massachusetts, have found ways to report detections that are below the LOQ but above the detection limit.⁵⁸

Second, the FDA's new MDLs for PFAS were calculated with a stricter methodology than the FDA has used for other foods, and this has resulted in fewer detects. In its methodology, the FDA defines the MDL as “the statistically calculated minimum concentration that can be measured with 99 percent confidence that the reported value is greater than zero.”⁵⁹ Notably, this is the same definition the EPA uses for wastewater and sludge permitting guidelines.⁶⁰ However, the FDA often does not use EPA guidelines for its validation of chemical test methods, given the differences between water and food. For example, the FDA used a 95 percent confidence level for its 2015 validation method to measure heavy metals in food in the 2015 Total Diet Study.⁶¹ A 99 percent confidence level rather than a 95 percent confidence level will likely result in fewer reported detections, artificially limiting FDA's overall estimate of the amount of PFAS present in food. If the FDA undercalculates the amount of PFAS present in food, it may also then underestimate the potential risk to human health.

Third, the FDA may be ignoring critical health effects in its risk analysis of PFAS chemicals. In its analysis of some PFAS substances thus far, the FDA has relied on the reference dose⁶² developed by the EPA to estimate safety thresholds.⁶³ That reference does not adequately consider some critical health effects associated with PFAS exposure, like altered mammary gland development⁶⁴ and reduced effectiveness of vaccines.⁶⁵ State governments like New Jersey⁶⁶ and Michigan⁶⁷ have relied in part on these health impacts to develop more health-protective reference doses. The European Food Safety Authority developed more health-

⁵⁸ Massachusetts Department of Environmental Protection, Draft Drinking Water PFAS Regulation, at 8, <https://www.mass.gov/doc/310-cmr-2200-pfas-amendments/download> (“If an analytical result is equal to or greater than one-third of the MRL but less than the MRL, then the Running Quarterly Average shall be calculated using one-half of the MRL as the concentration for that PFAS”). MRL stands for Minimum Reporting Level and, like, an LOQ, is defined as “the minimum concentration that can be reported as a quantitated value for a target analyte in a sample following analysis.”

⁵⁹ Genualdi & deJager, *supra* note 55, at 17.

⁶⁰ 40 C.F.R. Appendix B to Part 136, Definition and Procedure for the Determination of the Method Detection Limit- Revision 1.11.

⁶¹ Patrick J. Gray, William R. Mindak, & John Cheng, Elemental Analysis Manual for Food and Related Products: 4.7. Inductively Couple Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury and Other Elements in Food Using Microwave Assisted Digestion (March 2015), <https://www.fda.gov/media/87509/download>. See also Neltner & Maffini, *supra* note 57.

⁶² A reference dose is an estimate of a daily exposure level for the human population, including vulnerable populations, that is likely to be without an appreciable risk of harmful effects.

⁶³ See Env't'l Protection Agency, *supra* note 12.

⁶⁴ See, e.g., Tucker et al., Macon et al., & White et al., *supra* note 3.

⁶⁵ See Stoiber, *supra* note 6.

⁶⁶ See, e.g., Gloria B. Post & Jessie A. Gleason, Technical Support Document: Interim Specific Ground Water Criterion for Perfluorooctanoic Acid (PFOA, C8)(CAS #335-67-1; Chemical Structure: CF₃(CF₂)₆COOH), New Jersey Department of Environmental Protection, Division of Science, Research and Environmental Health, at 4 (Jan. 2019),

<https://www.nj.gov/dep/dsr/Technical%20Support%20Document%20Draft%20ISGWQC%20for%20PFOA.pdf>.

⁶⁷ Michigan Department of Health and Human Services, Division of Environmental Health, PFAS Action Response Team Human Health Working Group, Public Health Drinking Water Screening Levels for PFAS (Feb. 22, 2019), https://www.michigan.gov/documents/pfasresponse/MDHHS_Public_Health_Drinking_Water_Screening_Levels_for_PFA_651683_7.pdf.

protective weekly exposure amounts based on human data in epidemiological studies,⁶⁸ data the EPA also failed to consider when calculating its reference dose.

Fourth, the FDA is also failing to adequately assess the risks from short-chain PFAS, many of which were commercialized to replace long-chain PFAS phased out under pressure from the FDA and EPA. For at least one short-chain PFAS, the FDA is using as a safety threshold a 50 parts per billion concentration in the diet, which is 100 times higher than the default threshold being applied to PFOA and PFOS, two long-chain PFAS.⁶⁹ To justify the different safety thresholds, the FDA is drawing on the assumption that polymers of short-chain PFAS do not build up in the body.⁷⁰ But that assumption is inconsistent with a peer-reviewed study by the FDA's own scientists.⁷¹ According to the FDA peer-reviewed study, short-chain PFAS replacement chemicals can also build up in the body for long periods of time. Moreover, EPA toxicity assessments show that at least some short-chain PFAS chemicals, like GenX and PFBS, prompt many of the same health concerns as the long-chain PFAS they replaced.⁷²

In light of the health threats posed by PFAS and the FDA's failure to properly assess the safety of PFAS in food packaging, Congress should quickly end the use of PFAS in food packaging, as proposed by H.R. 2827, the Keep Food Containers Safe From PFAS Act of 2019.

There are many food-packaging alternatives available,⁷³ and states and retailers are not waiting for the FDA to remove harmful PFAS from food packaging. Washington state was the first to ban PFAS in 2018, which will take effect in 2022.⁷⁴ Maine also passed a law authorizing the state Department of Environmental Protection to ban PFAS in food packaging as early as 2022.⁷⁵ San Francisco has banned bowls that have been intentionally manufactured using PFAS.⁷⁶ California is considering reviewing and regulating PFAS in food packaging under its

⁶⁸ See EFSA Panel, *supra* note 13; see also Agency for Toxic Substances & Disease Registry, *supra* note 46.

⁶⁹ See Neltner & Maffini, *supra* note 48.

⁷⁰ See Neltner & Maffini, *supra* note 47.

⁷¹ Shruti V. Kabadi et al., *Internal Exposure-Based Pharmacokinetic Evaluation of Potential for Biopersistence of 6:2 Fluorotelomer Alcohol (FTOH) and its Metabolites*, 112 Food and Chemical Toxicology 375 (Feb. 2018), <https://www.sciencedirect.com/science/article/pii/S0278691518300127?via%3Dihub>. See also Maricel Maffini & Tom Neltner, *The Elephant in the Room: Potential Biopersistence of Short-Chain PFAS*, Environmental Defense Fund (Feb. 20, 2019), <http://blogs.edf.org/health/2019/02/20/potential-biopersistence-short-chain-pfas/>.

⁷² See National Toxicology Program, Per- and Polyfluoroalkyl Substances, <https://ntp.niehs.nih.gov/whatwestudy/topics/pfas/index.html> (last visited Jan. 27, 2020) (finding similar toxicity for long and short chain PFAS); Env't'l Protection Agency, GenX and PFBS Draft Toxicity Assessments (2018), <https://www.epa.gov/pfas/genx-and-pfbs-draft-toxicity-assessments>. See also Cheryl Hogue, *Short-Chain and Long-Chain PFAS Show Similar Toxicity*, US National Toxicology Program Says, Chemical & Engineering News (Aug. 24, 2019), <https://cen.acs.org/environment/persistent-pollutants/Short-chain-long-chain-PFAS/97/i33>.

⁷³ Several materials can be used as PFAS alternatives, including bamboo, palm leaf, bio-wax, and polylactic acid – which is a compostable bio-based material derived from renewable substances like potato, wheat and corn starch. In many cases, packaging materials can also simply be used without a coating material.

⁷⁴ H.B. 2658 (Wash. 2018).

⁷⁵ H.P. 1043, 129th Leg. (Maine 2019).

⁷⁶ City of San Francisco, Ordinance 201-18 (File No. 180519) (Aug. 10, 2018).

green chemistry law.⁷⁷ Denmark will ban all PFAS in paper and cardboard packaging by July 2020.⁷⁸

Responsible retailers are also moving away from PFAS. Burger King reportedly stopped using PFAS-coated paper in 2002,⁷⁹ and McDonald's pledged to move to PFAS-free coatings in 2006.⁸⁰ Panera has started the process for switching to PFAS-free baguette bags and will continue to transition to PFAS alternatives in 2020.⁸¹ Taco Bell will also phase out PFAS by 2025.⁸² In December 2018, both Whole Foods and Trader Joe's stated that they were working toward PFAS-free packaging.⁸³ Ahold Delhaize (parent company of Food Lion, Giant Food, GIANT/MARTIN'S, Hannaford, Peapod and Stop & Shop, and its U.S. services company, Retail Business Services) announced in September that it would put a restriction on PFAS and other chemicals.⁸⁴ As of Jan. 1, 2020, the Biodegradable Products Institute will no longer certify any product as compostable if it contains intentionally added PFAS.⁸⁵

Reducing the amount of PFAS in the environment, marketplace, and people will require swift and decisive action. Eliminating non-essential uses like food packaging is an important first step toward reducing exposures.⁸⁶

Congress should quickly pass H.R. 2827 and remove PFAS from food contact substances.

⁷⁷ California Department of Toxic Substances Control, *supra* note 18.

⁷⁸ See Press Release, The Minister of Food is Ready to Ban Fluoride Substances, Danish Veterinary and Food Administration (Sept. 2, 2019), <https://www.foedevarestyrelsen.dk/Nyheder/Aktuelt/Sider/Nyheder%202019/F%C3%B8devareministeren-er-klar-til-at-forbyde-fluorstoffer.aspx> (translated from Dutch). See also Katie Hunt, *Denmark Just Became the First Country to Ban PFAS 'Forever Chemicals' From Food Packaging*, CNN (Sept. 4, 2019), <https://www.cnn.com/2019/09/04/health/denmark-pfas-food-packaging-ban-intl/index.html>.

⁷⁹ Lyons, *supra* note 31, at 113.

⁸⁰ Sara Schaefer Muñoz, *EPA Probes Safety of Key Chemical in Teflon*, Wall Street Journal (Jan. 31, 2006).

⁸¹ Mind the Store, Retailer Report 2019, Panera Bread <https://retailerreportcard.com/retailer/panera-bread/> (last visited Jan. 25, 2020).

⁸² Press Release, Taco Bell® Rings in 2020 With Bold New Commitments (Jan. 9, 2020), <https://www.tacobell.com/news/taco-bell-2020-commitments?selectedTag=&selectYear=2020>.

⁸³ Mike Schade & Laurie Valeriano, *Whole Foods, Trader Joe's Pledge Initial Action on Toxic PFAS*, Safer Chemicals Healthy Families (Dec. 12, 2018), <https://saferchemicals.org/2018/12/12/whole-foods-trader-joes-pledge-initial-action-on-toxic-pfas/>.

⁸⁴ Press Release, Ahold Delhaize USA Brands Announce Commitment to Sustainable Chemistry, Transparent Products and Packaging (Sept. 19, 2019), <http://www.globenewswire.com/news-release/2019/09/19/1918074/0/en/Ahold-Delhaize-USA-Brands-Announce-Commitment-to-Sustainable-Chemistry-Transparent-Products-and-Packaging.html?culture=en-us>.

⁸⁵ Biodegradable Products Institute, Fluorinated Chemicals, <https://bpiworld.org/Fluorinated-Chemicals> (last visited Jan. 25, 2020).

⁸⁶ The Madrid Statement, endorsed by 200 scientists, argues for ending the use of PFAS when uses are non-essential or when safer alternatives exist Arlene Blum et al, *The Madrid Statement on Poly- and Perfluoroalkyl Substances*, 123 *Env't'l Health Perspectives* A107 (May 01, 2015), <https://ehp.niehs.nih.gov/doi/pdf/10.1289/ehp.1509934>. See also Ian T. Cousins et al., *The Concept of Essential Use for Determining When Uses of PFAS Can Be Phased Out*, 21 *Env't'l Science: Processes and Impacts* 1803 (2019), <https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h#!divAbstract>.

Congress should take other steps to reduce overall exposure to PFAS – including in water, food, cosmetics, and other household products. In particular, Congress should, as proposed in H.R. 535, the PFAS Action Act:

- Set a two-year deadline for the EPA to set a drinking water standard for PFOA and PFOS.
- Designate PFOS and PFOA as “hazardous substances” under the Superfund law and set a deadline for the EPA to determine whether other PFAS should also be designated as hazardous substances.
- Restrict industrial PFAS emissions into the air and water.
- Phase out other non-essential uses of PFAS and help consumers avoid PFAS in everyday products.
- Require new studies before approving new PFAS.

In addition, Congress should fix our badly broken system for assessing food additives and food contact materials. In particular, Congress should direct the FDA to follow the 1958 law and review the cumulative effects of similar chemicals authorized for use food additives and food contact materials, including background exposure from non-dietary sources. For substances that do not meet the rigorous safety standard of “reasonable certainty to cause no harm,” the FDA should be directed to revoke approval for those substances. The FDA should also revise its method for detecting PFAS chemicals in food and accurately measure PFAS in food.

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:]



Testimony
of
Paul C. DeLeo, Ph.D.

Principal
Integral Consulting Inc.

Before the

U.S. House of Representatives

Energy and Commerce Committee
Subcommittee on Health

On the

"Keep Food Containers Safe from PFAS Act of 2019"

January 29, 2020

Good morning, Chairwoman Eshoo, Ranking Member Burgess, and members of the Subcommittee. My name is Paul DeLeo, and I am a Principal at Integral Consulting Inc., which is an international science and engineering consulting firm, founded in 2002, serving a wide variety of clients across the public and private sectors. We have approximately 150 employees distributed nationwide, and I am based in Annapolis, Maryland. I am here today to express my scientific opinion, but no client or any other entity has retained me to offer this opinion.

I am pleased to be here today to share my perspective on H.R. 2827, the Keep Food Containers Safe from PFAS Act of 2019. H.R. 2827 would amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to deem perfluoroalkyl or polyfluoroalkyl substances (PFAS) used as a food contact substance (FCS) to be unsafe and therefore treated as adulterated. My colleagues and I came to the attention of the Subcommittee based on our expertise with PFAS, in particular recent peer-reviewed scientific publications on the topic.^{1,2} Additionally, I worked for six and a half years from 2000 to 2007 at the Food and Drug Administration (FDA) in the Office for Food Additive Safety, which is responsible for the regulation of food contact substances. So, I have firsthand knowledge of the regulatory process for the safety assessment of food contact substances and the staff who perform those safety assessments.

I testify today in opposition to H.R. 2827 as unnecessary, overly broad, and contrary to well-established scientific processes for the pre-market evaluation of chemical safety in the United States.

HR. 2827 Is Unnecessary

FDA has had responsibility for the regulation of food additives since 1938. As FDA notes on its website, “[p]rior to 2000, the FDA authorized the use of food contact substances through the food additive petition process, which resulted in a regulation establishing safe conditions of use in Title 21 of the Code of Federal Regulations. Consequently, there are a number of regulations for food contact substances as indirect food additives in the Code of Federal Regulations. Since 2000, the FDA authorizes the use of food contact substances through the Food Contact Notification (FCN) program.

The Inventory of Effective Food Contact Substance Notifications (FCN Inventory) is a publicly available database of all uses of food contact substances authorized through the

¹ Luz, A.L., J.K. Anderson, P. Goodrum, and J. Durda. 2019. Perfluorohexanoic acid toxicity, part I: Development of a chronic human health toxicity value for use in risk assessment. *Regulatory Toxicology and Pharmacology* 103:41-55. <https://doi.org/10.1016/j.yrtph.2019.01.019>.

² Anderson, J.K., A.L. Luz, P. Goodrum, and J. Durda. 2019. Perfluorohexanoic acid toxicity, part II: Application of human health toxicity value for risk characterization. *Regulatory Toxicology and Pharmacology* 103:10-20. <https://doi.org/10.1016/j.yrtph.2019.01.020>.

FCN program.³ According to the FDA online database for the FCS Inventory,⁴ FDA has received approximately 2,000 food contact notifications since the program was brought online in fiscal year 2000. According to research by the Environmental Defense Fund, as of October 22, 2019, there were 70 effective food contact notifications for PFAS, though seven of those have been voluntarily suspended by the manufacturer.⁵ In addition, a search of the FDA database Indirect Additives Used in Food Contact Substances using the search term “fluor” returns 48 substances, some of which might not meet the PFAS definition in H.R. 2827. Consequently, 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 for safety *prior* to being permitted to come to the market as a food contact substance.

It is important to note that there are substantial data requirements for an FCN and the agency has the authority to object to any FCN if it does not believe the proposed use of the food contact substance is safe. According to FDA guidance documents, an FCN may include a variety of short term and chronic toxicity studies such as those regarding carcinogenicity, or developmental and reproductive toxicity.^{6,7} In addition, the agency has the discretion to request additional data from the notifier to confirm their safety assessment before the food contact substance is permitted on the market.

In addition to the FCN program, there are other provisions already in place to insure the safety of food contact substances. For example, the FFDCA gives the agency the authority under Section 409(h)(3) 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. It does not appear these provisions have been exercised for PFAS. Also, agency staff have the opportunity to request more information from the submitter of the food contact notification, or to object to that submission entirely.

Once food contact substances are 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

³ <https://www.fda.gov/food/chemicals-and-polyfluoroalkyl-substances-pfas>

⁴ <https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN>

⁵ http://blogs.edf.org/health/2019/11/13/think-again-pfas-food-packaging-safety/#_ftnref2 [Accessed January 24, 2020]

⁶ Draft Guidance for Industry: Regulatory Submissions to OFAS, Part V Food Contact Substance Submissions, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-regulatory-submissions-ofas-part-v-food-contact-substance-submissions>

⁷ Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances (Toxicology Recommendations), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-food-contact-substances-toxicology>

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.^{8,9,10,11}

Moreover, FDA has the ability to act on new science as it learns of it. According to FDA “[t]he FDA reviews updated scientific information on food contact substances as it becomes available. The agency can revoke food contact authorizations when scientific data demonstrate that the authorized uses of a food contact substance are no longer safe. In addition, the FDA can also work with industry to remove food contact substances from the market through voluntary agreements. For example, in 2011, the FDA obtained voluntary agreements with the manufacturers of certain “long-chain” PFAS compounds authorized under food contact notifications to remove those substances from food contact applications. “Long-chain” and “short-chain” refer to the number of carbon atoms in the molecular structure of a subset of PFAS. In 2016, the FDA revoked the regulations that authorized the remaining uses of these long-chain PFAS in food packaging.”¹²

H.R. 2827 Is Overly Broad

H.R. 2827 would apply to any PFAS used as a food contact substance. While it appears that the universe of those PFAS currently approved by FDA is about 100 substances, according to FDA “[t]here are nearly 5,000 types of PFAS,”¹⁰ and H.R. 2827 makes no distinction among them. It also does not make the important distinction between polymeric PFAS (e.g., fluoropolymers) and non-polymeric PFAS. For example, fluoropolymers are not bioavailable or bioaccumulative and satisfy the widely accepted assessment criteria to be considered as “polymers of low concern” around the globe.¹³ Therefore, they are considered to be of low hazard to human health and the environment.

However, more importantly, the impacts of H.R. 2827 would be very broad because, although the number of individual chemicals may be modest, PFAS have been safely used through the food supply in a wide variety of applications for decades. Therefore, it is not possible to predict the implications for food safety and the potential unintended

⁸ Begley, T.H., K. White, P. Honigfort, M.L. Twaroski, R. Neches, and R.A. Walker. 2005. Perfluorochemicals, potential sources of and migration from food packaging. *Food Additives and Contaminants* 22(10):1023–1031.

⁹ Begley, T.H., W. Hsu, G. Noonan, and G. Diachenko. 2008. Migration of fluorochemical paper additives from food-contact paper into foods and food simulants. *Food Additives & Contaminants: Part A* 25:384–390.

¹⁰ Rice, P.A. 2015. C6-Perfluorinated compounds: The new greaseproofing agents in food packaging. *Curr. Envir. Health Rpt.* 2:33–40. <https://doi.org/10.1007/s40572-014-0039-3>

¹¹ Kabadi, S.V., J. Fisher, J. Aungst, and P. Rice. 2018. Internal exposure-based pharmacokinetic evaluation of potential for biopersistence of 6:2 fluorotelomer alcohol (FTOH) and its metabolites. *Food and Chemical Toxicology* 112:375–382. <https://doi.org/10.1016/j.fct.2018.01.012>.

¹² <https://www.fda.gov/food/chemicals-and-polyfluoroalkyl-substances-pfas>

¹³ Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integr Environ Assess Manag*, 14: 316–334. doi:[10.1002/ieam.4035](https://doi.org/10.1002/ieam.4035)

consequences such legislation might precipitate. Also, because there is compliance authority for food safety at the Federal level, the State level, and even at the local level (e.g., cities and counties), such changes with broad impacts will result in uneven application and confusion in the market without proper communication. Because the uses that would be prohibited have already been assessed for safety by FDA, it does not appear that there would be any benefit to H.R. 2827. However, these rapid and broad changes would lead to disruption and confusion in the food industry and potentially compromise the safety of the food supply.

H.R. 2827 Is Contrary to Well-Established Scientific Processes for the Pre-market Evaluation of Chemical Safety in the U.S.

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 market. Most of these programs are administered by FDA or the Environmental Protection Agency. Those programs have a long track record of success, and Congress has a track record of successful oversight and of reform or modernization 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 chemicals 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. While no process is perfect, U.S. regulatory agencies have been successful in addressing and adapting to limitations in these regulatory processes, and they should be allowed to be continued to do so.

Conclusion

In conclusion, my recommendation to Congress would be that, to the extent there is concern regarding PFAS used as food contact substances, 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 the agency has the tools and resources necessary to fully address PFAS as food contact substances.

We appreciate the Subcommittee's vigilance and commitment to improve the safety and transparency in America's food and drugs, and we would be pleased to help in any way we can.

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

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? OK. Good afternoon.

Ms. ESHOO. Move it closer, so——

Ms. MOUNTFORD. OK, there we go.

Ms. ESHOO [continue]. 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 reshelfed. 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:]



**Infant Nutrition Council of America
Testimony on H.R. 2267 – Infant Formula Protection Act of 2019**

The Infant Nutrition Council of America (INCA) appreciates the opportunity to testify on H.R. 2267, the Infant Formula Protection Act of 2019. INCA is an association representing manufacturers¹ of infant formula, and our member companies manufacture over 95% of the infant formula fed in the United States. INCA member companies are centers of excellence for scientific research and education in the area of global infant nutrition with a strong emphasis on infant growth, development, and positive health outcomes. 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 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 mothers initiate exclusive breastfeeding when their baby is born; however, many also use combination feeding (feeding both breast milk and formula) or switch to infant formula during the first year. For this reason, assuring the quality of infant formula is important to 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 the sole source of nutrition at a time of critical infant growth and development, making quality a key factor for regulatory oversight. U.S. infant formula products are manufactured with high-quality ingredients and with strict adherence to the U.S. Infant Formula Act and the U.S. Food & Drug Administration's (FDA) Good Manufacturing Practices for Infant Formula Manufacturers. 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, the infant formula provides the 30 essential nutrients listed on the infant formula label. Adhering to the "use by" date assures that a baby who is fed the formula receives the federally-regulated and required level of nutrients listed on the product label. Infant formula fed past the "use by" date may not deliver all nutrients at the exact levels listed on the label due to degradation 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, and as set forth in Section 342 of the Federal Food, Drug, and Cosmetic Act generally means a product is harmful or injurious to human health because it contains a poisonous or deleterious substance. And although Section 350a of the Act expands the definition of "adulterated" for infant formula to also include...

(1) an infant formula that does not provide the Federally mandated nutrients, (2) an infant formula that does not meet the quality factor requirements prescribed by FDA, or (3) an infant formula that was not manufactured in conformance with FDA's good manufacturing practices and quality control procedures.

...those are in specific reference to manufacturer activities rather than more general retailers and distributors. Accordingly, calling an infant formula that is past its "use by" date adulterated would be inconsistent with Section 342, and also ill-fitting with Section 350a.

¹ INCA members are Abbott Nutrition, Gerber Products Company, Perrigo Nutritional, and Reckitt Benckiser.



In this light, INCA suggests alternative language that would instead more succinctly prohibit the retail sales 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 (FSMA), when it implemented the hazard analysis and risk-based preventive controls at Section 350g. Instead of those violations rendering a food product "adulterated," Congress simply cut to the chase and made it a new "Prohibited Act" in Section 331. We suggest that the Infant Formula Protection Act of 2019 be implemented in a likewise manner.

For background information, in 1985, FDA amended its regulations with respect to infant formula to require that a "use by" date be placed prominently on every infant formula product. In codifying this requirement, FDA reasoned that: "Retail store employees can easily determine when to remove stock from store shelves based on a "use by" date."² FDA also underscored in this rulemaking the necessity for manufacturers to conduct stability testing to determine the appropriate "use by" date. As a result, infant formula manufacturers must be able to document that any infant formula consumed before its "use by" date will provide at the required levels all the nutrients specified by Section 412 of the Federal Food, Drug, and Cosmetic Act.

INCA and its member companies consistently work with stakeholders to ensure infant formula is safe and nutritious. INCA meets regularly with FDA's Office of Nutrition and Food Labeling to share information on infant feeding issues and seek alignment as needed. 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 re-shelved. INCA has also engaged with the U.S. Department of Agriculture 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.

Today we have the opportunity to establish statutory measures to ensure expired infant formula is not sold at retail. Indeed, while infant formula manufacturers have been required for nearly 35 years to provide "use by" date information on product labeling and to have data on hand supporting the propriety and accuracy of such dating, there has been no commensurate legal obligation to ensure that infant formula that is past its "use by" date is removed from store shelves and not sold to consumers.

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, so that it would unequivocally prohibit retailers from the sale of infant formula products beyond their "use by" date. Failure to abide by this restriction would constitute a prohibited act. We believe this would be the most effective method 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, Committee, and all interested stakeholders to determine a workable solution to this issue.

² Federal Register, Vol. 50, No. 9, Page 1838. January 14, 1985.

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 ten years old.

Ms. ESHOO. OK. Well, and you gave the example of when he was three?

Ms. DAY. Yes.

Ms. ESHOO. OK. 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 five to seven years; five to seven 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 now, 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. OK, 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 four 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 OK. 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 [continue]. 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 [continue]. 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 [continue]. 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, OK. 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. OK.

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. OK, 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 [continue]. 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. OK.

Ms. MOUNTFORD. And not getting the nutrients like for one 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 fundamen-

tally 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—yes.

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 six-month withdrawal and any of the meat that—Canada has a zero tolerance and once this meat is processed after six 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, OK. Thank you.

Ms. PERRY. Can I respond, Dr. Schrader?

Mr. SCHRADER. Well, my time is expired.

Ms. PERRY. OK.

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. OK.

Mr. BURGESS [continue]. 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. OK, thank you. Thank you.

OK, 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. OK. OK. 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. OK. 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 [continue]. You should not use it past this date.

Ms. MOUNTFORD. It is my understanding, yes.

Mr. CARTER. OK, fair enough. OK, 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 appears at the conclusion fo the hearing.]

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 gov-

ernment 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 [continue]. 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 qual-

ity 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. OK, 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.

However, one of the more troublesome exposures to PFAS that often goes unnoticed is the use of these chemicals in food packaging. Last year, Congress took an important first step in the NDAA bill to ban the use of PFAS in food packaging for MREs. My bill, the Keep Food Containers Safe from PFAS Act, would build on this success to provide FDA to deem PFAS substances in any food containers or cookware unsafe.

So I am going to direct these questions to Ms. Benesh. Ms. Benesh, what do we know about the health effects PFAS in food packaging? Does FDA have a safety threshold for PFAS that it uses to calculate how much PFAS in food is safe?

Ms. BENESH. So we do know that PFAS migrates from food packaging into food, and we know that some of the health effects broadly associated with PFAS chemicals includes some kinds of cancers and then at much lower doses reproductive harms, developmental

harms, and reduced effectiveness of vaccine. What is really concerning to me is FDA has said it is using EPA's reference dose for drinking water for PFOA and PFOS, which are two of the food packaging chemicals that are no longer being used.

But for all the PFAS that are still in food packaging, they have not calculated a reference dose and so they are 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. OK. 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 OK. 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. OK, 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 two 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, OK. 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. OK, 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. OK, 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. Schakowsky, 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 slaugh-

tered, 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 [continue]. 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 [continue]. 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 Web site. 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 [continue]. 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 [continue]. 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 [continue]. 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 appears at the conclusion of the hearing.]

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.

Ms. ESHOO. So at this time, the subcommittee is adjourned. Thank you, everyone.

[The information appears at the conclusion of the hearing.]

[Whereupon, at 2:27 p.m., the subcommittee was adjourned.]

PREPARED STATEMENT OF FRANK PALLONE, JR.

Today, the Subcommittee is meeting to continue our strong history of working to ensure the quality and safety of our country's food and drugs. We're here to learn about several proposals to increase transparency, set clear standards for certain foods, support the development of modern drug manufacturing, and reduce the gaming of incentives for drugs intended to treat rare diseases.

In Panel I, we will examine four bills aimed at increasing patient access to life-saving drugs and providing consumers with up-to-date and accurate information through modified labeling. The first bill, H.R. 4712, the "Fairness in Orphan Drug Exclusivity Act," would update the Orphan Drug Act of 1983 by requiring that manufacturers seeking orphan drug designations demonstrate a lack of any reasonable expectation that the costs incurred by manufacturing and distributing said drug would be recovered in U.S. sales, and to continue to make such demonstrations over a seven-year period of market exclusivity. It would further direct FDA and manufacturers to take into account the sales of all drugs for a specific rare disease or condition developed by the same manufacturer as well as all drugs containing the same components.

The next bill, H.R. 4866, the "National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act," introduced by Mr. Guthrie and myself, would amend the 21st Century Cures Act to direct FDA to designate National Centers of Excellence in Continuous Pharmaceutical Manufacturing (NCEs), which would work with FDA and industry to create a national framework for continuous manufacturing implementation, including supporting additional research and development of this technology, workforce development, standardization, and collaborating with manufacturers to support adoption of continuous manufacturing. We will then discuss H.R. 5663, the "Safeguarding Therapeutics Act," which would extend FDA's administrative destruction authority to medical devices.

Finally, rounding out our first panel, we have H.R. 5668, the "Making Objective Drug Evidence Revisions for New Labeling Act of 2020," or the "MODERN Labeling Act of 2020." This bill would give FDA authority to require updates of outdated labeling for generic drugs and requires that FDA report any actions taken under the bill to update labeling for covered drugs, including the number of drugs, description of the changes and the rationale behind them, as well as any FDA recommendation to modify the program.

Panel II will cover five bills involving food safety: H.R. 961, the "Safeguarding American Food Exports Act of 2020," H.R. 1769, the "DAIRY Pride Act," H.R. 2117, the "FASTER Act of 2019," H.R. 2267, the "Infant Formula Protection Act of 2019," H.R. 2827, the "Keep Food Containers Safe from PFAS Act of 2019," and H.R. 4487, the "CURD Act."

I want to thank all of the witnesses for taking the time to speak to us today, and I am confident that this hearing will serve as another example of the Energy and Commerce Committee's dedication to protecting Americans and their peace of mind when it comes to the safety of their food and drugs.

Thank you, I yield back.

116TH CONGRESS
1ST SESSION

H. R. 961

To prevent human health threats posed by the consumption of equines raised
in the United States.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 4, 2019

Ms. SCHAKOWSKY (for herself and Mr. BUCHANAN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To prevent human health threats posed by the consumption
of equines raised in the United States.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safeguard American
5 Food Exports Act of 2019”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

8 (1) unlike cows, pigs, and other domesticated
9 species, horses and other members of the equidae

1 family are not raised for the purpose of human con-
2 sumption;

3 (2) equines raised in the United States are fre-
4 quently treated with substances that are not ap-
5 proved for use in horses intended for human con-
6 sumption and equine parts are therefore unsafe
7 within the meaning of section 409 of the Federal
8 Food, Drug, and Cosmetic Act;

9 (3) equines raised in the United States are fre-
10 quently treated with drugs, including phenylbuta-
11 zone, acepromazine, boldenone undecylenate, omeprazole,
12 ketoprofen, xylazine, hyaluronic acid, nitrofurazone,
13 polysulfated glycosaminoglycan, clenbuterol,
14 tolazoline, and ponazuril, which are not approved for
15 use in horses intended for human consumption and
16 equine parts are therefore unsafe within the mean-
17 ing of section 512 of the Federal Food, Drug, and
18 Cosmetic Act; and

19 (4) consuming parts of an equine raised in the
20 United States likely poses a serious threat to human
21 health and the public should be protected from these
22 unsafe products.

1 **SEC. 3. PROHIBITIONS.**

2 Section 301 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 331) is amended by adding at the end the
4 following:

5 “(fff) Notwithstanding any other provision of this
6 section—

7 “(1) equine parts shall be deemed unsafe under
8 section 409 of this Act;

9 “(2) equine parts shall be deemed unsafe under
10 section 512 of this Act; and

11 “(3) the knowing sale or transport of equines or
12 equine parts in interstate or foreign commerce for
13 purposes of human consumption is hereby prohib-
14 ited.”.

○

116TH CONGRESS
1ST SESSION

H. R. 1769

To require enforcement against misbranded milk alternatives.

IN THE HOUSE OF REPRESENTATIVES

MARCH 14, 2019

Mr. WELCH (for himself, Mr. SIMPSON, Mr. GALLAGHER, Mr. GROTHMAN, Ms. STEFANIK, Mr. DUFFY, Mr. COURTNEY, Mr. THOMPSON of Pennsylvania, Mr. LARSEN of Washington, Mr. KIND, Ms. DELBENE, Mr. KILDEE, Mr. SCHRADER, Ms. KUSTER of New Hampshire, Mr. MARSHALL, Mr. REED, Mr. PETERSON, Mr. SENSENBRENNER, Mr. BRINDISI, Mr. GIBBS, Mr. JOYCE of Pennsylvania, Mr. TONKO, Mr. COLLINS of New York, Mr. CARTWRIGHT, Mr. MITCHELL, Mr. LONG, Mr. MOOLENAAR, Mr. SMUCKER, Mr. NEWHOUSE, and Mr. DELGADO) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require enforcement against misbranded milk alternatives.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Defending Against
5 Imitations and Replacements of Yogurt, Milk, and Cheese
6 To Promote Regular Intake of Dairy Everyday Act” or
7 the “DAIRY PRIDE Act”.

1 **SEC. 2. FINDINGS.**

2 Congress finds as follows:

3 (1) Dairy products are an important part of a
4 healthy diet for both children and adults, according
5 to the 2015–2020 Dietary Guidelines for Americans
6 (referred to in this section as the “Dietary Guide-
7 lines”) published by the Department of Health and
8 Human Services and the Department of Agriculture.
9 The Dietary Guidelines state that most Americans
10 are not meeting recommended intake for the dairy
11 food group. Consumption of dairy foods provides nu-
12 merous health benefits, including lowering the risk
13 of diabetes, metabolic syndrome, cardiovascular dis-
14 ease, and obesity.

15 (2) The Dietary Guidelines state that dairy
16 foods are excellent sources of critical nutrients for
17 human health, including vitamin D, calcium, and po-
18 tassium, all of which are under consumed by people
19 of the United States. When consumed in the
20 amounts recommended by the Food Patterns of the
21 Department of Agriculture, on average across the
22 calorie levels, dairy foods contribute about 67 per-
23 cent of calcium, 64 percent of vitamin D, and 17
24 percent of magnesium.

25 (3) About 30 percent of adolescent boys meet or
26 exceed the recommended 3-cup equivalents per day,

1 but less than 10 percent of adolescent females meet
2 or exceed this recommendation. An age-related de-
3 cline in dairy intake appears to begin in adolescence
4 and intakes persist at very low levels among adult
5 females across the age distribution. Less than 5 per-
6 cent of adult females consume the recommended 3-
7 cup equivalents per day. Overall, more than 80 per-
8 cent of the entire population of the United States
9 does not meet the daily dairy intake recommenda-
10 tion.

11 (4) The Dietary Guidelines state that vitamin
12 D and potassium amounts vary across plant-based
13 milk alternatives. The amount of calcium per calorie
14 is lower for most plant-based alternative milk prod-
15 ucts. To obtain the amount of calcium contained in
16 one cup of non-fat fluid milk from a plant-based
17 milk alternative, the portion size and calorie intake
18 must be greater.

19 (5) Imitation dairy products, such as plant-
20 based products derived from rice, nuts, soybeans,
21 hemp, coconut, algae, and other foods that imitate
22 milk, yogurt, and cheese, often do not provide the
23 same nutrition content as real milk, cheese, and yo-
24 gurt derived from dairy cows.

1 (6) Plant-based products labeled as milk are
2 misleading to consumers.

3 (7) The Food and Drug Administration has
4 regulations that define milk and cream as the “lac-
5 teal secretion, practically free from colostrum, ob-
6 tained by the complete milking of one or more
7 healthy cows” (section 131.110 of title 21, Code of
8 Federal Regulations). This definition further applies
9 to milk used to create other dairy products, includ-
10 ing yogurt and cheese, as specified in sections 131
11 and 133 of title 21, Code of Federal Regulations.

12 (8) Given the proliferation of plant-based prod-
13 ucts in the marketplace that are mislabeled as milk
14 despite the standard of identity defined for this sub-
15 stance, enforcement by the Food and Drug Adminis-
16 tration against these practices should be improved to
17 avoid misleading consumers.

18 **SEC. 3. PURPOSE.**

19 No food may be introduced or delivered for introduc-
20 tion into interstate commerce using a market name for
21 a dairy product if the food does not meet the criterion
22 set forth for dairy products under paragraph (z)(2) of sec-
23 tion 403 of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 343) (as added by section 4(a)).

1 **SEC. 4. ENFORCEMENT OF DEFINITION.**

2 (a) IN GENERAL.—Section 403 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 343) is amended by
4 adding at the end the following:

5 “(z)(1) If it uses a market name for a dairy product
6 described in subparagraph (3) and the food does not meet
7 the criterion for being a dairy product, as described in
8 subparagraph (2).

9 “(2) For purposes of this paragraph, a food is a dairy
10 product only if the food is, contains as a primary ingre-
11 dient, or is derived from, the lacteal secretion, practically
12 free from colostrum, obtained by the complete milking of
13 one or more hooved mammals.

14 “(3) A market name for a dairy product described
15 in this subparagraph means the dairy product terms de-
16 scribed in parts 131 and 133 of subchapter B of chapter
17 I of title 21, Code of Federal Regulations, and sections
18 135.110, 135.115, and 135.140 of title 21, Code of Fed-
19 eral Regulations (or any successor regulations), or any
20 other term for which the Secretary has promulgated a
21 standard of identity with respect to a food that is formu-
22 lated with a dairy product (as described in subparagraph
23 (2)) as the primary ingredient.”.

24 (b) GUIDANCE.—The Secretary of Health and
25 Human Services, acting through the Commissioner of
26 Food and Drugs, shall—

1 (1) not later than 90 days after the date of en-
2 actment of this Act, issue draft guidance on how en-
3 forcement of the amendment made by subsection (a)
4 will be carried out; and

5 (2) not later than 180 days after the date of
6 enactment of this Act, issue final guidance on such
7 enforcement.

8 (c) REPORT TO CONGRESS.—Not later than 2 years
9 after the date of enactment of this Act, the Secretary of
10 Health and Human Services, acting through the Commis-
11 sioner of Food and Drugs, shall report to Congress on en-
12 forcement actions taken under paragraph (z) of section
13 403 of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 343), as amended by this Act, including warnings
15 issued pursuant to such paragraph and penalties assessed
16 under section 303 of such Act (21 U.S.C. 333) with re-
17 spect to such paragraph. If food that is misbranded under
18 section 403(z) is offered for sale in interstate commerce
19 at the time of such report, the Commissioner of Food and
20 Drugs shall include in such report an updated plan for
21 enforcement with respect to such food.

○

116TH CONGRESS
1ST SESSION

H. R. 2117

To improve the health and safety of Americans living with food allergies and related disorders, including potentially life-threatening anaphylaxis, food protein-induced enterocolitis syndrome, and eosinophilic gastrointestinal diseases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 8, 2019

Ms. MATSUI introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To improve the health and safety of Americans living with food allergies and related disorders, including potentially life-threatening anaphylaxis, food protein-induced enterocolitis syndrome, and eosinophilic gastrointestinal diseases, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food Allergy Safety,
5 Treatment, Education, and Research Act of 2019” or the
6 “FASTER Act of 2019”.

1 **SEC. 2. FOOD ALLERGY SAFETY RECOMMENDATIONS OF**
2 **THE NATIONAL ACADEMY OF MEDICINE.**

3 (a) **COLLECTION OF FOOD ALLERGY DATA.**—The
4 Public Health Service Act is amended by inserting after
5 section 317T of such Act (42 U.S.C. 247b–22) the fol-
6 lowing new section:

7 **“SEC. 317U. COLLECTION OF FOOD ALLERGY DATA.**

8 “The Secretary, acting through the Director of the
9 Centers for Disease Control and Prevention, shall—

10 “(1) expand and intensify the collection of in-
11 formation on the prevalence of food allergies for spe-
12 cific allergens in the United States, such as through
13 the National Health and Nutrition Examination
14 Survey; and

15 “(2) include such information within annual or
16 other periodic reporting to the Congress and the
17 public on other surveillance activities.”.

18 (b) **ALLERGEN LABELING.**—

19 (1) **MAJOR ALLERGEN DEFINITION.**—Section
20 201(qq)(1) of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 3211(qq)(1)) is amended by striking
22 “and soybeans” and inserting “soybeans, and ses-
23 ame”.

24 (2) **ADDITIONAL ALLERGENS.**—Section 201(qq)
25 of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 3211(qq)(1)) is amended by adding at the
2 end the following:

3 “(3) Any other food ingredient that the Sec-
4 retary determines by regulation to be a major food
5 allergen, based on the prevalence and severity of al-
6 lergic reactions to the food ingredient.”.

7 **SEC. 3. REPORT ON USE BY FDA OF PATIENT EXPERIENCE**

8 **DATA ON TREATMENTS FOR PATIENTS WITH**
9 **FOOD ALLERGIES.**

10 Section 3004 of the 21st Century Cures Act (21
11 U.S.C. 355 note) is amended—

12 (1) by striking “Not later than” and inserting
13 the following:

14 “(a) IN GENERAL.—Not later than”; and

15 (2) by adding at the end the following:

16 “(b) TREATMENTS FOR PATIENTS WITH FOOD AL-
17 LERGIES.—Each report under subsection (a) shall include
18 a synopsis of the use by the Food and Drug Administra-
19 tion in regulatory decisionmaking of patient experience
20 data on treatments for patients with food allergies.”.

21 **SEC. 4. STUDY ON ECONOMIC COSTS OF FOOD ALLERGIES.**

22 The Director of the National Institutes of Health
23 shall seek to enter into an arrangement with the National
24 Academies of Sciences, Engineering, and Medicine (or if

1 the National Academies decline to enter into an arrange-
2 ment, another appropriate entity) to—

3 (1) study the economic costs of food allergies in
4 the United States, both individually and for the food
5 allergy population overall; and

6 (2) not later than 1 year after the date of en-
7 actment of this Act—

8 (A) complete such study;

9 (B) submit to the Congress a report on the
10 results of such study; and

11 (C) publish such report.

○

116TH CONGRESS
1ST SESSION

H. R. 2267

To amend the Federal Food, Drug, and Cosmetic Act to treat infant formula as adulterated if its use by date has passed.

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 2019

Ms. MENG (for herself and Ms. KUSTER of New Hampshire) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to treat infant formula as adulterated if its use by date has passed.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Infant Formula Pro-
5 tection Act of 2019”.

6 **SEC. 2. EXPIRED INFANT FORMULA.**

7 (a) ADULTERATION.—Section 412(a) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)) is
9 amended—

1 (1) in paragraph (2), by striking “or” at the
2 end;

3 (2) in paragraph (3), by striking the period at
4 the end and inserting “, or”; and

5 (3) by adding at the end the following:

6 “(4) the use by date of such infant formula, as
7 specified in the labeling of such formula in accord-
8 ance with section 107.20 of title 21, Code of Federal
9 Regulations (or any successor regulations), has
10 passed.”.

11 (b) APPLICABILITY.—The amendment made by sub-
12 section (a) applies beginning on the date that is 6 months
13 after the date of enactment of this Act.

○

116TH CONGRESS
1ST SESSION

H. R. 2827

To amend the Federal Food, Drug, and Cosmetic Act to deem any perfluoroalkyl or polyfluoroalkyl substance used as a food contact substance to be unsafe and therefore treated as adulterated under such Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 17, 2019

Mrs. DINGELL introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to deem any perfluoroalkyl or polyfluoroalkyl substance used as a food contact substance to be unsafe and therefore treated as adulterated under such Act, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Keep Food Containers
5 Safe from PFAS Act of 2019”.

1 **SEC. 2. PROHIBITION AGAINST FOOD CONTACT SUB-**
2 **STANCES CONTAINING PERFLUOROALKYL**
3 **AND POLYFLUOROALKYL SUBSTANCES.**

4 Paragraph (6) of section 409(h) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 348(h)(6)) is amend-
6 ed—

7 (1) by striking “(6)” and inserting “(6)(A)

8 DEFINITION.—”; and

9 (2) by adding at the end the following:

10 “(B) PERFLUORINATED COMPOUNDS.—

11 “(i) DEEMED UNSAFE.—Beginning on January
12 1, 2022, any PFAS used as a food contact sub-
13 stance is deemed to be unsafe for the purposes of
14 this section and the application of clause (2)(C) of
15 section 402(a).

16 “(ii) DEFINITIONS.—In this subparagraph:

17 “(I) The term ‘PFAS’ means a
18 perfluoroalkyl substance or a polyfluoroalkyl
19 substance that is man-made with at least 1
20 fully fluorinated carbon atom.

21 “(II) The term ‘perfluoroalkyl substance’
22 means a man-made chemical of which all of the
23 carbon atoms are fully fluorinated carbon
24 atoms.

25 “(III) The term ‘polyfluoroalkyl substance’
26 means a man-made chemical containing a mix

1 of fully fluorinated carbon atoms, partially
2 fluorinated carbon atoms, and nonfluorinated
3 carbon atoms.”.

○

116TH CONGRESS
1ST SESSION

H. R. 4487

To amend the Federal Food, Drug, and Cosmetic Act to define the term
natural cheese.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 2019

Mr. KIND (for himself, Mr. LONG, and Mr. SCHRADER) introduced the
following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
define the term natural cheese.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Codifying Useful Regu-
5 latory Definitions Act” or the “CURD Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) There is a need to define the term “natural
9 cheese” in order to maintain transparency and con-

1 sistency for consumers so that they may differen-
2 tiate “natural cheese” from “process cheese”.

3 (2) The term “natural cheese” has been used
4 within the cheese making industry for more than 50
5 years and is well-established.

6 **SEC. 3. DEFINITION OF NATURAL CHEESE.**

7 (a) DEFINITION.—Section 201 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by
9 adding at the end the following:

10 “(ss)(1) The term ‘natural cheese’ means cheese that
11 is a ripened or unripened soft, semi-soft, or hard product,
12 which may be coated, that is produced—

13 “(A) by—

14 “(i) coagulating wholly or partly the pro-
15 tein of milk, skimmed milk, partly skimmed
16 milk, cream, whey cream, or buttermilk, or any
17 combination of such ingredients, through the
18 action of rennet or other suitable coagulating
19 agents, and by partially draining the whey re-
20 sulting from the coagulation, while respecting
21 the principle that cheese-making results in a
22 concentration of milk protein (in particular, the
23 casein portion), and that consequently, the pro-
24 tein content of the cheese will be distinctly
25 higher than the protein level of the blend of the

1 above milk materials from which the cheese was
2 made; or

3 “(ii) processing techniques involving coagu-
4 lation of the protein of milk or products ob-
5 tained from milk to produce an end-product
6 with similar physical, chemical, and organolep-
7 tic characteristics as the product described in
8 subclause (i); and

9 “(iii) including the addition of safe and
10 suitable non-milk derived ingredients of the
11 type permitted in the standards of identity de-
12 scribed in clause (B) as natural cheese; or

13 “(B) in accordance with standards of identity
14 under part 133 of title 21, Code of Federal Regula-
15 tions (or any successor regulations), other than the
16 standards described in subparagraph (2) or any fu-
17 ture standards adopted by the Secretary in accord-
18 ance with subparagraph (2)(I).

19 “(2) Such term does not include—

20 “(A) pasteurized process cheeses as defined in
21 section 133.169, 133.170, or 133.171 of title 21,
22 Code of Federal Regulations (or any successor regu-
23 lations);

24 “(B) pasteurized process cheese foods as de-
25 fined in section 133.173 or 133.174 of title 21, Code

1 of Federal Regulations (or any successor regula-
2 tions);

3 “(C) pasteurized cheese spreads as defined in
4 section 133.175, 133.176, or 133.178 of title 21,
5 Code of Federal Regulations (or any successor regu-
6 lations);

7 “(D) pasteurized process cheese spreads as de-
8 fined in section 133.179 or 133.180 of title 21, Code
9 of Federal Regulations (or any successor regula-
10 tions);

11 “(E) pasteurized blended cheeses as defined in
12 section 133.167 or 133.168 of title 21, Code of Fed-
13 eral Regulations (or any successor regulations);

14 “(F) any products comparable to any product
15 described in any of clauses (A) through (E);

16 “(G) cold pack cheeses as defined in section
17 133.123, 133.124, or 133.125 title 21, Code of Fed-
18 eral Regulations (or any successor regulations);

19 “(H) grated American cheese food as defined in
20 section 133.147 of title 21, Code of Federal Regula-
21 tions (or any successor regulations); or

22 “(I) any other product the Secretary may des-
23 ignate as a process cheese.

24 “(3) For purposes of this paragraph, the term ‘milk’
25 has the meaning given such term in section 133.3 of title

1 21, Code of Federal Regulations (or any successor regula-
2 tions) and includes the lacteal secretions from animals
3 other than cows.”.

4 (b) LABELING.—Section 403 of the Federal Food
5 Drug and Cosmetic Act (21 U.S.C. 343) is amended by
6 adding at the end the following:

7 “(z) If its label or labeling includes the term ‘natural
8 cheese’ as a factual descriptor of a category of cheese un-
9 less the food meets the definition of natural cheese under
10 section 201(ss), except that nothing in this paragraph
11 shall prohibit the use of the term ‘natural’ or ‘all-natural’,
12 or a similar claim or statement with respect to a food in
13 a manner that is consistent with regulations, guidance, or
14 policy statements issued by the Secretary.”.

15 (c) NATIONAL UNIFORMITY.—Section 403A(a)(2) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 343–1(a)(2)) is amended by striking “or 403(w)” and in-
18 serting “403(w), or 403(z)”.

○

116TH CONGRESS
1ST SESSION

H. R. 4712

To amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 17, 2019

Ms. DEAN (for herself, Mr. VEASEY, Mr. CARTER of Georgia, and Mr. MCKINLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Fairness in Orphan
5 Drug Exclusivity Act”.

6 **SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICEN-**
7 **SURE OF ORPHAN DRUGS.**

8 (a) IN GENERAL.—Section 527 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

1 (1) in subsection (a), by striking “Except as
2 provided in subsection (b)” and inserting “Except as
3 provided in subsection (b) or (f)”; and

4 (2) by adding at the end the following:

5 “(f) LIMITATIONS ON EXCLUSIVE APPROVAL, CER-
6 TIFICATION, OR LICENSE.—

7 “(1) IN GENERAL.—For a drug designated
8 under section 526 for a rare disease or condition
9 pursuant to the criteria set forth in subsection
10 (a)(2)(B) of such section, the Secretary shall not
11 grant, recognize, or apply exclusive approval or licen-
12 sure under subsection (a), and, if such exclusive ap-
13 proval or licensure has been granted, recognized, or
14 applied, shall revoke such exclusive approval or licen-
15 sure, unless the sponsor of the application for such
16 drug demonstrates—

17 “(A)(i) with respect to an application ap-
18 proved or a license issued after the date of en-
19 actment of this subsection, upon such approval
20 or issuance, that there is no reasonable expecta-
21 tion at the time of such approval or issuance
22 that the cost of developing and making avail-
23 able in the United States such drug for such
24 disease or condition will be recovered from sales
25 in the United States of such drug, taking into

1 account all sales made or reasonably expected
2 to be made without a time limitation; or

3 “(ii) with respect to an application ap-
4 proved or a license issued on or prior to the
5 date of enactment of this subsection, not later
6 than 60 days after such date of enactment, that
7 there was no reasonable expectation at the time
8 of such approval or issuance that the cost of de-
9 veloping and making available in the United
10 States such drug for such disease or condition
11 would be recovered from sales in the United
12 States of such drug, taking into account all
13 sales made or reasonably expected to be made
14 without a time limitation; and

15 “(B) annually for the duration of the 7-
16 year period described in subsection (a) with re-
17 spect to the drug, that there continues to be no
18 reasonable expectation that the cost of devel-
19 oping and making available in the United
20 States such drug for such disease or condition
21 will be recovered from sales in the United
22 States of such drug, taking into account all
23 sales made or reasonably expected to be made
24 without a time limitation.

1 “(2) CONSIDERATIONS.—For purposes of sub-
2 paragraphs (A) and (B) of paragraph (1), the Sec-
3 retary and the sponsor of the application for the
4 drug designated for a rare disease or condition de-
5 scribed in such paragraph shall consider sales from
6 all drugs for such disease or condition that—

7 “(A) are developed or marketed by the
8 same sponsor or manufacturer of the drug (or
9 a licensor, predecessor in interest, or other re-
10 lated entity to the sponsor or manufacturer);
11 and

12 “(B) contain the same active moiety as the
13 drug, regardless of whether or not the drugs
14 also contain different or additional active
15 moieties.

16 “(3) CRITERIA.—No drug designated under
17 section 526 for a rare disease or condition pursuant
18 to the criteria set forth in subsection (a)(2)(B) of
19 such section shall be eligible for exclusive approval
20 or licensure under this section unless it met such
21 criteria under such subsection on the date on which
22 the drug was approved or licensed.”.

23 “(b) RULE OF CONSTRUCTION.—The amendments
24 made in subsection (a) shall apply to any drug that has
25 been or is hereafter designated under section 526 of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)
2 for a rare disease or condition pursuant to the criteria
3 under subsection (a)(2)(B) of such section regardless of—

4 (1) the date on which such drug is designated
5 or becomes the subject of a designation request
6 under such section;

7 (2) the date on which such drug is approved
8 under section 505 of such Act (21 U.S.C. 355) or
9 licensed under section 351 of the Public Health
10 Service Act (42 U.S.C. 262) or becomes the subject
11 of an application for such approval or licensure; and

12 (3) the date on which such drug is granted ex-
13 clusive approval or licensure under section 527 of
14 the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 360cc) or becomes the subject of a request
16 for such exclusive approval or licensure.

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116TH CONGRESS
1ST SESSION

H. R. 4866

To amend the 21st Century Cures Act to provide for designation of institutions of higher education that provide research, data, and leadership on continuous manufacturing as National Centers of Excellence in Continuous Pharmaceutical Manufacturing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 28, 2019

Mr. PALLONE (for himself and Mr. GUTHRIE) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the 21st Century Cures Act to provide for designation of institutions of higher education that provide research, data, and leadership on continuous manufacturing as National Centers of Excellence in Continuous Pharmaceutical Manufacturing, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “National Centers of
5 Excellence in Continuous Pharmaceutical Manufacturing
6 Act of 2019”.

1 **SEC. 2. NATIONAL CENTERS OF EXCELLENCE IN CONTIN-**
2 **UOUS PHARMACEUTICAL MANUFACTURING.**

3 (a) IN GENERAL.—Section 3016 of the 21st Century
4 Cures Act (21 U.S.C. 399h) is amended to read as follows:

5 **“SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN CON-**
6 **TINUOUS PHARMACEUTICAL MANUFAC-**
7 **TURING.**

8 “(a) IN GENERAL.—The Secretary of Health and
9 Human Services, acting through the Commissioner of
10 Food and Drugs—

11 “(1) shall solicit and, beginning not later than
12 180 days after the date of enactment of the National
13 Centers of Excellence in Continuous Pharmaceutical
14 Manufacturing Act of 2019, receive requests from
15 institutions of higher education to be designated as
16 a National Center of Excellence in Continuous Phar-
17 maceutical Manufacturing (in this section referred to
18 as a ‘National Center of Excellence’) to support the
19 advancement and development of continuous manu-
20 facturing; and

21 “(2) shall so designate any institution of higher
22 education that—

23 “(A) requests such designation; and

24 “(B) meets the criteria specified in sub-
25 section (c).

1 “(b) REQUEST FOR DESIGNATION.—A request for
2 designation under subsection (a) shall be made to the Sec-
3 retary at such time, in such manner, and containing such
4 information as the Secretary may require. Any such re-
5 quest shall include a description of how the institution of
6 higher education meets or plans to meet each of the cri-
7 teria specified in subsection (c).

8 “(c) CRITERIA FOR DESIGNATION DESCRIBED.—The
9 criteria specified in this subsection with respect to an in-
10 stitution of higher education are that the institution has,
11 as of the date of the submission of a request under sub-
12 section (a) by such institution—

13 “(1) physical and technical capacity for re-
14 search and development of continuous manufac-
15 turing;

16 “(2) scalable manufacturing knowledge-sharing
17 networks with other institutions of higher education,
18 large and small biopharmaceutical manufacturers,
19 generic and nonprescription manufacturers, contract
20 manufacturers, and other entities;

21 “(3) proven capacity to design and demonstrate
22 new, highly effective technology for use in contin-
23 uous manufacturing;

1 “(4) a track record for creating and transfer-
2 ring knowledge with respect to continuous manufac-
3 turing;

4 “(5) the potential to train a future workforce
5 for research on and implementation of continuous
6 manufacturing; and

7 “(6) the potential to participate in and lead a
8 continuous manufacturing technology partnership
9 with other institutions of higher education, large and
10 small biopharmaceutical manufacturers, generic and
11 nonprescription manufacturers, contract manufac-
12 turers, and other entities—

13 “(A) to support companies with continuous
14 manufacturing in the United States;

15 “(B) to support Federal agencies with
16 technical assistance for continuous manufac-
17 turing;

18 “(C) with respect to continuous manufac-
19 turing, to organize and conduct research and
20 development activities needed to create new and
21 more effective technology, capture and dissemi-
22 nate expertise, create intellectual property, and
23 maintain technological leadership;

1 “(D) to standardize systems and ap-
2 proaches for designing continuous manufac-
3 turing; and

4 “(E) to develop a plan to establish a con-
5 tinuous manufacturing workforce.

6 “(d) TERMINATION OF DESIGNATION.—The Sec-
7 retary may terminate the designation of any National Cen-
8 ter of Excellence designated under this section if the Sec-
9 retary determines such National Center of Excellence no
10 longer meets the criteria specified in subsection (c). Not
11 later than 60 days before the effective date of such a ter-
12 mination, the Secretary shall provide written notice to the
13 National Center of Excellence, including the rationale for
14 such termination.

15 “(e) CONDITIONS FOR DESIGNATION.—As a condi-
16 tion of designation as a National Center of Excellence
17 under this section, the Secretary shall require that an in-
18 stitution of higher education enter into an agreement with
19 the Secretary under which the institution agrees—

20 “(1) to collaborate directly with the Food and
21 Drug Administration to publish the reports required
22 by subsection (g);

23 “(2) to share data with the Food and Drug Ad-
24 ministration regarding best practices and research
25 generated through the funding under subsection (f);

1 “(3) to provide an annual report to the Food
2 and Drug Administration regarding the institution’s
3 activities under this section; and

4 “(4) to develop, along with industry partners
5 and another institution or institutions designated
6 under this section, if any, a roadmap for developing
7 a continuous manufacturing workforce.

8 “(f) FUNDING.—

9 “(1) IN GENERAL.—The Secretary shall award
10 funding to the National Centers of Excellence des-
11 ignated under this section for the purpose of study-
12 ing and recommending improvements to continuous
13 manufacturing, including such improvements as may
14 enable the Centers—

15 “(A) to continue to meet the conditions
16 specified in subsection (e);

17 “(B) to submit reports under subsection
18 (e)(3); and

19 “(C) to expand capacity for research on,
20 and development of, continuing manufacturing.

21 “(2) AUTHORIZATION OF APPROPRIATIONS.—
22 There is authorized to be appropriated to carry out
23 this subsection \$80,000,000 for the period of fiscal
24 years 2021 through 2025.

1 “(3) RULE OF CONSTRUCTION.—Nothing in
2 this section shall be construed as precluding a Na-
3 tional Center for Excellence designated under this
4 section from receiving funds under any other provi-
5 sion of this Act or any other Federal law.

6 “(g) ANNUAL REVIEW AND REPORTS.—

7 “(1) ANNUAL REPORT.—Beginning not later
8 than one year after the date on which the first des-
9 ignation is made under subsection (a), and annually
10 thereafter, the Secretary shall—

11 “(A) submit to Congress a report describ-
12 ing the activities, partnerships and collabora-
13 tions, Federal policy recommendations, previous
14 and continuing funding, and findings of, and
15 any other applicable information from, the Na-
16 tional Centers of Excellence designated under
17 this section; and

18 “(B) make such report available to the
19 public in an easily accessible electronic format
20 on the website of the Food and Drug Adminis-
21 tration.

22 “(2) REVIEW OF NATIONAL CENTERS OF EX-
23 CELLENCE AND POTENTIAL DESIGNEES.—The Sec-
24 retary shall periodically review the National Centers
25 of Excellence designated under this section to ensure

1 that such National Centers of Excellence continue to
2 meet the criteria for designation under this section.

3 “(3) REPORT ON LONG-TERM VISION OF FDA
4 ROLE.—Not later than 2 years after the date on
5 which the first designation is made under subsection
6 (a), the Secretary, in collaboration with the National
7 Centers of Excellence designated under this section,
8 shall submit a report to the Congress on the long-
9 term vision of the Department of Health and
10 Human Services on the role of the Food and Drug
11 Administration in supporting continuous manufac-
12 turing, including—

13 “(A) a national framework of principles re-
14 lated to the implementation and regulation of
15 continuous manufacturing; and

16 “(B) a plan for the development of Federal
17 regulations and guidance for how continuous
18 manufacturing can be incorporated into the de-
19 velopment, review, and approval process for
20 drugs and biological products.

21 “(h) DEFINITIONS.—In this section:

22 “(1) BIOLOGICAL PRODUCT.—The term ‘bio-
23 logical product’ has the meaning given such term in
24 section 351(i) of the Public Health Service Act (42
25 U.S.C. 262(i)).

1 “(2) CONTINUOUS MANUFACTURING.—The
2 term ‘continuous manufacturing’—

3 “(A) means a process where the input ma-
4 terials are continuously fed into and trans-
5 formed within the process, and the processed
6 output materials are continuously removed from
7 the system; and

8 “(B) consists of an integrated process that
9 consists of a series of two or more unit oper-
10 ations.

11 “(3) DRUG.—The term ‘drug’ has the meaning
12 given such term in section 201 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 321).

14 “(4) INSTITUTION OF HIGHER EDUCATION.—
15 The term ‘institution of higher education’ has the
16 meaning given such term in section 101(a) of the
17 Higher Education Act of 1965 (20 U.S.C. 1001(a)).

18 “(5) SECRETARY.—The term ‘Secretary’ means
19 the Secretary of Health and Human Services, acting
20 through the Commissioner of Food and Drugs.”.

21 (b) TRANSITION RULE.—Section 3016 of the 21st
22 Century Cures Act (21 U.S.C. 399h), as in effect on the
23 day before the date of the enactment of this section, shall

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- 1 apply with respect to grants awarded under such section
- 2 before such date of enactment.

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116TH CONGRESS
2D SESSION

H. R. 5663

To amend the Federal Food, Drug, and Cosmetic Act to give authority to the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to destroy counterfeit devices.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 21, 2020

Mr. GUTHRIE (for himself and Mr. ENGEL) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to give authority to the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to destroy counterfeit devices.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safeguarding Thera-
5 peutics Act”.

6 **SEC. 2. AUTHORITY TO DESTROY COUNTERFEIT DEVICES.**

7 Section 801(a) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 381(a)) is amended—

1 (1) in the fourth sentence insert “or counterfeit
2 device” after “counterfeit drug”; and

3 (2) by striking “The Secretary of the Treasury
4 shall cause the destruction of” and all that follows
5 through “liable for costs pursuant to subsection
6 (c).” and inserting the following: “The Secretary of
7 the Treasury shall cause the destruction of any such
8 article refused admission unless such article is ex-
9 ported, under regulations prescribed by the Sec-
10 retary of the Treasury, within ninety days of the
11 date of notice of such refusal or within such addi-
12 tional time as may be permitted pursuant to such
13 regulations, except that the Secretary of Health and
14 Human Services may destroy, without the oppor-
15 tunity for export, any drug or device refused admis-
16 sion under this section, if such drug or device is val-
17 ued at an amount that is \$2,500 or less (or such
18 higher amount as the Secretary of the Treasury may
19 set by regulation pursuant to section 498(a)(1) of
20 the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and
21 was not brought into compliance as described under
22 subsection (b). The Secretary of Health and Human
23 Services shall issue regulations providing for notice
24 and an opportunity to appear before the Secretary
25 of Health and Human Services and introduce testi-

1 mony, as described in the first sentence of this sub-
2 section, on destruction of a drug or device under the
3 seventh sentence of this subsection. The regulations
4 shall provide that prior to destruction, appropriate
5 due process is available to the owner or consignee
6 seeking to challenge the decision to destroy the drug
7 or device. Where the Secretary of Health and
8 Human Services provides notice and an opportunity
9 to appear and introduce testimony on the destruc-
10 tion of a drug or device, the Secretary of Health and
11 Human Services shall store and, as applicable, dis-
12 pose of the drug or device after the issuance of the
13 notice, except that the owner and consignee shall re-
14 main liable for costs pursuant to subsection (e).”.

○

.....
(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R. 5668

To amend the Federal Food, Drug, and Cosmetic Act to modernize the labeling of certain generic drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

January 24, 2020

M____ introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to modernize the labeling of certain generic drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the “Making Objective Drug
5 Evidence Revisions for New Labeling Act of 2020” or the
6 “MODERN Labeling Act of 2020”.

1 **SEC. 2. MODERNIZING THE LABELING OF CERTAIN GE-**
2 **NERIC DRUGS.**

3 Chapter V of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 351 et seq.) is amended by inserting after
5 section 503C the following:

6 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN**
7 **DRUGS.**

8 “(a) DEFINITIONS.—For purposes of this section:

9 “(1) The term ‘covered drug’ means a drug ap-
10 proved under section 505(c)—

11 “(A) for which there are no unexpired pat-
12 ents included in the list under section 505(j)(7)
13 and no unexpired period of exclusivity;

14 “(B) for which the approval of the applica-
15 tion has been withdrawn for reasons other than
16 safety or effectiveness; and

17 “(C) for which, with respect to the label-
18 ing—

19 “(i) new scientific evidence is available
20 regarding the conditions of use of the
21 drug;

22 “(ii) there is a relevant accepted use
23 in clinical practice that is not reflected in
24 the approved labeling; or

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1 “(iii) the labeling of such drug does
2 not reflect current legal and regulatory re-
3 quirements.

4 “(2) The term ‘period of exclusivity’, with re-
5 spect to a drug approved under section 505(c),
6 means any period of exclusivity under clause (ii),
7 (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii),
8 or (iv) of section 505(j)(5)(F), or section 505A,
9 505E, or 527.

10 “(3) The term ‘generic version’ means a drug
11 approved under section 505(j) whose reference drug
12 is a covered drug.

13 “(4) The term ‘relevant accepted use’ means a
14 use for a drug in clinical practice that is supported
15 by scientific evidence that appears to the Secretary
16 to meet the standards for approval under section
17 505.

18 “(5) The term ‘selected drug’ means a covered
19 drug for which the Secretary has determined
20 through the process under subsection (c) that the la-
21 beling should be changed.

22 “(b) IDENTIFICATION OF COVERED DRUGS.—The
23 Secretary may identify covered drugs for which labeling
24 updates would provide a public health benefit. To assist

1 in identifying covered drugs, the Secretary may do one or
2 both of the following:

3 “(1) Enter into cooperative agreements or con-
4 tracts with public or private entities to review the
5 available scientific evidence concerning such drugs.

6 “(2) Seek public input concerning such drugs,
7 including input on whether there is a relevant ac-
8 cepted use in clinical practice that is not reflected in
9 the approved labeling of such drugs or whether new
10 scientific evidence is available regarding the condi-
11 tions of use for such drug, by—

12 “(A) holding one or more public meetings;

13 “(B) opening a public docket for the sub-
14 mission of public comments; or

15 “(C) other means, as the Secretary deter-
16 mines appropriate.

17 “(e) SELECTION OF DRUGS FOR UPDATING.—If the
18 Secretary determines, with respect to a covered drug, that
19 the available scientific evidence meets the standards under
20 section 505 for adding or modifying information to the
21 labeling or providing supplemental information to the la-
22 beling regarding the use of the covered drug, the Secretary
23 may initiate the process under subsection (d).

24 “(d) INITIATION OF THE PROCESS OF UPDATING.—
25 If the Secretary determines that labeling changes are ap-

1 appropriate for a selected drug pursuant to subsection (c),
2 the Secretary shall provide notice to the holders of ap-
3 proved applications for a generic version of such drug
4 that—

5 “(1) summarizes the findings supporting the
6 determination of the Secretary that the available sci-
7 entific evidence meets the standards under section
8 505 for adding or modifying information or pro-
9 viding supplemental information to the labeling of
10 the covered drug pursuant to subsection (c);

11 “(2) provides a clear statement regarding the
12 additional, modified, or supplemental information for
13 such labeling, according to the determination by the
14 Secretary (including, as applicable, modifications to
15 add the relevant accepted use to the labeling of the
16 drug as an additional indication for the drug); and

17 “(3) states whether the statement under para-
18 graph (2) applies to the selected drug as a class of
19 covered drugs or only to a specific drug product.

20 “(e) RESPONSE TO NOTIFICATION.—Within 30 days
21 of receipt of notification provided by the Secretary pursu-
22 ant to subsection (d), the holder of an approved applica-
23 tion for a generic version of the selected drug shall—

24 “(1) agree to change the approved labeling to
25 reflect the additional, modified, or supplemental in-

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1 formation the Secretary has determined to be appro-
2 priate; or

3 “(2) notify the Secretary that the holder of the
4 approved application does not believe that the re-
5 quested labeling changes are warranted and submit
6 a statement detailing the reasons why such changes
7 are not warranted.

8 “(f) REVIEW OF APPLICATION HOLDER’S RE-
9 SPONSE.—

10 “(1) IN GENERAL.—Upon receipt of the appli-
11 cation holder’s response, the Secretary shall prompt-
12 ly review each statement received under subsection
13 (e)(2) and determine which labeling changes pursu-
14 ant to the Secretary’s notice under subsection (d)
15 are appropriate, if any. If the Secretary disagrees
16 with the reasons why such labeling changes are not
17 warranted, the Secretary shall provide opportunity
18 for discussions with the application holders to reach
19 agreement on whether the labeling for the covered
20 drug should be updated to reflect available scientific
21 evidence, and if so, the content of such labeling
22 changes.

23 “(2) CHANGES TO LABELING.—After consid-
24 ering all responses from the holder of an approved
25 application under paragraph (1) or (2) of subsection

1 (e), and any discussion under paragraph (1), the
2 Secretary may order such holder to make the label-
3 ing changes the Secretary determines are appro-
4 priate and meet the standards under section 505 for
5 adding or modifying information or providing sup-
6 plemental information to such labeling. Such holder
7 of an approved application shall—

8 “(A) update its paper labeling for the drug
9 at the next printing of that labeling;

10 “(B) update any electronic labeling for the
11 drug within 30 days of such order; and

12 “(C) submit the revised labeling through
13 the form, ‘Supplement—Changes Being Ef-
14 fected’.

15 “(g) VIOLATION.—If the holder of an approved appli-
16 cation for the generic version of the selected drug does
17 not comply with the requirements of subsection (f)(2),
18 such generic version of the selected drug shall be deemed
19 to be misbranded under section 502.

20 “(h) LIMITATIONS; GENERIC DRUGS.—

21 “(1) IN GENERAL.—With respect to any label-
22 ing change required under this section, the generic
23 version shall be deemed to have the same conditions
24 of use and the same labeling as a reference drug for
25 purposes of clauses (i) and (v) of section

1 505(j)(2)(A). Any labeling change so required shall
2 not have any legal effect for the applicant that is
3 different than the legal effect that would have re-
4 sulted if a supplemental application had been sub-
5 mitted and approved to conform the labeling of the
6 generic version to a change in the labeling of the ref-
7 erence drug.

8 “(2) SUPPLEMENTAL APPLICATIONS.—Changes
9 to labeling made in accordance with this section
10 shall not be eligible for an exclusivity period under
11 this Act.

12 “(i) RULES OF CONSTRUCTION.—

13 “(1) APPROVAL STANDARDS.—This section
14 shall not be construed as altering the applicability of
15 the standards for approval of an application under
16 section 505. No order shall be issued under this sub-
17 section unless the scientific evidence supporting the
18 changed labeling meets the standards for approval
19 applicable to any change to labeling under section
20 505.

21 “(2) SECRETARY AUTHORITY.—Nothing in this
22 section shall be construed to limit the authority of
23 the Secretary to require labeling changes under sec-
24 tion 505(o).

1 “(j) REPORTS.—Not later than 4 years after the date
2 of the enactment of the Making Objective Drug Evidence
3 Revisions for New Labeling Act of 2020, and every 4 years
4 thereafter, the Secretary shall prepare and submit to the
5 Committee on Health, Education, Labor, and Pensions of
6 the Senate and the Committee on Energy and Commerce
7 of the House of Representatives, a report that—

8 “(1) describes the actions of the Secretary
9 under this section, including—

10 “(A) the number of covered drugs and de-
11 scription of the types of drugs the Secretary
12 has selected for labeling changes and the ra-
13 tionale for such recommended changes; and

14 “(B) the number of times the Secretary
15 entered into discussions concerning a disagree-
16 ment with an application holder or holders and
17 a summary of the decision regarding a labeling
18 change, if any; and

19 “(2) includes any recommendations of the Sec-
20 retary for modifying the program under this sec-
21 tion.”.



January 24, 2020

The Honorable Eliot Engel
U.S. House of Representatives
2426 Rayburn House Office Building
Washington, DC 20510

The Honorable Brett Guthrie
U.S. House of Representatives
2434 Rayburn House Office Building
Washington, DC 20510

Dear Representatives Engel and Guthrie,

I am writing to you on behalf of the Healthcare Supply Chain Association (HSCA) to thank you for introducing the "Safeguarding Therapeutics Act" (H.R. 5663), which will help to support quality, prevent counterfeit drugs and devices from entering the healthcare supply chain, and preserve patient care.

HSCA represents the nation's leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America's 7,000+ hospitals, as well as the vast majority of 68,000+ long-term care facilities, surgery centers, clinics, and healthcare providers. We work with our healthcare provider partners to negotiate competitive prices and enable a safe and reliable supply of high-quality healthcare products. Collectively, GPOs save the entire healthcare system up to \$34.1 billion annually and reduce supply-related purchasing costs of healthcare providers by 13.1 percent. The value that GPOs deliver allows healthcare providers and physicians to focus on their core mission: providing first-class patient care.

HSCA and its member companies are committed to protecting patients, including from counterfeit drugs or devices that could cause serious harm. The Safeguarding Therapeutics Act will strengthen the U.S. Food and Drug Administration's (FDA) authority to destroy counterfeit drugs and medical devices at American ports of entry, preventing such products from entering the supply chain and helping to ensure a safe and reliable supply of products. This legislation will help to protect patients from counterfeit drugs and devices and is an important step forward as we work to drive quality, safety, and efficacy throughout the healthcare system.

We thank you for your continued commitment to quality and patient safety, and we look forward to continuing to work with your offices and other Members of Congress to pursue solutions that ensure continued patient access to safe and affordable healthcare. If HSCA can be a resource for your staff and you on quality and patient safety, please do not hesitate to contact me directly at (202) 629-5833.

Sincerely,

Khaterah Calleja, J.D.
President & CEO
Healthcare Supply Chain Association

HSCA MEMBERS



CONSENSUS STATEMENT

Healthy Beverage Consumption in Early Childhood

Recommendations from Key National Health
and Nutrition Organizations

**Healthy Eating
Research**

September 2019



Healthy Beverage Consumption in Early Childhood

Recommendations from Key National Health and Nutrition Organizations

September 2019

INTRODUCTION

Establishing healthy dietary patterns in early childhood (0 to 5 years) is important to help prevent future diet-related chronic diseases, as well as to support optimal physical and cognitive growth and development and overall health.¹⁻⁴ Healthy beverage intake is critical in early childhood as beverages can make a significant contribution to dietary intake during this period,⁵ and thus may serve as important sources of essential nutrients. However, many beverages also contain added sugars and saturated fats, which can be harmful when consumed in excess.⁶ Overconsumption of unhealthy beverages along with inadequate consumption of healthy beverages in early childhood can contribute to risk of diet-related chronic diseases, such as obesity, type 2 diabetes, or dental caries.⁷ This makes beverages a critical target for improving the health and well-being of infants and young children.

Despite the importance of healthy beverages in early childhood, many young children's beverage intakes diverge from evidence-based recommendations. For example, many infants consume milk and 100% juice before their first birthday, which can increase their risk for nutrient deficiencies, such as anemia.⁶ Among 2 to 5-year-olds, close to half (44%) consume a sugar-sweetened beverage (SSB) daily,⁸ and the prevalence of SSB consumption increases throughout childhood.⁵ There are also significant differences in beverage intake by race/ethnicity and income groups in early childhood that need to be addressed.^{9,10}

BACKGROUND

Many authoritative bodies have issued guidance and recommendations for healthy beverage intake,^{5,11,12} but important gaps exist as these recommendations have not been comprehensive in the age groups covered or in the types of beverages discussed. There also are inconsistencies in certain aspects of existing recommendations, such as suggested consumption amounts or recommended ages for introduction, potentially contributing to misunderstanding among health care providers, parents, and caregivers.

Given the importance of beverage consumption in early childhood and the need for comprehensive and consistent evidence-based recommendations, Healthy Eating Research (HER), a national program of the Robert Wood Johnson Foundation (RWJF), convened an expert panel representing 4 key national health and nutrition organizations to develop comprehensive recommendations for beverage consumption

consistent with a healthy diet for children from birth to age 5. The 4 organizations represented on the expert panel are (in alphabetical order) the Academy of Nutrition and Dietetics (AND), the American Academy of Pediatric Dentistry (AAPD), the American Academy of Pediatrics (AAP), and the American Heart Association (AHA).

The resulting recommendations focus exclusively on beverage consumption among 0 to 5-year-olds and support a life course approach to the development of healthy dietary patterns and prevention of chronic disease. The expert panel did not address breast milk or infant formula as recommendations in these areas vary by the infant's age, weight, and developmental milestones, and are generally well understood and widely accepted. For detailed recommendations on these topics, please refer to *Pediatric Nutrition* from the American Academy of Pediatrics and HER's *Feeding Guidelines for Infants and Young Toddlers*.^{12,13}

DEFINITIONS



100% Juice

Beverage made from the extraction or pressing of the natural liquid found in fruits or vegetables; 100% juice means that everything in the container came from a fruit or vegetable with no added sugars or artificial ingredients.



Plain, Pasteurized Milk

Cow's milk that has been heated to a specified temperature and for a specific length of time to kill pathogens that may be found in raw milk, and to which no caloric sweeteners, artificial sweeteners, or flavorings have been added. Common varieties include whole milk (also known as Vitamin D milk), reduced fat (2%), low-fat (1%), and skim (fat-free).



Beverages with Low-Calorie Sweeteners (LCS)

Beverages with no- or reduced-calorie sweeteners. The term LCS includes the six high-intensity sweeteners currently approved by the U.S. Food and Drug Administration as food additives (saccharin, aspartame, acesulfame-K, sucralose, neotame, and advantame) and 2 additional high-intensity sweeteners permitted for use in the food supply (steviol glycosides and monk fruit). Other terms for LCS include non-nutritive sweeteners, artificial sweeteners, and sugar substitutes.¹⁴



Plant Milks/Non-Dairy Beverages

Non-dairy, alternative milk beverages that are derived from plant-based ingredients (e.g., rice, nuts/seeds, coconut, oats, peas, or blends of these ingredients) and often fortified with nutrients found in dairy milk. Many plant milks come in both sweetened and unsweetened varieties; sweetened varieties generally contain added sugars.



Caffeinated Beverages

Drink that contains caffeine, a legal stimulant that is mildly addictive. Common caffeinated beverages include coffee, tea, soft drinks, and energy drinks.



Sugar-Sweetened Beverages (SSB)

Liquids to which any forms of sugar are added. This category does not include beverages sweetened with low-calorie sweeteners (see definition for "Beverages with LCS"), 100% juice, or flavored dairy and/or plant-based milks.



Flavored Milk

Cow's milk to which caloric sweeteners have been added for the main purpose of improving palatability. Common examples include chocolate milk or strawberry milk. These products have also been referred to as sweetened milk.



Toddler Milk

Milk drink supplemented with nutrients and often contains added sugars.¹⁵ These products are marketed as appropriate for children ages 9 to 36 months, and may be marketed as "transition formulas," "follow-on formulas," or "weaning formulas" for children 9 to 24 months and "toddler milk," "growing-up milk," or "young child milk" for children ages 12 to 36 months.¹⁶



Plain Drinking Water

Unflavored, unsweetened, uncarbonated, fluoridated drinking water.



Whole Fruit

Fresh, frozen, canned, and dried forms of fruit that do not have added caloric or low-calorie sweeteners.³

METHODOLOGY

HER used a multi-step process to develop the evidence-based recommendations detailed below:

- 1 Convening an expert panel of representatives from 4 national health and nutrition organizations, as well as a scientific advisory committee;
- 2 Conducting an extensive review of approximately 50 existing source documents and reports from domestic and international authoritative bodies on recommendations and guidance for beverage consumption during early childhood;
- 3 Conducting structured narrative scientific literature reviews for beverages where there was a lack of existing recommendations or where recommendations were incomplete or inconsistent;
- 4 Hosting in-person and virtual expert panel meetings to discuss preliminary consensus recommendations based on available evidence gathered in steps 2 and 3; and
- 5 Developing and reviewing final consensus recommendations by expert panelists and scientific advisory committee members.

The expert panel was comprised of 2 representatives from each of the 4 national health and nutrition organizations, a chair, and a research consultant. Panelists were experts in pediatrics, nutrition, and dentistry. HER also recruited a scientific advisory committee of 6 individuals with extensive expertise in establishing dietary guidance, early childhood nutrition, and nutrition science. The scientific advisory committee provided input on the background research strategy and protocols, identified important resources or papers to be included in the technical report and consensus statement, and reviewed the final consensus recommendations for scientific rigor and accuracy. The expert panel met approximately 1-2 times per month over a 6-month period, and also held an in-person meeting to review the evidence, discuss gaps, conduct literature reviews, agree on research terms and content, and develop the final consensus recommendations.

For additional details on the consensus process and methodology, <https://healthyteatingresearch.org/research/technical-scientific-report-healthy-beverage-consumption-in-early-childhood-recommendations-from-key-national-health-and-nutrition-organizations/>.

SUMMARY OF KEY PANEL FINDINGS AND RECOMMENDATIONS

	0-6 months	6-12 months	12-24 months	2-3 years	4-5 years
 Plain drinking water	not needed	0.5-1 cups/day	1-4 cups/day	1-4 cups/day	1.5-5 cups/day
 Plain, pasteurized milk	not recommended		2-3 cups/day whole milk	≤2 cups/day skim or low-fat milk	≤2.5 cups/day skim or low-fat milk
 100% juice	not recommended		≤0.5 cups/day	≤0.5 cups/day	≤0.5-0.75 cups/day
 Plant milks/ Non-dairy beverages	not recommended		medical indication/dietary reasons only		
 Flavored milk					
 Toddler milk					
 Sugar-sweetened beverages (SSB)					
 Beverages with low-calorie sweeteners (LCS)					
 Caffeinated beverages					

Full key panel findings and recommendations listed in Appendix A on page 14.

BEVERAGES RECOMMENDED AS PART OF A HEALTHY DIET IN EARLY CHILDHOOD



Plain Drinking Water and Overall Hydration

Expert Panel Recommendations

- 0-6 months: No supplemental drinking water needed.
- 6-12 months: Offer a total of $\frac{1}{2}$ to 1 cup (4-8 ounces) per day of plain, fluoridated drinking water in a cup during meal times.
- 1-3 years (12-36 months): 1 to 4 cups (8-32 ounces) per day of plain, fluoridated drinking water*.
- 4-5 years (37-60 months): 1.5 to 5 cups (12-40 ounces) per day of plain, fluoridated drinking water*.

*The specific amount of plain water consumed between 1 and 5 years is determined for each child based on the total amount of milk consumed per day. For example, if a 3-year-old does not consume any milk in a given day, all fluid needs should be met via plain water, and thus 4 cups of plain water would be advised. However, if the same 3-year-old drank 2 cups of milk in a given day, approximately 2 cups of plain water per day would suffice to meet total fluid needs.

If 100% juice is consumed, this additional fluid should also be factored into the amount of plain drinking water to consume. If plain drinking water is the only fluid consumed to meet total fluid needs, careful dietary planning is essential to promote adequate nutrient intake from foods.

Rationale

Water is essential for life, yet there is no single daily requirement of total water or fluid for a given person. Individual fluid needs vary on a day-to-day basis because of differences in physical activity, climate, and other foods and beverages consumed.¹⁷ Furthermore, the human body is generally able to compensate for some degree of over- and under-hydration in the short term, and thus, normal hydration can be maintained over a range of water intakes.

Due to this variation in an individual's total water needs, the expert panel proposed ranges of plain water intake that are dependent on the amount of other recommended beverages consumed throughout the day. Infants younger than 6 months of age need only breast milk or infant formula to maintain adequate fluid intake.¹¹ For 6 to 12-month-olds, offering a small amount of plain water (4-8 ounces total per day) in an open, sippy, or strawed cup is recommended.¹² This drinking water is not intended to replace any amount of breast milk or infant formula, and practically speaking, it is unlikely that much of this drinking water will be ingested as many infants 6 to 12-months-old are still developing cup-drinking skills. This practice is suggested to help familiarize the infant with plain water.

The proportion of total daily water intake that is consumed via foods is approximately 30% for children ages 1 to 3 years and 4 to 8 years.¹⁷ Therefore, the expert panel used only 70% of the reference value for recommended total water intakes (based on the Dietary Reference Intakes for water) to calculate the recommended ranges for plain drinking water. It is important to note that individual requirements will be determined based on amounts of other beverages a child consumes (e.g., milk or 100% juice) in a given day.



Plain, Pasteurized Milk

Expert Panel Recommendations

- 0-12 months: Children under 12 months should not consume milk.
- 12-24 months:
 - At 12 months of age, plain, pasteurized whole milk may be introduced. 2 to 3 cups per day (16-24 ounces) whole milk is recommended until 2 years of age*.
 - Reduced-fat (2%) or low-fat (1%) milk may be considered, in consultation with a pediatrician, especially in the presence of excessive weight gain or family history of obesity, dyslipidemia, or other cardiovascular diseases (CVD).
- 2-5 years:
 - At 2 years of age (24 months), children should transition to plain, pasteurized fat-free (skim) or low-fat (1%) milk.
 - Total daily milk intake may be up to 2 cups per day (16 ounces) for children ages 2 to 3 years and up to 2.5 cups per day (20 ounces) for children ages 4 to 5 years.

*For 12 to 24-month-olds, individual needs will depend on the amount of solid food consumed. As toddlers transition from getting most of their daily calories and nutrient needs from liquids (e.g. breast milk, formula, cow's milk) to eating more solid foods, less milk is needed to meet daily calcium and caloric needs. However, milk remains an important dietary source of protein, calcium, and vitamin D for young children during this time.

Rationale

These recommendations are in alignment with recommendations from the Dietary Guidelines for Americans (DGAs), the AAP, and a prior HER expert panel on infant and toddler feeding guidelines.

The dairy food group is an important source of calcium, phosphorous, vitamins A and D, B vitamins, and protein. Milk is the number one source of energy, calcium, vitamin A, vitamin D, and zinc for infants and young children, making it a critical component of a healthy diet.⁶

The expert panel recognizes that there has been recent research and discussion regarding the role of dairy fat in healthy dietary patterns; however, in the absence of clear evidence justifying a departure from current recommendations, the panel chose to remain consistent with current guidance recommending whole milk for most children ages 12 to 24 months and fat-free (skim) or low-fat (1%) milk for children ages 2 years and older.

BEVERAGES TO LIMIT AS PART OF A HEALTHY DIET IN EARLY CHILDHOOD



100% Juice

Expert Panel Recommendations

It is ideal for young children to meet their daily fruit requirements primarily by eating fruits in fresh, canned, or frozen forms, without added sugars or LCS. However, the expert panel recognizes that for some families and individuals, 100% fruit juice may be an important component of meeting daily fruit recommendations, and thus, achieving a healthy eating pattern. As such, the following recommendations are considered upper limits for daily servings of 100% fruit juice, not minimum requirements:

- 0-6 months: Juice is not recommended.
- 6-12 months: Juice is not recommended.
- 1-3 years (12-36 months): No more than 4 ounces of 100% juice per day.
- 4-5 years (37-60 months): No more than 4 to 6 ounces of 100% juice per day.

These recommendations also extend to 100% fruit and vegetable juice blends.

Regarding juice products that are comprised of 100% juice diluted with other liquids, such as purified water or coconut water, the proportion of these products that is 100% juice is generally not clearly labeled on the package. In addition, there is not clear guidance from the U.S. Food and Drug Administration (FDA) regarding the composition of these products, and it may be difficult for consumers to distinguish these products from fruit-flavored drinks with added sweeteners, which are not recommended for consumption among 0 to 5-year-olds. Thus, the expert panel suggests that the most straight-forward approach is for consumers to purchase products comprised only of 100% juice and dilute them with water at home if desired (noting that the proportion of 100% juice in the final beverage should adhere to the portion sizes outlined above). This approach is also generally more cost-effective for families.

Rationale

The fruit food group, as defined by the DGAs, includes both whole fruit and 100% fruit juice. 100% fruit juice can be part of a healthy eating pattern; however, it is lower in dietary fiber than whole fruit and can contribute extra calories when consumed in excess. Thus, it is important to adhere to recommended portion sizes. The 2015 DGAs include 100% juice guidelines for 2 to 5-year-olds, and in 2017, the AAP released updated, evidence-based recommendations for fruit juice consumption in 0 to 5-year-olds.^{5,18}

The expert panel's recommendations align with the 2015 DGA and 2017 AAP recommendations for 100% fruit juice consumption.

100% fruit juice may be an important contributor to achieving adequate fruit intake in young children, particularly in certain populations for whom access to and affordability of fruit is limited. In addition, the available evidence suggests that when consumed in recommended amounts, 100% fruit juice does not appear to promote excess weight gain in young children but may, based on limited data, influence consumption of fruit juice and SSB later in childhood.^{19,20,21} The panel concluded that if young children cannot meet their daily fruit requirements by eating fruits in fresh, canned, or frozen forms, without added sugars or LCS, then consuming a combination of fruit and 100% fruit juice is preferred to not meeting daily fruit intake goals. As such, the recommendations are considered upper limits, not minimum requirements, for daily servings of 100% fruit juice.

BEVERAGES NOT RECOMMENDED AS PART OF A HEALTHY DIET IN EARLY CHILDHOOD



Plant Milks/Non-Dairy Beverages

Expert Panel Recommendations

- 0-12 months: Plant milks/non-dairy beverages are not recommended.
- 1-5 years (12-60 months): Plant milks/non-dairy beverages are not recommended for exclusive consumption in place of dairy milk (with the exception of soy milk); consume only when medically indicated or to meet specific dietary preferences.

Rationale

Plant-based milks are growing in popularity, but it is important to note that they are not nutritionally equivalent to cow's milk. They have varying nutritional profiles based on their plant source and many often contain added sugars. With the exception of soy milk, the DGAs do not include these beverages as part of the dairy group because their overall nutritional content is not similar to dairy foods.

The expert panel identified published analyses of the nutritional composition of plant milks compared to cow's milk.^{22,23} Although plant milks may be fortified to attain similar nutrient levels as cow's milk, it is not known whether the bioavailability of these added nutrients is comparable to that of their naturally-occurring counterparts in cow's milk. These studies concluded that cow's milk should not be removed from the diets of young children unless there is a medical indication or specific dietary preference, and that non-dairy milk beverages should not be considered adequate nutritional substitutes for cow's milk until nutrient quality and bioavailability are established.

Thus, the expert panel agrees with the DGAs that plant milks are not generally a good substitute for meeting daily serving recommendations from the dairy food group.

For 0 to 12-month-olds, plant milks/non-dairy beverages should not be used as a substitute for breast milk or infant formula. Use of alternative beverages as a major component of the diet during this period has been associated with malnutrition.¹¹ For children 1 to 5 years of age, plant milks may be useful for those with allergies or intolerances to cow's milk. For those children, the choice to consume plant milk should be undertaken in consultation with a health care provider, such as a pediatrician and/or registered dietitian nutritionist, so that intake of nutrients commonly obtained from dairy milk can be considered in dietary planning.



Flavored Milk

Expert Panel Recommendations

- 0-12 months: Do not consume milk (flavored or plain).
- 1-5 years (12-60 months): Consume only plain, pasteurized milk*; flavored milk is not recommended.

*See section on plain milk for amounts and types of plain milk recommended for 1 to 5-year-olds.

Rationale

Flavored milk contains caloric sweeteners, and the expert panel concurs with the American Heart Association's recommendation to avoid added sugars for children younger than 2 years old.²⁴ For older children (ages 2 to

5 years), the expert panel considered it appropriate to recommend avoiding flavored milk in order to minimize intake of added sugars and avoid contributing to early establishment of a preference for sweet taste as well as potential negative impacts on nutrient intake and diet quality.

The expert panel's recommendations on flavored milk are consistent with the federal Child and Adult Care Food Program (CACFP) nutrition standards, as well as the National Academies of Sciences, Engineering and Medicine recommendation that only unflavored milk be permitted in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) food package.^{25,26}

The expert panel reviewed literature on the impact of flavored milk consumption in early childhood on diet quality, taste preference development, bone density, type 2 diabetes, CVD, and body weight. There was limited evidence surrounding the health effects of flavored milk consumption in 0 to 5-year-olds, and the evidence related to weight and dietary intake was inconsistent.²⁷⁻³⁰



Toddler Milk

Expert Panel Recommendations

- 0-12 months: Avoid supplementation with "transition" or "weaning" formulas; nutrient needs should be met primarily through human milk and/or infant formula.
- 1-5 years (12-60 months): Toddler milk is not recommended; nutrient needs should be met primarily through nutritionally adequate dietary patterns.

Rationale

The World Health Organization has called toddler milks or transition formulas unnecessary and unsuitable as a breast milk substitute, and suggests that they undermine sustained breastfeeding up to 2 years and beyond.^{31,32} The AAP has noted that follow-up or weaning formulas offer no clear advantage for infants consuming sufficient amounts of iron- and vitamin-containing solid food.³³ Moreover, some toddler milks or transition formulas have added caloric sweeteners.

The expert panel did not identify any longitudinal studies on consumption of these beverages in early childhood and their impact on health outcomes. Although there is not currently evidence to indicate that these products are harmful, the expert panel concluded that they offer no unique nutritional value beyond what could be obtained with healthy foods; furthermore, they may contribute added sugars to the diet. Therefore, they are not recommended as part of a healthy diet in early childhood. If nutrient-rich food intake appears to be inadequate, other strategies to increase food acceptance should be tried first, such as repeated exposures to healthy foods. Toddler milk and transition formulas are also more expensive than an equivalent volume of cow's milk.



Sugar-Sweetened Beverages (SSB)

Expert Panel Recommendations

- 0-5 years: SSB are not recommended, including, but not limited to, soft drinks/soda, fruit drinks, fruit-flavored drinks, fruitades, sports drinks, energy drinks, sweetened waters, and sweetened coffee and tea beverages.⁵

Rationale

Consumption of SSB in early childhood has a negative impact on overall dietary intake and health outcomes, such as dental caries, overweight and obesity, and type 2 diabetes.⁷ Thus, it is prudent to limit children's

exposure to added sugars in early childhood, and SSB are the largest source of added sugars in young children's diets.³⁴ Fruit-flavored drinks (e.g., fruitades, fruit cocktails, fruit punch) are the most commonly consumed SSB in young children. Therefore, additional attention should be paid to reducing consumption of these beverages to limit children's exposure to added sugars in early childhood, including through policy strategies.³⁵

No research has been conducted to examine the impact of SSB consumption in early childhood on the development of flavor preferences. However, children's innate preference for sweetness is well-documented, and it is plausible that early and consistent introduction of SSB could lead to increased preference for sweet foods and beverages and poor diet quality later in life.⁷



Beverages with Low-Calorie Sweeteners (LCS)

Expert Panel Recommendations

- 0-5 years: Beverages with LCS are not recommended.

Rationale

The use of LCS in the food supply has increased in recent years alongside demand for lower-sugar products. In 2018, the AHA released a science advisory cautioning against children's prolonged consumption of LCS beverages, stating "...there is a dearth of evidence on the potential adverse effects of LCS beverages relative to health benefits."³⁶ The expert panel likewise identified little evidence regarding the short and long-term health impacts of beverages with LCS, particularly among young children,³⁷⁻⁴¹ and therefore, concluded that a precautionary approach was prudent. Given that early childhood is a critical developmental period in children's lives with rapid physical, brain, cognitive, and social growth and development, along with the lack of evidence regarding the short- and long-term health impacts of beverages with LCS in young children, it is this panel's expert opinion that beverages with LCS should be avoided between the ages of 0 to 5 years. Moreover, it is plausible that given children's innate preference for the taste of sweetness, frequent early life exposure to and familiarization with highly sweet substances may contribute to their vulnerability to poor dietary habits as they age.



Caffeinated Beverages

Expert Panel Recommendations

- 0-5 years: Do not consume caffeinated beverages.

Rationale

Compared to adults, there is less certainty about the safe level of caffeine intake in children and adolescents. There are currently no specific recommendations for caffeine intake, and caffeine content is not required to be disclosed on nutrition labels, making it difficult to gauge intake.

Average caffeine intakes for children are typically low; however, it is the opinion of this expert panel that caffeinated beverages should not be consumed among 0 to 5-year-olds due to potential for adverse effects.⁴²⁻⁴⁴

CONCLUSIONS

Adequate intake of healthy beverages in early childhood is critical to meeting the nutritional needs of infants and young children and supporting healthy development. Despite efforts in recent years to improve beverage intake patterns among children, many children are still not meeting recommendations and disparities in intake persist. The beverage recommendations put forward by this expert panel are based on the best available evidence and provide consistent messages that can be used by health care providers, public health practitioners, and parents and caregivers to improve the beverage intake patterns of infants and young children.

This expert panel uncovered many areas requiring additional rigorous research in order to inform future dietary guidance for 0 to 5-year-olds. Researchers should focus future efforts on

longitudinal studies of the impact of consumption of beverages, such as flavored milk, plant milks/non-dairy beverages, and beverages with LCS in early childhood and diet-related disease outcomes.

These consensus recommendations are a strong basis for practitioners, providers, and advocates to develop tailored materials for a wide variety of stakeholders, such as parents, health care providers, policymakers, and industry representatives. The level of collaboration and consistency among major national health and nutrition organizations represented in these recommendations is unprecedented and has the capacity to make meaningful change and improve the health and well-being of infants and young children throughout the United States.

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About Healthy Eating Research

Healthy Eating Research (HER) is a national program of the Robert Wood Johnson Foundation. Technical assistance and direction are provided by Duke University under the direction of Mary Story PhD, RD, program director, and Megan Lott, MPH, RDN, deputy director. HER supports research to identify, analyze, and evaluate environmental and policy strategies that can promote healthy eating among children and prevent childhood obesity. Special emphasis is given to research projects that benefit children and adolescents and their families, especially among lower-income and racial and ethnic minority population groups that are at highest risk for poor health and well-being and nutrition-related health disparities. For more information, visit www.healthyeatingresearch.org or follow HER on Twitter at [@HERResearch](https://twitter.com/HERResearch).

About the Robert Wood Johnson Foundation

For more than 45 years the Robert Wood Johnson Foundation has worked to improve health and health care. We are working alongside others to build a national Culture of Health that provides everyone in America a fair and just opportunity for health and well-being. For more information, visit www.rwjf.org. Follow the Foundation on Twitter at [www.rwjf.org/twitter](https://twitter.com/rwjf) or on Facebook at www.rwjf.org/facebook.



Robert Wood Johnson Foundation

APPENDIX A: KEY PANEL FINDINGS AND RECOMMENDATIONS

Table 1: Summary of Recommendations for Healthy Beverage Consumption, Ages 0-5 Years*

	0-6 months		6-12 months	12-24 months	2-5 years		Notes
					2-3 years	4-5 years	
Beverages Recommended as Part of a Healthy Diet	Plain drinking water	No supplemental drinking water needed	Approximately 0.5-1.0 cups (4-8 oz.)/day in a cup. Begin offering during meals once solid foods are introduced.	1-4 cups (8-32 oz.) per day	1-4 cups (8-32 oz.) per day	1.5-5 cups (12-40 oz.) per day	Where an individual child falls within these ranges for 12 months to 5 years will depend on the amounts of other beverages consumed during the day.
	Plain, pasteurized milk	Not recommended	Not recommended	2-3 cups (16-24 oz.) per day whole milk	Up to 2 cups (16 oz.) per day skim (fat-free) or low-fat (1%) milk	Up to 2.5 cups (20 oz.) per day skim (fat-free) or low-fat (1%) milk	For 12-24 months, reduced-fat (2%) or low-fat (1%) milk may be considered in consultation with a pediatrician, especially if weight gain is excessive or family history is positive for obesity, dyslipidemia, or other cardiovascular disease; the total amount of milk consumed during this age will depend on how much solid food is being eaten.
Beverages to Limit	100% juice	Not recommended	Not recommended	Whole fruit preferred. No more than 0.5 cup (4 oz.) per day 100% juice.	Whole fruit preferred. No more than 0.5 cup (4 oz.) per day 100% juice.	Whole fruit preferred. No more than 0.5-0.75 cup (4-6 oz.) per day 100% juice.	Amounts listed for ages 12 months to 5 years are upper limits (not minimum requirements) that may be consumed only if fruit intake recommendations cannot be met with whole fruit.

Beverages Not Recommended as Part of a Healthy Diet					
	0-6 months	6-12 months	12-24 months	2-5 years	Notes
Plant milks/ Non-dairy beverages	Not recommended	Not recommended	Not recommended for exclusive consumption in place of dairy milk; consume only when medically indicated (e.g., cow's milk allergy or intolerance) or to meet specific dietary preferences (e.g., vegan)	Consume only when medically indicated (e.g., allergy or intolerance) or to meet specific dietary preferences (e.g., vegan)	Consumption of these beverages as a full replacement for dairy milk should be undertaken in consultation with a health care provider so that adequate intake of key nutrients commonly obtained from dairy milk can be considered in dietary planning.
Flavored milk	Not recommended	Not recommended	Not recommended	Not recommended	Added sugars intake should be avoided in children <2 years old and minimized in children 2-5 years old to avoid contributing to early establishment of a preference for sweet taste as well as potential negative impacts on nutrient intake and diet quality.
Toddler milk	Not recommended	Not recommended	Not recommended	Not recommended	These products offer no unique nutritional value beyond what a nutritionally adequate diet provides and may contribute added sugars to the diet and undermine sustained breastfeeding.
Sugar-sweetened beverages (SSB)	Not recommended	Not recommended	Not recommended	Not recommended	Strong evidence demonstrates the adverse health effects of SSB, which include, but are not limited to, soft drinks/soda, fruit drinks, fruit-flavored drinks, fruitades, sports drinks, energy drinks, sweetened waters, and sweetened coffee and tea beverages.
Beverages with low-calorie sweeteners (LCS)	Not recommended	Not recommended	Not recommended	Not recommended	This recommendation is based on expert opinion given that early childhood is a critical developmental period, and there is a lack of evidence regarding the long-term health impact(s) of LCS consumption in young children.
Caffeinated beverages	Not recommended	Not recommended	Not recommended	Not recommended	Caffeinated beverages are not appropriate for young children.

Note: All amounts listed are per day, unless otherwise noted; 1 cup = 8 fluid ounces.

*The expert panel did not address breast milk or infant formula, as recommendations in these areas vary by the infant's age, weight, and developmental milestones and are generally well understood and widely accepted.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



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January 23, 2019

The Honorable Scott Gottlieb, MD
C/O Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2018-N-3522 Use of the Names of Dairy Foods in the Labeling of Plant-Based Products

Dear Commissioner Gottlieb:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, I write to respond to FDA's Request for Comment on the Use of the Names of Dairy Foods in the Labeling of Plant-Based Products.

The AAP is pleased by the efforts FDA has undertaken in recent years to modernize regulations for nutrition-related labeling to reflect current science, provide information in ways that are understandable and useful to consumers, and encourage industry efforts to develop and introduce healthier food products through innovation or reformulation.

Dairy products play an important role in the diet of children. Milk, yogurt, cheese, and other milk products supply calcium for building and maintaining strong bones and teeth and protecting bones from osteoporosis.^{i,ii} They also provide children with the protein, vitamins, and minerals that they need to thrive including phosphorous, vitamin A, vitamin D, riboflavin, vitamin B12, potassium, zinc, choline, magnesium, and selenium.ⁱⁱⁱ In fact, milk is the leading food source of three of the four nutrients of public health concern (calcium, vitamin D, and potassium) in the diet of American children 2-18 years.^{iv}

AAP recommends that children consume two to three servings per day of milk and milk products.^v For adolescents, three or more servings per day of milk and milk products are recommended.^{vi} These recommendations are consistent with those of the Dietary Guidelines for Americans (DGA).^{vii} The DGA also notes that while average dairy intake for most young children ages 1-3 meets recommended amounts, all other age groups have average intakes that are below recommendations.^{viii}

Dairy-free alternatives to milk are becoming increasingly popular, even among

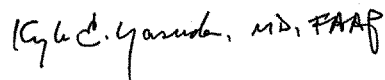
children who do not have a medical condition that prevents the consumption of dairy.^{ix} While some of these products are fortified with calcium and protein, many of these products lack the essential nutrients that dairy products contain to promote the healthy development of children, notably protein, calcium, and vitamin D.^x These essential nutrients can be difficult to replace in a healthy dietary pattern, and if plant-based alternative beverages are substituted in place of milk without the addition of other foods to supply the missing nutrients, Americans may move further away from dietary recommendations.^{xi}

Pediatricians report that using the term “milk” in the labeling of dairy-free alternatives has caused parental confusion, leading to the purchase of products that they assume contain traditional dairy ingredients and, thereby, unintentionally causing harmful nutritional deficiencies in their children. Consumer studies reinforce these anecdotal reports, indicating that consumers do not understand the nutritional differences between milk and plant-based alternative beverages labeled “milk”.^{xii} Further, many of these plant-based alternative products are perceived as having the same or more vitamins, protein, or other key nutrients as compared to milk.^{xiii}

Given the importance of dairy products in the diet of children and the confusion that parents exhibit with regards to the nutrients contained in plant-based alternative products, the AAP recommends that FDA reserve the label of “milk” solely for traditional dairy products to ensure that children receive the optimal nutrition they need to thrive.

Thank you for the opportunity to respond to this request for comments. The AAP looks forward to working with FDA to ensure that the nutritional needs of all children and families are met. If we may be of further assistance, please contact Tamar Magarik Haro in our Washington, DC office at 202-347-8600 or tharo@aap.org.

Sincerely,



Kyle E. Yasuda, MD, FAAP

KEY/mrc

ⁱ Holt, K, et al, *Bright Futures Nutrition*, 3rd Edition, 2011.

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^v American Academy of Pediatrics Committee on Nutrition, *Pediatric Nutrition*. 2014, Elk Grove Village, IL: American Academy of Pediatrics.

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- ^{xii} Midwest Dairy Association, *Clean and Clear Labeling Survey (March-April 2016)*; National Osteoporosis Foundation (NOF) member-survey (July 2017).
- ^{xiii} National Dairy Council, *Consumer Perceptions: Dairy Milk and Plant-based Milk Alternatives* (October 2019).

January 29, 2020

Congresswoman Grace Meng (NY-06)
Statement to the Energy and Commerce Committee

Chairman Pallone, Ranking Member Walden, Subcommittee Chair Eshoo, and Subcommittee Ranking Member Burgess, I write to express my support and gratitude for today's hearing, which includes my bill – H.R. 2267 – the Infant Formula Protection Act. I also want to thank Representative Kuster for her support of the bill.

As a mom, I know the fear and the pressure that comes with caring for a newborn; all a new parent wants is to make sure their baby is healthy and safe. Busy parents need to be able to rely on the safety of products, like formula, that they purchase from grocery stores to make sure their newborns are well-fed and healthy. Unfortunately, grocery stores that stock expired formula – even by just a few days – pose real health risks to infants.

Although regulations require expiration dates to be placed on formula, there is no federal law that prohibits the sale of the product after it has expired. As a result, many stores continue to keep the expired items on their shelves even though the products are outdated.

That is why I introduced the Infant Formula Protection Act of 2019, which would categorize expired infant formula as “adulterated.” A grocery store that stocks an adulterated substance can incur fines and other penalties. We cannot take any chances with what we feed our babies, and parents must be able to trust the safety of the products that they buy in their stores.

One of the first bills I ever introduced since becoming a Member of Congress, back in the 113th Congress, the Infant Formula Protection Act is one that is near and dear to my heart. I am grateful for your careful consideration of this bill today. I hope to see it further advance through this committee, and finally enacted into law. Thank you again, to the Chairman Pallone, Ranking Member Walden, Subcommittee Chair Eshoo, and Subcommittee Ranking Member Burgess, for supporting the needs and health of our families.

Consumer Federation of America

Kids In Danger

Public Citizen

January 28, 2020

The Honorable Frank Pallone
United States House of Representatives
Washington, DC 20515

The Honorable Greg Walden
United States House of Representatives
Washington, DC 20515

Dear Chairman Pallone and Ranking Member Walden,

As organizations dedicated to working to improve child product safety, we write to express our support for H.R. 2267, the Infant Formula Protection Act of 2019.

H.R. 2267 would protect infants by prohibiting the sale of infant formula past its expiration date. Currently, any retailer that sells infant formula, including pharmacies, supermarkets, and convenience stores, can sell expired infant formula.

According to the Food and Drug Administration (FDA), “While breastfeeding is strongly recommended and many mothers hope to breastfeed their infants, most infants in the U.S. rely on infant formula for some portion of their nutrition. An estimated 1 million infants in the United States are fed formula from birth, and by the time they are three months old, about 2.7 million rely on formula for at least part of their nutrition.”¹

Unlike other foods, infant formula must meet certain nutrient specifications, which are prescribed by federal regulations.² The FDA also requires a “use by date” on infant formula. “The ‘use by’ date on infant formulas is a date, selected by the manufacturer based on tests and other information, to inform retailers and consumers about the quality of the infant formula. Until that declared date, the infant formula will contain no less than the amount of each nutrient declared on the product label and will otherwise be of acceptable quality. The ‘use by’ date is required by FDA regulations on each container of infant formula.”³ The FDA does not prohibit the sale of infant formula after the “use by date.”

For infant formula, the “use by date” is significant for safety because, according to the FDA, “Consumption by this date ensures the formula contains not less than the quantity of each nutrient as described on the label. Formula must maintain an acceptable quality to pass through

¹ <https://www.fda.gov/consumers/consumer-updates/fda-takes-final-step-infant-formula-protections>.

² “FDA has requirements for nutrients in infant formulas, which are located in section 412(i) of the FFDCa and 21 CFR 107.100. These nutrient specifications include minimum amounts for 29 nutrients and maximum amounts for 9 of those nutrients. If an infant formula does not contain these nutrients at or above the minimum level or within the specified range, it is an adulterated product.” <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-frequently-asked-questions-about-fdas-regulation-infant-formula>

³ <https://www.fda.gov/food/people-risk-foodborne-illness/questions-answers-consumers-concerning-infant-formula>
(Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.)

an ordinary bottle nipple.”⁴ In other words, after the “use by” date has passed, consumers cannot have confidence that the infant formula for sale contains the nutrients required under federal law. Nevertheless, despite requiring the ‘use by’ date on each container of infant formula, FDA does not prohibit the sale of infant formula after that date has passed.

Clearly, no caregiver should feed an infant expired formula. For example, a publication about infant formula feeding by WIC Works, a resource system that provides education and training for the staff of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC),⁵ explicitly encourages caregivers to “[c]heck the infant formula’s expiration date on the label, lid, or bottom of the can. If the expiration date has passed, then the infant formula has expired and should not be used.”⁶

We support H.R. 2267 since it will protect infants from potential harms caused by expired infant formula and is consistent with recommendations urged by government agencies and professionals with expertise in infant nutrition.

We urge support for H.R. 2267 and support its passage.

Thank you for your consideration.

Sincerely,

Rachel Weintraub
Legislative Director and General Counsel
Consumer Federation of America

Thomas Gremillion
Director of Food Policy
Consumer Federation of America

Nancy Cowles
Executive Director
Kids In Danger

Remington A. Gregg
Counsel for Civil Justice and
Consumer Rights
Public Citizen

Cc: Representative Meng

⁴ <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/food-product-dating/food-product-dating>, (under the header, “What are the Requirements for Dating Infant Formula?”)

⁵ See <https://wicworks.fns.usda.gov/>.

⁶ https://wicworks.fns.usda.gov/wicworks/Topics/FG/Chapter4_InfantFormulaFeeding.pdf at 89.



January 27, 2020

Dear Chairman Pallone, Subcommittee on Health, House Committee on Energy and Commerce:

The United States Harness Racing Alumni Association strongly endorses the Safeguard American Food Export Act for all Standardbred horses, particularly the Standardbred harness race horses, which will be significantly impacted by passage of this legislation. Although many of our owners and trainers nationwide have been concerned about the outcome of race horses sold to auctions and slaughter buyers to be shipped to Canada and Mexico for the meat trade, we currently have no laws that prohibit these sales.

To sustain our horse racing sport, we must ensure that our horses which have given us so much, will be retired or re-homed, not sent to slaughter.

Our race horses receive medications and drugs which are not intended to be used in animals for human consumption. These animals are for racing and competition, and were never intended to be a part of the meat trade.

Respectfully,

Freddie Hudson
Executive Director, U.S. Harness Racing Alumni Association
fhudsonscva@yahoo.com
631-896-9838

Susan Arrington
Director of Federal Affairs
noblejadeshows@gmail.com
703-597-2385



January 28, 2020

Representative Anna Eshoo
202 Cannon House Office Building
Washington, DC 20515

Representative G.K. Butterfield
2080 Rayburn House Office Building
Washington, DC 20515

Representative Michael Burgess
2161 Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Eshoo, Vice Chairman Butterfield, and Ranking Member Burgess,

On behalf of Animal Protection of New Mexico (APNM) and its legislative arm Animal Protection Voters (APV), I am writing in support of the Safeguard American Food Exports (SAFE) Act, H.R. 961. This vital legislation would ban the export of American horses abroad for slaughter, and permanently prohibit the practice in our country.

APNM was founded in 1979 by concerned citizens with a goal to change the systems that cause animal cruelty in New Mexico. We are proud that APNM and APV have improved the quality of life for countless animals and communities through ensuring the passage of animal protection laws and regulations, as well as providing financial and provisional aid to families in need of support in caring for their animals. For example, our Equine Protection Fund, initiated in 2010, has saved over 1,200 horses, donkeys, and mules from slaughter by providing emergency feed, sterilization, and veterinary assistance to horse owners in financial distress, law enforcement agencies, and rescues and shelters.

Currently, approximately 80,000 American horses are still being sent across our borders for slaughter each year. Horse slaughter is cruel and dangerous, and rightfully unpopular. Horses are flight animals who cannot be slaughtered humanely, making death in a slaughterhouse full of acute pain, trauma and suffering.

Animal Protection of New Mexico, Inc. APNM.org info@apnm.org
ALBUQUERQUE: PO Box 11395, Albuquerque, NM 87192 SANTA FE: 1111 Paseo de Peralta, Santa Fe, NM 87501
505-265-2322 505-265-2488 (fax)

Furthermore, polling shows that 70% of New Mexicans oppose horse slaughter here in our state. We see firsthand, with a boots-on-the-ground view and working closely with equine shelters and rescue groups: The support for responsible stewardship and truly humane outcomes for equines is tremendous.

In addition to the horrific and unacceptable cruelty involved in the horse slaughter industry, I urge you to also consider the serious health risks posed to the consumers of the meat that is produced. Many people don't realize that the horses who ultimately end up in slaughter plants were once working, racing, or companion animals. Throughout their lives many of these horses were given drugs—including routine medications and sometimes illegal substances—that are toxic to humans. This fact becomes even more frightening when you consider that the U.S. Department of Agriculture has no system in place to track which horses have been dosed with which substances, putting unsuspecting consumers at risk.

For all these reasons and more, I urge you to pass the SAFE Act (H.R. 961) for the sake of both horses and humans. Your support is crucial, and Americans are counting on your leadership on this legislation. Thank you for your consideration.

Sincerely,



Laura Bonar
Chief Program & Policy Officer
Animal Protection New Mexico
Animal Protection Voters



January 28, 2020

Representative Anna Eshoo
Chair, Health Subcommittee
Committee on Energy and Commerce
2125 Rayburn House Office Bldg.
Washington, DC 20515

Representative Michael Burgess, M.D.
Ranking Member, Health Subcommittee
Committee on Energy and Commerce
2322 A Rayburn House Office Bldg.
Washington, DC 20515

Dear Chairman Eshoo & Ranking Member Burgess:

I write today to express opposition to H.R.778, the DAIRY PRIDE Act, which is the subject of a hearing of the House Energy and Commerce Committee's Health Subcommittee on January 29, 2020, entitled "Improving Safety and Transparency in America's Food and Drugs."

The Plant Based Foods Association (PBFA) was founded in 2016 to represent the interests of companies producing plant-based meat and dairy alternatives. Today the association has grown to include 170 members, ranging from small start-up food companies to established brands to ingredient suppliers. Many of our members make and sell dairy alternatives, including plant-based milk, cheese, yogurt and ice cream.

Companies selling dairy alternatives are using easy to understand, clear, descriptive and truthful language on labels. Our members and others in this category are using common English words that consumers understand: milk, cheese, yogurt and butter, with qualifiers to distinguish them from their animal-derived alternatives. These terms are readily understood by consumers as representative of the products functionality, form and taste, not necessarily the origin of the primary ingredient. Qualifiers such as "non-dairy," "dairy-free," "plant-based," and / or "vegan," along with the ingredient and nutrition facts panel, make the contents labels clear.

FDA has recently announced plans "modernize" standards of identity, an effort that PBFA fully supports. We expect that the results of FDA's modernization effort will encourage the type of innovation currently taking place in the plant-based foods industry and elsewhere. Today's consumers are searching for a range of options to meet their dietary, social, cultural, and taste preferences. Accordingly, we have urged FDA to allow plant-based milk and other dairy alternatives to continue using the term "milk" and similar terms, to reflect what is happening in the marketplace due to consumer demand and understanding.

PBFA voluntary standards

In 2018 PBFA convened a Standards Committee to establish voluntary industry guidance for the labeling of plant-based milks. The resulting voluntary standards were announced later that year. The standards recommend that labels clearly identify the main ingredient as part of the word "milk" or be labeled as a "plant-based milk," along with a clear disclosure of the main ingredient.

We also recommend that the principal display panel contain the words "dairy-free" or "non-dairy," as these were the phrases that were the most meaningful to consumers to connote that these products did not contain cow's milk, as referenced above.

PBFA members, along with others in industry, participated in the standards development process. We believe that these guidelines suggest a clear and concise approach to labeling that allows flexibility while creating enough standardization across the category.

First Amendment Concerns

The free speech clause of First Amendment to the U.S. Constitution protects companies that label their foods with truthful, non-misleading names. PBFA's legal analysis indicates that it's highly unlikely that efforts to ban certain words such as "milk" or to require pejorative qualifiers would survive a court challenge under the First Amendment's free speech clause, especially given all the previous case law where courts have thrown out claims of consumer deception. When a company engages in truthful, non-misleading speech, in order limit that speech, the FDA would have to demonstrate a "substantial government interest". If consumer confusion is that interest, several courts have already indicated that argument is not even remotely plausible.

In recent years, the Supreme Court has placed an even higher bar on government restrictions on "commercial speech". Thus it's highly unlikely that action to disallow words such as "milk" or "yogurt," when accompanied by clear qualifying labels such as "non-dairy" or "plant-based" would be upheld as constitutional in an inevitable First Amendment legal challenge that would follow such action.

Conclusion

We are living in a time of rapid innovation in food and America is leading the way. Consumers are entitled to the benefits of this innovative American spirit and the delicious new plant-based offerings in the marketplace.

Enacting new restrictive labeling laws would create unnecessary, confusing, and costly label changes that likely violate the First Amendment and would be struck down in court.

We urge the subcommittee to reject proposals such as the DAIRY Pride Act that stifle innovation. If plant based foods are forced to be identified by obscure, contrived names that consumers are unfamiliar with, innovation will likely be stifled, and consumers will be deprived of the choices they deserve.

Thank you for your consideration of PBFA's concerns.

Sincerely,

Michele Simon

Michele Simon



January 28, 2020

The Honorable Anna Eshoo
Chair
Subcommittee on Health
U.S. House of Representatives
Washington, D.C. 20510

The Honorable Michael Burgess
Ranking Member
Subcommittee on Health
U.S. House of Representatives
Washington, D.C. 20510

Dear Chairwoman Eshoo and Ranking Member Burgess:

The American Forest & Paper Associationⁱ (AF&PA) appreciates the opportunity to share our perspective on legislation on perfluoroalkyl and polyfluoroalkyl substances (PFAS) under consideration by the Subcommittee on Health. We oppose H.R. 2827, the Keep Food Containers Safe from PFAS Act of 2019. The bill would "amend the Federal Food, Drug, and Cosmetic Act to deem any perfluoroalkyl or polyfluoroalkyl substance used as a food contact substance to be unsafe, and therefore, treated as adulterated under such Act," which would effectively ban all PFAS chemistry used in food packaging.

We believe U.S. Food and Drug Administration (FDA)-regulated food packaging should be excluded from PFAS-related legislation. The FDA's careful study and approval of the use of several short-chain PFAS chemistries allows for continued production of safe and reliable food packaging. The specific short-chain PFAS chemistries currently used in food packaging have been carefully reviewed and approved by the FDA under a comprehensive federal regulatory program that ensures the safety of food packaging for public health and the environment. We understand that FDA is conducting a review of their science. AF&PA supports FDA's role in ensuring safe food packaging and believes Congress should not circumvent FDA's authority to regulate these substances.

AF&PA members are committed to ensuring the safety of their products, including the safety of chemicals used in their manufacturing processes. AF&PA believes that chemical and product-related legislation and regulations should be protective of health, cost-effective and based on the best available science. AF&PA also supports studies and research to achieve science-based assessments that ultimately may be used as the basis for establishing regulations. Policy and regulations should be based on credible science and reflect actual exposure to and risk from chemicals in specific products, not merely whether de minimis or trace levels of a chemical may be present.

PFAS are a large and diverse class of chemicals with widely varying uses and properties. AF&PA is opposed to any legislation, such as H.R. 2827, that does not account for the diversity within this class of chemistry. At a minimum, any legislation focused on PFAS chemistries should distinguish between short and long-chain PFAS.

January 28, 2020
Page 2

AF&PA member companies do not manufacture PFAS. To the extent AF&PA members intentionally utilize any PFAS chemistries in food packaging, those substances are sold to us by PFAS manufacturers for use as additives to impart heat, grease and/or moisture resistance. AF&PA member companies began using modified formulas that do not contain long-chain PFAS chemistries such as perfluorooctanoic acid (PFOA) and perfluorooctanesulfonate (PFOS) around 2011 – ahead of the 2016 FDA ban on various long-chain PFAS chemicals. Any law or regulation that restricts the use of all PFAS chemistry in food packaging without a realistic timeline for the development and implementation of safe and effective substitutes would be counterproductive and could significantly harm the paper recycling industry.

We thank the Subcommittee for their consideration on this important matter and stand ready to assist you as you shape policy on this issue. For additional information, please contact Laura Pickard, Director of Government Affairs, AF&PA at (202) 463-2755 or laura_pickard@afandpa.org.

Sincerely,



Elizabeth Bartheld
Vice President, Government and Industry Affairs

ⁱ The American Forest & Paper Association serves to advance a sustainable U.S. pulp, paper, packaging, tissue and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative — [Better Practices, Better Planet 2020](#). The forest products industry accounts for approximately four percent of the total U.S. manufacturing GDP, manufactures nearly \$300 billion in products annually and employs approximately 950,000 men and women. The industry meets a payroll of approximately \$55 billion annually and is among the top 10 manufacturing sector employers in 45 states.



January 24, 2020

The Honorable Frank Pallone
Chair
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Eliot Engel
2426 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Pallone, Walden, Guthrie and Engel:

As strong supporters of drug and medical device quality, we are proud to write in support of H.R. 5663, the *Safeguarding Therapeutics Act*, to improve the FDA's authority to seize and destroy counterfeit medical devices.

The American Pharmacists Association ("APhA"), founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

We appreciate the U.S. House's previous efforts to promote the safety of the drug market by combatting counterfeit drug importation, including its 2012 amendment of Section 801(a) of the Federal Food Drug & Cosmetic Act granting the FDA the authority to destroy refused drugs valued at \$2500 or less. Given the vast global marketplace of unscrupulous opportunists with no regard for public health, it is crucial to ensure the FDA has clear authority to take appropriate action against all forms of counterfeit medical products, whether they are drugs or devices. APhA supports the preservation of the integrity of our nation's supply of medical products and believes that expanding the FDA's regulatory destruction authority to include counterfeit devices will promote this preservation.

APhA looks forward to continuing our work with you and the FDA to uphold the safety of the drug and device market. We appreciate your commitment to bipartisan Congressional efforts to ensure this standard. If you have any questions please contact, Alicia Kerry Mica, Senior Lobbyist, by email amica@aphanet.org or phone (202) 429-7507.

Sincerely,

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

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Angela Calabro
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Dianna Dawson
Amber Midthunder

January 27, 2020

The Honorable Anna Eshoo
Chairwoman, Subcommittee on Health
House Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Eshoo and Ranking Member Burgess:

Return to Freedom Wild Horse Conservation respectfully urges members of the House Energy and Commerce Committee to support H.R. 961, the Safeguard American Food Exports Act of 2019 (the SAFE Act), a bill with strong bipartisan support that would protect America's horses, wild and domestic, and human health, at home and abroad.

Return to Freedom (RTF) is a 22-year-old national nonprofit dedicated to preserving the freedom, diversity, and habitat of America's wild horses and burros through sanctuary, education, advocacy, and conservation, while enriching the human spirit through direct experience with the natural world. In addition to being a nationally respected voice on wild horses issues, it operates the American Wild Horse Sanctuary, which cares for 465 wild horses and 51 burros at four California locations.

RTF strongly supports the SAFE Act for a number of reasons, chief among them the ongoing protection of wild horses and burros removed from the range. Of the tens of thousands of American horses still shipped legally to Mexico and Canada for slaughter, an unknown number were once free-roaming mustangs protected by federal law.

Under a 2004 sale authority law, commonly called the "Burns Amendment," the Bureau of Land Management (BLM) is directed to sell "without limitation" captured wild horses and burros ages 10 and older or younger horses who have not been adopted after three tries.

BLM has sold more than 5,900 wild horses and burros since 2005. Those sold between 2005 and 2010 went for an average of just \$17 apiece, devaluing federally protected animals that the government spends millions of taxpayer dollars annually to manage on our public lands.

Through appropriations language, Congress has repeatedly made clear that BLM and the U.S. Forest Service are not to sell wild horses and burros for purposes of slaughter. Protection of wild horses from slaughter has been a bipartisan effort under in both chambers in Congress and under both Republican and Democratic administrations.

However, even if the agency abides by the law and its own policy not to sell the kill buyers, the threat of slaughter looms: Once title is given to the wild horse's new owner,

the animal loses its protected status under the Wild Free-Roaming Horses and Burros Act of 1971 (Act), its eventual fate unknown. Likewise, after adopters receive title after one year, a former wild horse or burro can be sold and end up auctioned off to a kill buyer.

Passage of the SAFE Act would be consistent with the spirit of the 1971 Act intended to protect these icons of the West and with the wishes of the American people, as expressed consistently in public opinion polls in which they overwhelmingly support the protection of wild horses and opposition to slaughter, and of bipartisan members of Congress.

Domestic horses

As an organization focused on the welfare of horses, generally, and on educating the public about their importance to our country's history and culture, RTF also supports the SAFE Act on behalf of domestic horses, which do not deserve an inhumane end. Horses remain our companions and partners in competition, work and recreation, and those that roam our public lands remain a symbol of freedom throughout the world.

RTF's legislative representative, Chris Heyde, initiated the national campaign to end horses slaughter in 2001 and is one of the few to have been inside operating a horse slaughter facility operating in the United States, gone undercover at auctions across the country and tracked trucks hauling horses to Mexico and Canada.

In 2016-17, RTF played an instrumental role in preventing horses impounded by the State of South Dakota from being sent to auction where kill buyers were waiting, helping to rehome more than 900 across the country – proof that Americans stand ready and willing to help horses in need. In all, RTF has helped rescue some 2,000 horses, including those at its sanctuary.

In the first 11 months of 2019, more than 59,000 American horses were shipped to their deaths in Mexico and Canada. That includes 49,708 through November to Mexico and 9,986 through September to Canada, from which available statistics lag by two months.

While the numbers remain horrific, it appeared that horse exports for slaughter were on pace to drop for the seventh straight year, down from a 19-year high of 166,572 in 2012.

The steady decline is all the more reason for Congress to end the inhumane work of kill buyers, yet the 2007 shuttering of the last horse slaughterhouse in the United States. While not the ultimate solution or our goal from the start, RTF has worked hard to ensure a defund amendment is included in federal funding bills with bipartisan support.

Supported year after year by Appropriators, the language prohibits the U.S. Department of Agriculture (USDA) cannot use tax dollars to hire horse-meat inspectors. That has created an effective year-to-year ban on horse slaughter. This is effective only within U.S. borders and is only a temporary solution. It's time to make that ban permanent.

The defund amendment does nothing to stop wild horses from being trucked out of the country to Mexico or Canada. The terror, trauma and pain that horses endure in transport to slaughterhouses and on the killing floor – where they have been documented to have their throats cut while they are fully

conscious – is unacceptable. More than 90 percent of these exported horses are in “good” condition, according to a USDA study.

A threat to human health

Importantly, because American horses are not raised to be eaten, they frequently are given more than 100 veterinary medications banned for human consumption by the USDA. No regulations require the sharing of information about substances previously ingested by a horse up for auction. There, horses are often purchased by kill buyers with the intent on sending them to slaughter.

In conclusion:

- When polled more than 80 percent of Americans oppose horse slaughter and a similar percentage support protecting wild horses and burros;
- Congress itself has repeatedly prevented the use of taxpayer funding to hire horsemeat inspectors and has barred government agencies from selling wild horses and burros for purposes of slaughter, all on a bipartisan basis;
- No slaughter plant has operated in the United States since 2007 and the number of horses exported for slaughter has fallen for seven straight years
- Those horses that are exported meet a brutal, inhumane end, and the meat is contaminated with dozens of medications unsafe for human consumption.

It is well past time for Congress to pass the SAFE Act to ban horse slaughter in the United States and the export of American horses abroad for slaughter. H.R. 961 enjoys overwhelming bipartisan support from a majority of House members and vast public support. RTF strongly and respectfully urges the committee to support its passage into law.

On behalf of Return to Freedom’s board of directors, honorary board and advisory board,



Neda DeMayo
President
Return to Freedom
Wild Horse Conservation

cc: Members of the Subcommittee on Health
Representative Jan Schakowsky
Representative Vern Buchanan



**PROFESSIONAL
RODEO COWBOYS
ASSOCIATION**

101 PRO RODEO DR
COLORADO SPRINGS, CO 80919

January 28, 2020

The Honorable Frank Pallone, Jr.
Chairman, House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Chairman Pallone,

I am writing on behalf of the Professional Rodeo Cowboys Association (PRCA) to express opposition to the *Safeguard American Food Exports Act of 2019* (H.R.961). This legislation would ban the only remaining humane and economically viable option for unwanted horses.

This bill not only bans the consumption of horse meat, but also bans the transportation of horses out of the United States for slaughter. It puts an undue burden upon all parties involved and closes the last available avenue open to producers, as euthanasia is not a financially feasible option. This bill will likely cause a public safety crisis as well as a possible environmental crisis.

Unwanted horses will be neglected or abandoned, and equine slaughter will be driven underground. The PRCA is not only concerned for the producer, but also fears for the well-being of any unwanted horse.

The PRCA is the oldest, largest rodeo-sanctioning body in the world. We sanction over 700 events annually and are highly vested in the equine industry. We are the leader in animal welfare for the rodeo industry and we are highly concerned that this legislation will negatively impact rodeo as well as any industry that is involved with horses.

The PRCA is committed to the safety and humane treatment of all horses and supports finding a solution for any unwanted horse. We respectfully ask for your opposition to the SAFE Act (H.R. 961).

Best regards,

Scott Dorenkamp
Manager, Livestock Welfare and Government Relations

Cc: Ranking Member Greg Walden

January 29, 2020

The Honorable Frank Pallone Jr., Chair
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo, Chair
Subcommittee on Health
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Greg Walden, Ranking Member
Committee on Energy & Commerce
U.S. House of Representatives
2322 Rayburn House Office Building
Washington, DC 20515

The Honorable Michael Burgess, Ranking Member
Committee on Energy & Commerce
U.S. House of Representatives
2322 Rayburn House Office Building
Washington, DC 20515

Re: Support for H.R. 4712, the Fairness in Orphan Drug Exclusivity Act

Dear Chairman Pallone, Chairwoman Eshoo, Ranking Member Walden, and Ranking Member Burgess:

For 15 years both my passion and job was as the vice president for public policy of the National Organization for Rare Disorders (NORD), which represents the 30 million American patients with rare diseases. Through programs of education, advocacy, research and patient services, NORD seeks to advance medical treatments and medical support services for patients with rare disorders. I remain passionate about the quest to help provide people with rare disorders a better quality and longer life.

One of the most significant and forceful tools that has aided patients with rare diseases is the Orphan Drug Act (ODA). It was passed by Congress in 1983 to provide incentives for the development of newer and better therapies. These incentives have supported the development of hundreds of drugs for rare or orphan diseases since 1983. The law has truly been successful, and the successes have accelerated in the last few years.

In the past few years, fully one-third of new drugs approved by the FDA have been for rare diseases. The total number of orphan indications approved by the FDA jumped from 594 in 2016 to more than 770 in 2018. These approvals reflect not just a commitment by the FDA but also the success of the ODA. It gives companies seven years of exclusivity for drugs with an orphan indication, a 25% tax credit for qualified clinical trials, and the waiver of application fees.

However, more than 90% of the 7,000 rare diseases identified so far don't have any FDA-approved treatments. And insurers, whether private or government-financed, are increasingly making it more challenging for patients to access orphan drugs. The challenges of access will likely become more acute as gene therapy — products that alter a patient's genetic makeup and cure disease — become more available.

Diane Edquist Dorman
 Comments Submitted to the Committee on Energy and Commerce
 Page 2
 January 29, 2020

Because we have so much more to accomplish, we must make sure the law remains strong. But a loophole exploited by a pharmaceutical company (but recently corrected by the FDA in a one-time act) identified a threat to the integrity of this important law. We must address this loophole so that other companies do not use it in the future to their own financial advantage but to the disadvantage of patients.

H.R. 4712 provides a fix by closing the loophole. I urge you to move this bill through the Congress as quickly as possible.

This loophole was unbeknownst to me until last year when I read a news story about how in 1994 a pharmaceutical company received orphan status for a drug used to treat opioid addiction, even though opioid addiction isn't a rare disease. As I learned, the drug's maker based its application on a rarely used provision in the ODA that permits FDA to grant orphan drug designation when a manufacturer can show that a drug is unlikely to be profitable and will not recover its research and development (R&D) costs.

The law now provides that this orphan drug designation is automatically granted to later products from the same manufacturer that contain the same ingredient if they are shown to be superior to previously-approved drugs containing the same ingredient. The manufacturer thus can gain another seven years of exclusivity.

The loophole is obscure and not well understood. But it does not constitute sound health or public policy for a manufacturer to gain basically a renewal of orphan drug exclusivity without having to demonstrate an inability to recoup its R&D costs.

Over a seven-year period economic circumstances can and often do change, and thus the inability of a manufacturer to be able to recoup its R&D costs can easily disappear. But because the law does not require the manufacturer to again demonstrate that it cannot recoup its R&D costs, a drug could literally make billions due to changing circumstances, and still maintain its orphan designation.

H.R. 4712 addresses this loophole. It would require a company that obtains the economic orphan designation to show after its initial seven-year exclusivity period that it continues to be unable to cover its R&D costs.

H.R. 4712 would only apply to products that received orphan drug designation because the manufacturer has demonstrated an inability to recoup its R&D costs. It would require that for a new (follow on) product to receive orphan designation it would need to show once again – as the original product did – that it would not be able to recoup its R&D costs. It would **NOT** impact orphan products that received designation due to disease prevalence.

While I no longer represent the millions of Americans with an orphan disease, I strongly believe that we must maintain the integrity of the Orphan Drug Act. Drugs that exist thanks to the ODA have saved lives, and future lives depend on this law continuing to work well. We cannot allow mischief and mayhem to stand in the way of the missions of the Law and the incredible outcomes it has produced for people across the country.

H.R. 4712 would do just that.

My work on behalf of patients with rare diseases was the most important thing I have ever done. I appreciate this opportunity to once again represent the best interests of the millions of men, women and children affected by rare diseases. Thank you for your consideration.

Respectfully Submitted,

Diane Edquist Dorman

RE: Support for H.R. 961, the Safeguard American Food Exports (SAFE) Act

January 28, 2020

The Honorable Frank Pallone
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
Committee on Energy & Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Anna G. Eshoo
Chairwoman
Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Michael C. Burgess
Ranking Member
Subcommittee on Health
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member Walden,

On behalf of the Humane Society of the United States, the Humane Society Legislative Fund and our millions of members nationwide, we are writing to express our strong support for H.R. 961, the Safeguard American Food Exports (SAFE) Act. This bill would prevent the re-introduction of horse slaughter in the U.S. for human consumption, end the current export of American horses for slaughter abroad, and protect the public from consuming potentially toxic horsemeat.

Each year, tens of thousands of American horses are brutally slaughtered so their meat can be sent overseas to Asia and Europe for human consumption. The entire process is inherently inhumane, starting with the horses' transport to foreign slaughter plants over long distances without food, water or rest. On this journey, many horses sustain serious injuries that can lead to death in transit.

These ghastly incidents are not attributed solely to the transport of horses to slaughter plants abroad. When such plants previously operated domestically, the U.S. Department of Agriculture documented horrific injuries and cruelty.

Once they arrive at the slaughter plant, horses' suffering only continues to worsen.

There is no humane way to slaughter a horse. Because of their natural flight instincts, they often panic in the kill box, making them difficult to stun accurately and subjecting them to repeated blows to the head with a captive bolt gun. Sometimes the horses are still conscious while they are suspended by a back leg, bled out, and dismembered.

Horse slaughter is unacceptable not only because of this inherent cruelty, but also due to the risk it creates for human health. Horses are treated as companion animals and they are often raised for use in show, sport, work, and recreation. As a result, these horses are regularly administered

drugs and other substances that are known to be dangerous to humans or expressly prohibited by current federal regulations for use in animals intended for human consumption. There is no system in the U.S. to track the medications given to horses to ensure that their meat is safe for human consumption, which results in meat that is potentially toxic to humans.

In addition to all of these issues, slaughtering horses in the U.S. is fiscally irresponsible. Millions of U.S. taxpayer dollars should not be spent on overseeing new horse slaughter plants or inspecting horses being exported for slaughter, when 80% of American voters oppose the slaughter of horses for human consumption. There is no market for horsemeat in the U.S. and public opinion is clearly against this practice.

This legislation is supported by the nation's leading animal welfare organizations, as well as many veterinarians, equestrians and equine groups across the country. We join them—and the American public—in supporting the SAFE Act to end the slaughter of American horses here and abroad.

We respectfully request your leadership in advancing this important animal protection and consumer safety legislation and helping to secure its passage.

Sincerely,

Keith Dane
Senior Adviser, Equine Protection
The Humane Society of the United States



Tracie Letterman
Vice President
Humane Society Legislative Fund



Celebrating 10 years



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VETERINARY MEDICAL
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Vincetown, NJ
Liz White, RVT
Woodland Hills, CA

January 28, 2020

RE: Veterinary Support for H.R. 961/S. 2006, the Safeguard American Food Exports (SAFE) Act

Dear Chairman Pallone and Ranking Member Walden,

We are writing on behalf of the Humane Society Veterinary Medical Association (HSVMA), to express our support for H.R. 961/S. 2006, the Safeguard American Food Exports (SAFE) Act. This bill would prevent the re-introduction of horse slaughter operations in the U.S., end the current export of American horses for slaughter abroad, and protect the public from consuming potentially toxic horse meat. HSVMA is an association of approximately 9,000 veterinary professionals nationwide, with a focus on the health and welfare of all animals, including horses.

Each year, more than 100,000 American horses—working, racing and even children's ponies—are brutally slaughtered so their meat can be sent overseas to Asia and Europe for human consumption. Horses are transported long distances without food, water or rest and are often seriously injured or killed in transit. Once they arrive at the slaughter plant, their suffering only intensifies.

As skittish animals, horses often panic in the kill box, making them difficult to stun accurately—and are sometimes conscious while they are suspended by a back leg, bled out, and dismembered. When horse slaughter plants previously operated on U.S. soil, the U.S. Department of Agriculture documented horrific injuries and cruelty.

Beyond being inherently cruel, the horse slaughter industry also poses serious food safety concerns to humans. Horses are raised for use in show, sport, work and recreation in the U.S. and are regularly administered drugs and other substances that are known to be dangerous to humans or expressly prohibited by current federal regulations for use in animals intended for human consumption. Horses are gathered from random sources, and there is no system in the U.S. to track the medications and veterinary treatments given to horses to ensure that their meat is safe for human consumption.

Furthermore, it makes no sense to spend millions of U.S. taxpayer dollars to oversee new horse slaughter plants when 80% of American voters oppose the slaughter of horses for human consumption.

This legislation is supported by the nation's leading animal welfare organizations, as well as many veterinarians and equine groups across the country. We join them—and the American public—in supporting the SAFE Act to end horse slaughter once and for all.

700 Professional Drive, Gaithersburg, MD 20879 | P.O. Box 208, Davis, CA 95617
MD: t 301-548-7771 f 301-548-7726 | CA: t 530-759-8106 f 530-759-8116
hsvma.org info@hsvma.org

Celebrating 10 years



We urge your humane leadership in supporting this important animal protection and consumer safety legislation.

Sincerely,

Barbara Hodges, DVM, MBA
HSVMA Director of Advocacy & Outreach

Holly Cheever, DVM
HSVMA Leadership Council Member

Gail Hansen, DVM, MPH
HSVMA District of Columbia Representative

Patricia Zinna, DVM, MS
HSVMA New Jersey Representative

Kate Maher, DVM
HSVMA Louisiana Representative

David Stansfield, BVSc, MRCVS
HSVMA North Carolina Representative

Nicholas Dodman, BVMS, DACVB, DACVAA
HSVMA Massachusetts & Maryland Rep

Pamela Greenwald, DVM, MS
HSVMA Michigan Representative



National Cattlemen's
Beef Association



AMERICAN FARM BUREAU FEDERATION®

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January 28, 2019

The Honorable Lindsey Graham
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Collin Peterson
Chairman
House Committee on Agriculture
1301 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Dianne Feinstein
Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Conaway
Ranking Member
House Committee on Agriculture
1301 Longworth House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Chairmen Graham, Peterson, and Pallone and Ranking Members Feinstein, Conaway, and Walden:

The Public Lands Council (PLC), National Cattlemen's Beef Association (NCBA), American Sheep Industry Association (ASI), American Farm Bureau Federation (AFBF), and American Quarter Horse Association (AQHA) strongly oppose S. 2006 and H.R. 961, the Safeguard American Food Exports (SAFE) Act. PLC is the only national organization dedicated solely to representing the roughly 22,000 ranchers who hold federal grazing permits and operate on federal lands. NCBA is the beef industry's largest and oldest national marketing and trade association, representing American cattlemen and women who provide much of the nation's supply of food and own or manage a large portion of America's private property. ASI is a federation of forty-five state sheep associations representing a diverse industry since 1865 and has been the national trade organization representing the interests of the 100,000 sheep ranchers located throughout the country who produce America's lamb and wool. AFBF is the nation's largest general farm organization, representing the interests of agricultural producers in every state and Puerto Rico, including those involved in both crop and livestock production. AQHA is the largest Equine Breed Registry in the world with a primary mission to record and preserve the pedigree of the American Quarter Horse while maintaining the integrity of the breed and welfare of its horses.

Horse processing facilities have been closed in the United States since 2007 after funding for U.S. Department of Agriculture (USDA) inspection of these plants and the inspection of horses in transit for slaughter was halted in the Fiscal Year 2006 appropriations bill. While proponents of the ban on horse slaughter see bypassing the legislative authorization process as a necessary means to an end, the negative impact this has had on horse welfare is abundantly clear. Horse owners must have a means for humanely dealing with equines at the end of their lives. Costly veterinarian euthanasia services and remains disposal are affordable to only a fraction of the population.

In 2011, the Government Accountability Office (GAO) submitted a report to Congress which concluded that horse welfare in the U.S. had generally declined since 2007, as evidenced by the notable increase in horse abandonments and investigations for abuse and neglect. However, the number of U.S. horses purchased for slaughter has not decreased. Rather, horses are now transported significantly longer distances for slaughter in Mexico and Canada. The number of horses exported to Mexico for slaughter has increased by 273 percent since 2006, and the funding prohibition on the inspection of horses prior to slaughter has impeded USDA's ability to properly ensure horse welfare.

In addition to potentially harming domesticated horses in private care, these bills are a back-door means to codify the ban on processing wild horses and burros in the care of the Bureau of Land Management (BLM) and U.S. Forest Service (USFS). The Wild and Free-Roaming Horses and Burros Act of 1971 allows for the slaughter of equids as a population management strategy:

The Secretary shall cause additional excess wild free-roaming horses and burros for which an adoption demand by qualified individuals does not exist to be destroyed in the most humane and cost efficient manner possible [16 U.S.C. § 1333(b)(2)(C)].

The Wild and Free-Roaming Horses and Burros Act further allows for the sale of excess wild equids for the ultimate purpose of destruction into commercial products:

An excess animal that meets either of the criteria in paragraph (1) shall be made available for sale without limitation...[16 U.S.C. § 1331(e)(2) et seq.].

Unfortunately, in addition to the appropriations funding prohibition on USDA inspections, the Consolidated Appropriations Acts of the past several fiscal years have prohibited both the humane processing of excess horses and burros and their sale for processing into commercial products. These policy riders have placed a significant burden on BLM and USFS managers as they struggle to curb the overpopulation of wild horses and burros and maintain the Appropriate Management Level (AML).

While NCBA, PLC, and AFBF have recently reached an agreement with animal advocacy organizations to reverse population growth trends and make progress toward AML by nonlethal means, the undersigned organizations do not support a wholesale ban on horse processing as a population control tool. We remain confident that our proposal, if adequately funded by Congress and properly implemented by the BLM, will be successful in its mission, but it is short-sighted to eliminate lethal options in perpetuity.

The U.S. livestock industry depends upon an economically viable and healthy horse industry, as well as a system that offers responsible management options and a humane end of life for unwanted horses. The SAFE Act will result in an animal welfare crisis and a massive contraction of the U.S. Equine industry with a current annual economic impact to the U.S. Economy of \$122 billion.

Decisions about animal welfare should be based on solid scientific facts and sound animal husbandry, not merely on emotion. The humane processing of horses is upheld by the American Association of Equine Practitioners and the American Veterinary Medical Association. Without this option, unwanted horses will be subject to a continued life of discomfort, pain and possibly inadequate care or abandonment. Both the House and Senate versions of the SAFE Act are incompatible with the professional opinions of these animal welfare experts and the undersigned organizations that represent those who advocate sound animal husbandry. We urge your opposition to S. 2006 and H.R. 961.

Sincerely,

American Farm Bureau Federation
American Quarter Horse Association
American Sheep Industry Association
National Cattlemen's Beef Association
Public Lands Council

Dr. John W. Boyd, Jr., President
 68 Wind Rd.
 Baskerville, VA 23915
 Ph: (804) 691-8528
 Ph: (434) 848-1865
<http://www.blackfarmers.org>



National Black Farmers Association



27 January 2020

The Honorable Anna Eshoo
 Chairwoman, Subcommittee on Health
 House Energy and Commerce Committee
 United States House of Representatives
 2125 Rayburn House Office Building
 Washington, DC 20515

Dear Chairwoman Eshoo and Ranking Member Burgess:

On behalf of the National Black Farmers Association, I am writing to express my **strong support for H.R. 961, the Safeguard American Food Exports (SAFE) Act**. I am President and founder of the National Black Farmers Association, which has more than 94,000 members in 46 states. The National Black Farmers Association is dedicated to serving America's Black and other small farmers through outreach and technical assistance. I am a fourth-generation farmer, and I own and operate a 210-acre farm in Mecklenburg County, Virginia where I raise soybeans, corn, wheat and beef cattle. My total operation consists of farms in three counties.

An avid horseman, I currently keep two Saddlebreds and two mules, and have owned multiple Quarter Horses. My mules, fondly known as '40 Acres' and 'Struggle' are hard workers and in fact, they accompanied me to Washington, D.C. in 2003 when they pulled my wagon from my farm to the nation's capital to raise awareness about racial discrepancies in the U.S. Department of Agriculture's farm lending program. The journey was the subject of much press attention and my mules seemed to revel in the spotlight.

I first learned that American horses are being slaughtered for human consumption overseas when HBO's Real Sports aired a segment called "Hidden Horses" in 2008. Like many Americans, I was unaware that such an industry even existed and was horrified to learn that foreign-owned companies were preying on our horses for such an un-American purpose. To me as a horse-owning farmer, and to the members of the National Black Farmers Association, horses are part of the farm and part of the family. They are to be respected and treated with dignity and for that, they provide us with hard labor and companionship. They are not raised for slaughter and

it is unconscionable that any horseman or woman would choose to end his or her horse's life in such a brutal manner.

I was so shocked to learn of this secretive trade that I immediately contacted Chris Heyde in Washington, D.C. to offer my support for the campaign to end horse slaughter. Not only did the National Black Farmers Association endorse Congressional efforts to end horse slaughter including H.R. 961, the Safeguard American Food Exports (SAFE) Act, but I offered to help place horses at risk of slaughter on my and my members' farms.

Since 2008, I have become deeply immersed in the subject and have spent significant time on Capitol Hill testifying in support of an earlier version of this bill before the Judiciary Committee which approved the legislation, meeting with legislators and their staff to express the National Black Farmers Association's support for the SAFE Act. The experience has been an interesting one during which I have heard all sorts of excuses about why we need horse slaughter in this country. As someone whose life is all about agriculture, a working farmer, I believe I am particularly well qualified to address these points and to demonstrate exactly why we can and must end the practice of horse slaughter for good.

Before that, however, I think it is worth noting that prior to my involvement with this effort I was not only unaware of the practice of horse slaughter but I was unaware – and remain so to this day – of any flood of 'unwanted' horses roaming the countryside, as some of our opponents have claimed with no evidence while the number of horses being sent to slaughter has continued to decline. The notion that horses are being turned out, abandoned, neglected and abused in increasing number as a direct result of the campaign to end horse slaughter simply hasn't been borne out where I come from, and I say this as a working farmer with horses.

This speaks to the first argument raised by those who oppose an end to horse slaughter; the idea that we need slaughter to dispose of unwanted horses, ironically a term and concept only coined after the original bill was introduced by those advocating for slaughter. The truth is that most horses going to slaughter are being purposely bought by middlemen, known as killer-buyers, working for the slaughterhouses rather than being sold to slaughter by their owners. In short, the slaughter market exists not to provide an outlet for unwanted horses but so that the foreign-owned slaughterhouses can profit from the trade.

However, should anyone have concerns about surplus of horses that might conceivably exist should this bill pass into law, the National Black Farmers Association stands ready, along with other equine organizations, to assist in finding homes to such horses.

I have also been told that passage of the SAFE Act will disproportionately affect economically disadvantaged horse owners and that we must leave slaughter on the table as an option for those who need to dispose of a horse and whose pocketbooks are tight. The truth is that it costs a couple of hundred of dollars to have a veterinarian put a horse down, and that a person can make a couple of hundred of dollars by selling a horse to slaughter, but money isn't

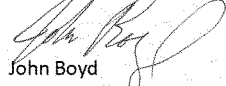
everything. The fact is that my organization is largely made up of lower-income, economically disadvantaged farmers and we are saying that we neither want nor need horse slaughter as an option in this country. We are willing to provide quality care for our horses and when the time comes to end our horses' lives, we opt to do so by truly humane means – not by shipping them to slaughter for a quick buck.

Another point I've heard time and time again from those opposed to a ban on horse slaughter is that horse slaughter is a form of humane euthanasia. This notion is as preposterous as it is false. There is a huge difference between having a veterinarian put my horse down on my farm when the time comes, and putting my horse onto a trailer packed with dozens of other horses to travel for more than a day and night without any food or water or rest, only to be brutally handled and slaughtered in the most fearful and terrifying environment. A five-year-old could see the difference between these two scenarios and it is stunning and disingenuous to me that anyone would attempt to equate the two practices. Bottom line, horse slaughter isn't humane, it's downright cruel.

Some have said that banning horse slaughter will be the start of a slippery slope – that the animal rights people will seek to ban cattle or pig slaughter next. This is a sad, yet far too typical political spin on a serious issue of animal welfare and as a farmer – a cattle farmer at that – I find this notion ridiculous. If I had any fear that banning horse slaughter would hinder my ability to raise cattle, sheep, pigs or chickens for food I wouldn't support this legislation, but the fact is that there is no connection, no chance that ending horse slaughter will result in such a hampering of American agriculture. Americans don't raise horses for slaughter, and we don't eat them. Horses are a revered animal in American history and culture. They may technically be livestock, but they are much, much more and that is why Americans strongly support an end to their slaughter for human consumption overseas.

I commend you, Chairwoman Eshoo, a long standing supporter of legislation banning horse slaughter, as well as the sponsor and lead cosponsor Representative Schakowsky and Representative Buchanan and all the supporters of this important legislation for bringing this issue to light and for offering a way to end this abject cruelty. I thank you for receiving my letter in support of H.R. 961, the Safeguard American Food Exports (SAFE) Act and urge the committee to speedily approve the legislation so that it may move through the United States Congress and pass into law.

Sincerely,



John Boyd
President and Founder

cc: Subcommittee on Health
Representative Jan Schakowsky
Representative Vern Buchanan



January 3, 2020

Dear U.S. Representative,

The Safeguard American Food Exports Act of 2019 (H.R. 961) would permanently ban domestic horse processing for human consumption as well as the interstate transportation of horses for the purpose of being processed abroad. For the following reasons, R-CALF USA urges you to oppose the SAFE Act.

Horses are integral to America's cattle farming and ranching enterprises and R-CALF USA is the largest producer-only trade association representing independent U.S. cattle farmers and ranchers. R-CALF USA has nearly 5,300 dues-paying members in 42 states, most of which are cow/calf and yearling producers; many of whom use horses in their day-to-day operations.

Unfortunately, a horse's useful life is finite, and America's ranchers must have a humane means of removing horses from their operations when they can no longer contribute to their operations. Today's economics do not allow for the ongoing feeding and grazing of no-longer-useful horses as such feedstuffs must be dedicated to profit-generating livestock.

Today, America's ranchers no longer have the option of disposing of no-longer-useful horses by offering them to a United States-controlled processing facility where the horses would be dispatched under the humane guidance of United States' inspectors. Presently, they are limited to offering their no-longer-useful horses to exporters, which continues to be economical but without the assurance of humane controls because the processing is not conducted under U.S. supervision.

The SAFE Act would prohibit even today's less desirable means of disposing of no-longer-useful horses, but at least it is economical as it does not force cattle farmers and ranchers to incur what can be considerable costs to dispose of such animals on their own.

Therefore, the SAFE Act will eliminate the last remaining option available to today's farmers and ranchers to economically dispose of no-longer-useful horses. The SAFE Act will cause them to incur more costs in an industry already suffering from an economic cost-price squeeze. Meaning it will likely worsen the current exodus of United States cattle farmers and ranchers, many of whom are already experiencing more costs than the depressed U.S. cattle market can absorb.

In addition, the SAFE Act would impose an inappropriate restriction on an individual's right to dispose of his or her personal property in a manner that results in a beneficial use.

The U.S. cattle farming and ranching industry must have an orderly and humane means of disposing of no-longer-useful horses and because the SAFE Act eliminates all available means, we respectfully request that you oppose the SAFE Act (H.R. 961).

Sincerely,

Bill Bullard, CEO



Animal Rights Driven SAFE Act Threatens American Equine Welfare

ANIMAL RIGHTS LEGISLATION WITH A DECEPTIVE TITLE - The deceptively titled Safeguard American Food Exports (SAFE) Act is animal rights-based legislation that would greatly harm the actual welfare of the overall United States horse population, by banning the necessary and humane practice of processing unwanted horses for meat.

HORSEMEAT IS A STAPLE- It is important to note that while Americans hold a highly romanticized and ethnocentric view of horses, largely due to the way horses are often portrayed in movies and television, horse meat is a staple in many countries, such as France, Italy, Belgium, and Japan. In addition, horse meat is utilized in countless zoos and animal parks around the globe.

HORSES CAN BE HUMANELY PROCESSED- Thousands of cattle, pigs, and sheep, large exotics such as bison and elk are humanely processed for consumption every day. Different methods are used for each type of animal and there are humane methods for processing horses as well. Major veterinary associations, such as American Association of Equine Practitioners (AAEP) and the American Veterinary Medical Association (AVMA), deem the penetrating captive bolt gun utilized in horse processing plants as humane.

WHERE WILL UNWANTED HORSES GO? - The last domestic horse processing plants closed in 2007, and since that time, an average of 115,000 unwanted horses have been shipped to Canada and Mexico annually. The SAFE Act would make it illegal to ship unwanted horses to those countries, creating an excess of unwanted horses and a resulting animal welfare crisis.

In 2011, a Government Accountability Office (GAO) report showed a dramatic increase in cases of neglect, abandonment, and abuse of horses following the closure of domestic plants in the United States, as the existing rescue network could not absorb the excess. This situation has not changed and will only worsen if the SAFE Act is signed.

BASIC FOOD SCIENCE MUST NOT BE IGNORED - The SAFE Act is based on misinformation that ignores basic animal and food science. The SAFE Act makes the false assertion that any and all horse meat from the United States is not safe for human consumption because of medications given to horses. The NSAID phenylbutazone is a particular focus.

- Only a small percentage of working and performance horses are actually given drugs like phenylbutazone, to occasionally reduce pain and inflammation.
- Professor Dame Sally Davies, a past United Kingdom Department of Health Chief Medical Officer, was quoted as saying: "Horsemeat containing phenylbutazone presents a very low risk to human health..."
- All drugs have a withdrawal time where they are no longer detectable in the body.
- Modern meat production includes rigorous testing and safety protocols, whether the meat is from horses, cattle, pigs, sheep, chicken or exotics such as bison, elk. In the unlikely event that drugs remained in an animal's system, testing assures that the tainted meat will not continue into the food supply.

Our American heritage is important, vital and what we value most. Unfortunately, extremists are working to control farming and ranching, land use, and to restrict animal ownership. As farmers, ranchers, sportsmen, livestock and pet owners, we need to stand up and protect our way of life.



Dave Duquette 541-571-7588
www.protecttheharvest.com

Representative Anna Eshoo
202 Cannon House Office Building
Washington, DC 20515

January 28, 2020

Representative G.K. Butterfield
2080 Rayburn House Office Building
Washington, DC 20515

Representative Michael Burgess
2161 Rayburn House Office Building
Washington, DC 20515

Dear Ranking Member Burgess, Chairwoman Eshoo, Vice Chairman Butterfield, and other members of the Subcommittee on Health,

My name is Julie Caramante. I am the Vice President of the Texas State Horse Council (TSHC), a non-profit dedicated to raising public awareness about the importance of the horse industry to the economic, social and cultural well-being of Texas. On behalf of the TSHC, I am writing to ask you to support the Safeguard American Food Exports (SAFE) Act, H.R. 961, to ban the slaughter of America's horses for human consumption and stop their exportation for that purpose.

As you know, in 1952, the Texas state legislature had the good sense to outlaw the sale, possession, or transfer of horsemeat for human consumption. Horse slaughter does not stop or prevent horse neglect, and it is the antithesis of humane euthanasia. The horses who end up in slaughterhouses are not unwanted, just unlucky enough to catch the attention of the slaughter buyers.

Texas residents know only too well about the immediate and long-term damage that slaughterhouses inflict on the communities in which they operate. Case in point: The city of Kaufman, where the Dallas Crown horse slaughterhouse operated before it was forced to close under state law in 2007. The negative impact of the facility on the city included contaminated ground water, unhealthy air quality, low-wage jobs, and lowered property values. A photo essay compiled by [Forbes Magazine](#) details these violations, and [frequent testimony from Kaufman residents](#) offer stark evidence of the horse slaughter industry's destructive history in our state. While wreaking all that havoc, the plant paid only \$5.00 in taxes on \$12,000,000 of income.

According to a Texas A&M study, the horse industry directly or indirectly contributes \$5.9 billion annually, in addition to 52,000 jobs. Those figures include the use of horses in recreation, farming, entertainment, and therapy programs.

Please join the 80 percent of Americans who oppose the slaughter of our horses; please support the SAFE Act, S. 2006. Thank you very much for your consideration. I look forward to hearing from you.

Sincerely,



Julie Caramante
Vice President, Texas State Horse Council
PO Box 1123
Hutto, TX 78634



January 3, 2020

The Honorable Mike Pence
The White House
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Vice President Pence,

On behalf of its nationwide membership of cow-calf producers, feedlot operators, backgrounders, and livestock haulers, the United States Cattlemen's Association (USCA) writes in opposition to the *Safeguard American Food Exports Act of 2019* (H.R.961). This legislation would not only ban the consumption of horse meat, but also impede interstate and foreign commerce by prohibiting the transportation of equines for human consumption.

USCA opposes any efforts to restrict horse slaughter and/or the transportation of horses to slaughter. We share that sentiment with groups like the American Association of Equine Practitioners¹, American Quarter Horse Association², and the American Veterinary Medical Association³, all of which also oppose national federal bans on horse slaughter.

Our members did not arrive at this conclusion for lack of compassion towards our equine partners. Rather, it is with great compassion and humanity that USCA supports the availability of all options for end-of-life care for equines.

A Government Accountability Office (GAO) report from June 2011⁴ stated that "... state, local government, and animal welfare organizations report a rise in investigations for horse neglect and more abandoned horses since 2007... State, local, tribal, and horse industry officials generally attributed these increases in neglect and abandonments to cessation of domestic slaughter and the economic downturn."

USCA believes that the cessation of horse slaughter only exacerbates the "unwanted horse" problem.

According to United Nations data, in 2005 and 2006, the three operating U.S. horse meat plants processed almost 100,000 horses annually and exported about 40,000 live horses to Canada and Mexico each year. About 10% of that product was sold to domestic zoos and wildlife operations, with the rest netting \$60 million per year in export value to Belgium, France, and Japan. From 2008 to 2010, the industry continued exporting horses to Canada and Mexico at a rate of 140,00 to 160,000 each year.⁵

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2034431/>

² <https://thehorse.com/152031/american-quarter-horse-assn-position-on-slaughter/>

³ <https://www.avma.org/about/unwanted-horses-and-horse-slaughter.aspx/unwanted-horses-and-horse-slaughter-faq>

⁴ <https://www.gao.gov/assets/320/319926.pdf>

⁵ <https://www.animallaw.info/article/detailed-discussion-horse-slaughter-human-consumption>



According to the American Veterinary Medical Association, horse rescue and retirement facilities in the U.S. have a maximum capacity of about 6,000 horses. Under current circumstances, it would be an impossible task to expand facilities or create new ones that could accommodate the 100,000 horses every year that are unwanted. These facilities are not federally regulated so there is no way to ensure the horses living there receive adequate care.

Disposing of euthanized horse carcasses creates environmental and wildlife concerns that must be considered. Chemical agents used in the process can kill scavenger species. Also, burial is not permitted in many areas because chemicals can contaminate the soil, and cremation can cost \$1500 per animal, which is an expense not many horse owners cannot afford.

Much of the public debate over the ban on horse slaughter has become emotionally charged rather than offering sound solutions to the problem of unwanted horses. Instead of passing legislation that creates more economic, animal welfare, and environmental problems, USCA urges Congress and the Administration to oppose the *Safeguard American Food Exports Act of 2019*.

Sincerely,

Dr. Brooke Miller
Vice President,
U.S. Cattlemen's Association



January 28, 2020

TO: Members of the Health Subcommittee of the Energy and Commerce Committee

On behalf of the American Chemistry Council's Chemical Products and Technology Division (ACC-CPTD), I am writing to provide input on the House's consideration of H.R. 2827, a bill which would prohibit all per- and polyfluoroalkyl substances (PFAS) in any food contact materials (FCM).

The chemical industry supports a comprehensive approach to managing PFAS that helps to ensure protection of human health and the environment. This includes appropriate, science-based policies and regulations for PFAS. Unfortunately, H.R. 2827 takes an extremely broad and non-science-based approach that will have a wide range of unintended consequences and will prevent implementation of effective regulatory policies. Consequently, we oppose H.R. 2827 in its current form.

Regulation or legislation should not group all PFAS together or take a one-size fits all regulatory approach. Furthermore, federal actions should be conducted within or consistent with existing, appropriate federal agencies' regulatory frameworks, allowing the scientific and safety data on specific PFAS to guide public policy. In this case, the PFAS used in food packaging materials are already subject to strict regulation by the U.S. Food and Drug Administration (FDA) and only a small number of PFAS are authorized for use in food contact materials in the U.S.

Safety of food packaging safeguarded by robust and transparent regulation. PFAS used in food packaging are regulated as food additives by FDA. Packaging materials that contact food – including coatings and other chemical components of food wrappers, cartons, containers, etc. – are regulated as “food additives” under Section 201(s) of the Federal Food Drug and Cosmetic Act (FFDCA). FDA uses the term “food contact substance” to describe food additives from packaging materials.

Before a food contact substance can be sold or distributed in commerce it must be reviewed by FDA, and under the statute, FDA can only provide authorization for a food contact substance if the agency concludes that there is sufficient scientific data to demonstrate that the substance is safe for its intended use in packaging.



FDA requires extensive scientific data upfront. In order to demonstrate that a food contact substance is safe for its intended use, FDA requires submission of extensive upfront test data and scientific information regarding:

- The chemical composition of the food contact substance, including all impurities and potential degradation products;
- The levels of impurities that may be released from the food contact substance under intended cooking conditions and the potential dietary concentrations of those substances;
- Toxicity data (and any other relevant health and safety data) on all impurities, degradation products and other components of the food contact substance.

Ongoing safety review and monitoring by FDA. FDA can also withdraw its acceptance of a food contact substance at any time if available data no longer demonstrate that the food contact substance is safe for its intended use. If FDA withdraws its approval, the food contact substance can no longer be distributed in commerce.

Unfortunately, as currently drafted, H.R. 2827 would circumvent these existing, robust regulatory processes currently in place and implemented by FDA, and would also inappropriately group together chemistries with significant differences in physical, chemical, and toxicological properties and uses. We urge members to consider these points as the House deliberates H.R. 2827, and we remain committed to working with Congress as it further considers policies to address PFAS.

Sincerely,



Renée M. Lani
Manager



January 28, 2019

TO: Members of the Health Subcommittee of the Energy and Commerce Committee

FluoroCouncil appreciates this opportunity to provide input on the House's consideration of H.R. 2827. FluoroCouncil is a global organization representing the world's leading manufacturers of products based on per- and polyfluoroalkyl substances (PFAS), including fluoropolymers and fluoroelastomers.¹ FluoroCouncil has a fundamental commitment to product stewardship and rigorous, science-based regulation, and, as part of its mission, addresses science and public policy issues related to PFAS.

As currently drafted, H.R. 2827 would prohibit all PFAS in food contact materials (FCM). This is an extremely broad bill, which circumvents an established, robust regulatory process without supporting scientific justification. Consequently, FluoroCouncil opposes H.R. 2827 in its current form.

Regulation or legislation should not group all PFAS together or take a one-size fits all regulatory approach. PFAS are a diverse family of chemistry that includes a broad range of substances with different physical, chemical, and toxicological properties and uses. Hence, the hazard and risk profile of various PFAS are very different. It is neither scientifically-accurate nor appropriate to group all PFAS together or take a one-size-fits-all regulatory approach for this wide range of substances. This will deter innovation, undermine effective product design, and may even lead to the elimination of an entire chemistry that is an enabling technology for a broad array of vital products.

For instance, fluoropolymers, one type of PFAS, can be found in everyday items such as implantable medical devices, cell phones, and automobiles (including electric vehicles). Fluoropolymers are also used in certain repeat-use FCMs, such as tubing and hoses in soda and ice cream dispensers, and components of food processing equipment such as gaskets, sealants, and filters. Notably, fluoropolymers do not pose a significant risk to human health or the environment due to their stability and lack of bioavailability, among other properties. However, in its current form, H.R. 2827 would indiscriminately ban fluoropolymer use in FCMs.

It is also important to understand that those PFAS with commercial uses are not used interchangeably. Different PFAS impart different properties, and those in the marketplace have

¹ FluoroCouncil's member companies are AGC Inc., Daikin Industries, Ltd., Solvay Specialty Polymers, and The Chemours Company LLC. FluoroCouncil is affiliated with the American Chemistry Council.

been designed for specific uses, making it important for public policy to be based on the potential risks associated with exposure to individual substances in particular uses. For example, fluoropolymers are not used in paper food packaging applications.

As a result of the significant diversity within the family of PFAS, it is inappropriate to address PFAS as a broad class in H.R. 2827. FluoroCouncil thanks the Subcommittee for taking these points into consideration and welcomes the opportunity to work with members as they consider legislation addressing PFAS.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Simon', with a stylized flourish at the end.

Robert Simon
On behalf of FluoroCouncil



Animal Welfare Institute

900 Pennsylvania Avenue, SE, Washington, DC 20003
awionline.org phone: (202) 337-2332 fax: (202) 446-2131

January 29, 2020

Honorable Frank Pallone
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Honorable Greg Walden
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, D.C. 20515

Honorable Anna G. Eschoo
Chairwoman
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Honorable Michael Burgess
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Pallone, Chairwoman Eschoo, Ranking Member Walden, and Ranking Member Burgess:

The Animal Welfare Institute, one of the nation's oldest animal welfare organizations, would like to express its strong support for the Safeguard America's Food Exports (SAFE) Act (H.R. 961). Introduced by Reps. Jan Schakowsky (D-IL) and Vern Buchanan (R-FL), this popular, commonsense, bipartisan bill would protect horses and the public from the inhumane and dangerous horse slaughter industry.

Tens of thousands of American horses are shipped each year to Canada and Mexico to be slaughtered for human consumption—a practice that 80 percent of American voters oppose. American horses are not raised for food and routinely receive a wide range of medications that are expressly prohibited for use in meat products. Even so, the problem of horses and burros being butchered for human consumption persists because "kill-buyers" can legally purchase horses at auctions or from unsuspecting owners in order to ship them to slaughterhouses abroad.

On the way to the slaughterhouse, horses endure long, stressful journeys without food, water, or rest and can experience severe injuries and even death. Additionally, during the slaughter process, it can be extremely difficult to accurately stun horses—who react to noise, smells, and sounds in a commercial plant with their natural flight response. Improperly stunned horses may even remain conscious during the butchering and dismemberment process. The inherent cruelty of sending horses to slaughter is evident at each stage of their journey and was well

documented—even in the presence of government oversight—when slaughterhouses existed in the United States.

In addition to the terrible abuse and cruelty that is inherent to horse slaughter, the food safety threats that plague the industry continue to attract attention here and abroad. The U.S. Food and Drug Administration currently bans the presence of 379 common equine drugs in animals slaughtered for human consumption. However, procedures do not exist for ensuring that American horses, sold to slaughterhouses and killed for human consumption, are free of these FDA-banned substances. When horses are sold, especially through an auction, a transfer of information regarding the substances they received during their lifetime is not required. Therefore, no mechanism is in place to ensure horses frequently bought at auction by kill-buyers have not been given dangerous substances before they become part of the food chain.

Currently supported by 225 cosponsors, the SAFE Act addresses these serious concerns by banning horse slaughter in the United States while further ensuring American horses are not exported out of the country for the same purpose. The Animal Welfare Institute is grateful for the Health Subcommittee's focus on the SAFE Act this week. We urge your support for H.R. 961 and we look forward to working with you as this bill advances.

Sincerely,

A handwritten signature in cursive script that reads "Nancy Blaney".

Nancy Blaney
Director
Government Affairs
nancy@awionline.org

Committee on Energy and Commerce
Subcommittee on Healthcare

Hearing on:
Improving Safety and Transparency in America's Food
and Drugs

January 29, 2020

Statement for the Record
Submitted by ASHP



American Society of Health-System Pharmacists

4500 East West Highway, Suite 900
Bethesda, MD 20814
Email: gad@ashp.org
Phone: 301-664-8692

ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Energy and Commerce Health Subcommittee hearing on “Improving Safety and Transparency in America’s Food and Drugs”

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization’s nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

We applaud the Committee's efforts to address safety and transparency in America’s drugs. ASHP’s vision is that medication use will be optimal, safe, and effective for all people all of the time. A primary tenet of that vision includes access to affordable medications needed to save or sustain lives. Addressing the issue of medication safety and the accessibility of prescription drugs is one of ASHP’s highest and longstanding public policy priorities.

Poor access to medications can lead to increased morbidity and mortality, and can cause healthcare costs to increase. According to a 2019 Kaiser Health Tracking Poll, 29% of adults report that they are not taking their medications as prescribed due to increased cost with 8% of those individuals reporting that their condition has worsened as a result of poor medication adherence.¹

ASHP has been proactively addressing challenges related to the manufacturing of prescription drugs on several fronts, including implementing proper safety measures and safeguards, and educating members of Congress about the unsustainable burdens drug shortages pose on patients, healthcare providers, and the entire healthcare system.

ASHP is committed to advancing policies that will ensure the manufacturing of prescription drugs is safe and effective, promote open competition in the marketplace, and provide patients with the proper access to care. We appreciate the opportunity to work with you and your colleagues on this issue.

ASHP supports the passage of H.R. 4866 the “National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act.” Disruptions in the drug supply often stem from quality challenges in the manufacturing of final dosage forms. The U.S. Food and Drug Administration (FDA) has identified continuous manufacturing as a potential alternative to traditional batch manufacturing, which could improve the quality of drug manufacturing. Investment in domestic continuous manufacturing also offers potential to reduce our dependence on highly concentrated foreign sources of drug manufacturing.

We are hopeful that H.R. 4866 will accelerate adoption of continuous manufacturing in the United States.

ASHP also encourages Congress to consider the following additional solutions to reduce the frequency and duration of drug shortages:

- 1. Require manufacturers to provide FDA with more information on the causes of shortages and their expected durations and allow public reporting of this information.**

¹ Kirzinger, A., Lopes, L., Wu, B., & Brodie, M. (2019, March 15). KFF Health Tracking Poll – February 2019: Prescription Drugs. Retrieved March 8, 2019, from <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

Current law requires manufacturers to notify FDA when there is a discontinuance or interruption in manufacturing. However, manufacturers are not required to disclose the cause of the interruption or provide a timeline for resolution. Some manufacturers do this voluntarily, but inconsistent information hinders FDA's ability to mitigate shortages. Title X of the Food and Drug Administration Safety and Innovation Act (FDASIA) should be strengthened to require these notifications be published in the FDA drug shortages database and include the cause of the interruption and a timeline to address the shortage.

2. Require drug manufacturers to disclose manufacturing sites, including use of contract manufacturers, and sources of active pharmaceutical ingredients (APIs) to FDA.

FDA lacks access to key information to assist in preparation and improve resilience of drug manufacturing operations in the face of regional disasters, geopolitical instability, or manufacturing problems at specific sites. The Federal Food, Drug, and Cosmetic Act (FFDCA) should be strengthened to require manufacturers to disclose to FDA the location of drug production, including when a contract manufacturer is used, and sources of APIs. FDA can use this information to more accurately assess the scope and duration of a shortage as well as identify potential supply disruption for related products, including associated medical devices.

3. Require manufacturers to establish contingency plans to maintain supply of a drug in the event of a manufacturing disruption.

Manufacturers cannot always predict when a shortage will occur. Manufacturing disruptions can be caused by natural disasters, quality issues, or business decisions which may include discontinuation of a product. Such shortages negatively impact patient safety and access to care. The FFDCA should be amended to include a requirement that manufacturers develop and maintain business continuity contingency plans for future supply disruptions that are reviewed during FDA plant inspections.

4. Establish incentives to encourage manufacturers to produce drugs in shortage or at risk of shortage.

Drugs with fewer than 3 manufacturers are at greatest risk for shortages. FDA should recommend incentives to encourage manufacturers to begin producing drugs that are in shortage.

5. Require the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS) to conduct a risk assessment of national security threats associated with manufacturing and distribution of critical drugs, their APIs, and associated medical devices used for preparation or administration.

Relying predominantly on other countries for necessary ingredients to manufacture crucial drugs, APIs, and devices required to safely prepare and administer these drugs presents a potential threat to the stability of the US drug supply. At present, more than 80% of API is produced in China and India – this leaves our supply chain vulnerable to disruption and puts API sourcing at risk. In addition to critical drug products, medical devices necessary for the preparation and administration of drugs are a critical part of healthcare infrastructure. Devices like syringes, needles, and tubing for administration of intravenous drugs have been affected by shortages.

HHS and DHS should 1) conduct a review of priority risks to API and finished pharmaceutical manufacturing and distribution systems, including identification of ways the U.S. government can support preparedness and resilience of critical infrastructure in the pharmaceutical sector, and 2) conduct an assessment of risk for foreign manufacturing of API, finished pharmaceuticals, and medical devices, and 3) establish a standing forum to engage the private sector, including pharmacists, hospitals, physicians and manufacturers, to mitigate these risks.

6. Require FDA to publish quality ratings for drug manufacturers and 503B outsourcing facilities preparing copies of drug products under the exemption for products on FDA's shortage list or make public such information that would allow purchasers to assess the relative quality of 503B outsourcing facilities

Drug shortage data indicate that a majority of recent shortages were due to manufacturing quality issues. Hospitals and health systems often make purchasing decisions without any ability to access manufacturing quality data. FDA inspection notices and warning letters describe inspections that are several months old and do not provide timely information of satisfactory resolution of problems identified and do not identify specific products manufactured at that facility. Healthcare personnel need a mechanism to inform purchasing decisions based on manufacturer quality.

FDA should publish manufacturing quality ratings, or make public information that would allow purchasers to compare manufacturing quality when making purchasing decisions. Similar ratings or information should be made public to assess quality of products produced in 503B outsourcing facilities.

7. Require the Federal Trade Commission (FTC) to evaluate the potential for drug product supply chain interruptions when considering manufacturer consolidations.

Consolidation in the pharmaceutical industry has disrupted manufacturing lines and created quality issues, resulting in extended duration shortages of critical drug products. To prevent shortages related to mergers and acquisitions, FTC review of proposed consolidations in the pharmaceutical industry should require analysis of potential public health impacts – specifically, the likelihood the transaction will create new and/or exacerbate existing drug shortages.

CONCLUSION

ASHP thanks the Energy and Commerce Committee Subcommittee on Health for holding this important hearing. ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.

January 28, 2020

Chairman Frank Pallone
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20510

Chairwomen Anna Eshoo
Subcommittee on Health
House Committee on Energy and Commerce
202 Cannon House Office Building
Washington, DC 20510

Ranking Member Greg Walden
House Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, DC 20510

Ranking Member Michael Burgess
Subcommittee on Health
House Committee on Energy and Commerce
2161 Rayburn House Office Building
Washington, DC 20510

Dear Chairman Pallone, Ranking Member Walden, Subcommittee Chairwoman Eshoo, and Subcommittee Ranking Member Burgess:

The undersigned organizations, representing millions of patients, advocates, caregivers, and health care professionals urge the House Energy and Commerce Committee to take swift action to address a major public health concern for patients and their physicians by passing H.R. 5668, the Making Objective Drug Evidence Revisions for New Labeling Act (MODERN Labeling Act).

Patients and their caregivers, physicians, and nurses, need high quality sources of information about the prescription drugs they use, and that means up-to-date drug labels. While many sources of information exist, none can deliver as strong assurances of reliability and scientific accuracy as FDA-approved product labels. Labels are the most carefully-vetted sources of prescribing information available today and play a critical role in safeguarding the public health. A recent study by Friends of Cancer Research (*Friends*) shows that many drug labels are considerably out of date, despite the critical role they can play in informing treatment decisions, and offer guidance to prescribers on the appropriate and safest use of drugs to treat patients.

Representatives Doris Matsui (D-CA) and Brett Guthrie(R-KY) have introduced H.R. 5668, the MODERN Labeling Act. The bill addresses a discrepancy that can occur when new scientific information relevant to a drug's indication is not incorporated into its label. This often occurs to generic drugs, particularly those whose reference listed drug (RLD) has been removed, which leaves an inaccurate or incomplete generic drug label "frozen in time". The legislation addresses this issue by giving the FDA the authority to require updating of generic drug labels where the RLD has been removed to reflect new information relevant to the drug and its use. This Act also determines a process through which the FDA can identify labels to be updated, notice label holders, and allows for a process for label holders to submit modifications to the notice.

We urge immediate passage of the MODERN Labeling Act by the House Energy and Commerce Committee, and the full House, to address this public health concern to ensure the FDA can update outdated labels and protect patients across the country.

Sincerely,

Alliance for Aging Research
American Association for Cancer Research (AACR)
American Cancer Society Cancer Action Network (ACS CAN)
Cancer Support Community
Children's Cancer Cause
Fight Colorectal Cancer
Friends of Cancer Research
GO2 Foundation for Lung Cancer
LUNGevery Foundation
National Alliance on Mental Illness
National Comprehensive Cancer Network (NCCN)
National Multiple Sclerosis Society
National Organization for Rare Disorders
St. Baldrick's Foundation
Susan G. Komen



The Jockey Club

40 East 52nd Street, New York, NY 10022
Phone: (212) 371-5970 | Fax: (212) 371-6123

January 29, 2020

The Honorable Frank Pallone
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
Committee on Energy & Commerce
U.S. House of Representatives
2322-A Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Chairwoman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Michael Burgess
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2322-A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone, Ranking Member Walden, Chairwoman Eshoo and Ranking Member Burgess:

I write on behalf of The Jockey Club to express our support for the Safeguard American Food Exports (SAFE) Act (H.R. 961; S.2006) to end the slaughter of American horses in the U.S. and abroad. This bill enjoys overwhelming support in Congress, among the American public, and in the Thoroughbred community across the country.

As a steward of the Thoroughbred since 1894, we believe that our equine athletes should be treated humanely throughout their lives – before, during, and after their racing careers. Our organization has been instrumental in protecting racehorses through track policies that expressly prohibit trainers or owners from selling their horse to slaughter. And though these measures are crucial in the interim, the only guaranteed way to protect our nation's equines from this fate is to ban the practice in perpetuity.

We are proud of the steps that our industry has taken towards facilitating new careers for retired racehorses, and for providing resources towards aftercare programs across the country. Valuing our equine athletes throughout their lives is a hallmark of the Thoroughbred industry, which is why it is critical both for the welfare of our equines and for the sustainability of our industry that American horses no longer fall prey to the slaughter pipeline. Americans, and particularly the equine community, overwhelmingly oppose this practice.

We respectfully urge your support of the SAFE Act and hope to see this bill move forward in the near future.

Thank you for your consideration of this important issue.

Sincerely,

James L. Gagliano
President & Chief Operating Officer

reuters.com

Special Report: As Baby Powder concerns mounted, J&J focused marketing on minority, overweight women

Chris Kirkham

LOS ANGELES (Reuters) - Pressure was mounting on Johnson & Johnson and its signature Baby Powder.



FILE PHOTO: A bottle of Johnson and Johnson Baby Powder is seen in a photo illustration taken in New York, February 24, 2016. REUTERS/Shannon Stapleton/Illustration/File Photo

In 2006, an arm of the World Health Organization began classifying cosmetic talc such as Baby Powder as “possibly carcinogenic” when women used it as a genital antiperspirant and deodorant, as many had been doing for years. Talc supplier Luzenac America Inc started including that information on its shipments to J&J and other customers.

J&J, meanwhile, looked for ways to sell more Baby Powder to two key groups of longtime users: African-American and overweight women. The “right place” to focus, according to a 2006 internal J&J marketing presentation, was “under developed geographical areas with hot weather, and higher AA population,” the “AA” referring to African-Americans.

“Powder is still considered a relevant product among AA consumers,” the presentation said. “This could be an opportunity.”

In the following years, J&J turned those proposals into action, internal company documents show. It distributed Baby Powder samples through churches and beauty salons in African-American and Hispanic neighborhoods, ran digital and print promotions with weight-loss and wellness company Weight Watchers and launched a \$300,000 radio advertising campaign in a half-dozen markets aiming to reach “curvy Southern women 18-49 skewing African American.”

These are only some of the more recent examples of J&J’s decades-long efforts to offset declining Baby Powder sales amid rising concern about the health effects of talc, based on a Reuters review of years of J&J print, radio and digital advertising campaigns and thousands of pages of internal marketing documents and email correspondence.

Adults have been the main users of Johnson’s Baby Powder since at least the 1970s, after pediatricians started warning of the danger to infants of inhaling talc. As adults became ever more crucial to the brand – accounting for 91 percent of Baby Powder use by the mid-2000s – J&J honed its powder pitches to court a variety of targeted markets, from teen-focused ads touting the product’s “fresh and natural” qualities, to promotions aimed at older minority and overweight women.

Today, women who fall into those categories make up a large number of the 13,000 plaintiffs alleging that J&J’s Baby Powder and Shower to Shower, a powder brand the company sold off in 2012, caused their ovarian cancer or mesothelioma.

Many of the ovarian cancer lawsuits have blamed the disease on perineal use of J&J cosmetic talcs – a claim supported by some studies showing an association between such use and increased cancer risk. The most recent cases have alleged that J&J’s talc products contained asbestos, long a known carcinogen.

In an investigation published Dec. 14 [here](#) Reuters revealed that J&J knew for decades that small amounts of asbestos had occasionally been found in its raw talc and in Baby Powder and Shower to Shower, based on test results from the early 1970s to the early 2000s – information it did not disclose to regulators or the public.

J&J challenged the findings of the Reuters report, describing them as inaccurate and misleading.

BABY POWDER “EVERYWHERE”

Krystal Kim, a 53-year-old African-American, was one of 22 plaintiffs whose case in St. Louis resulted in a jury verdict last summer of \$4.69 billion against J&J. Kim said Baby Powder and

Shower to Shower were household staples among her family and friends when she was growing up in New Jersey. Kim played baseball as a teenager, she said, and her mother told her to apply Baby Powder to avoid being “the stinky girl.”

“Every time I took a shower, I put Baby Powder on,” recalled Kim, whose ovarian cancer, first diagnosed in 2014, is now in remission. “I put it on my panties, on my clothes, everywhere.”

J&J is appealing the St. Louis verdict. The company did not respond to requests for an interview with Chief Executive Officer Alex Gorsky or any other executive to discuss the company’s marketing of cosmetic powders.

In an emailed response to questions from Reuters, J&J said its Baby Powder is safe and asbestos-free. It noted that the company’s marketing over the years has been directed at many demographics and groups, and that “we’re proud pioneers of the practice of multicultural marketing.” It also pointed out that some Baby Powder ads have featured the cornstarch version of Baby Powder, the safety of which isn’t questioned.

Reports by Bloomberg News, the New York Times and the Post and Courier of Charleston, South Carolina, have cited some internal J&J documents revealing the company’s focus on African-American and overweight women at certain times. But the full timeline and scale of the marketing efforts, particularly those aimed at teenage girls, in minority communities and through organizations such as Weight Watchers, are reported here for the first time.

Most businesses know the demographic profiles of those who buy their products and, as a matter of course, direct their marketing at those groups. Some – fast-food companies and soft-drink makers, for example – have courted minority customers to increase sales among heavy users at times of growing public concern about the possible health effects of their products.

In a lawsuit filed in Mississippi state court in 2014, Mississippi Attorney General Jim Hood alleges that J&J failed to warn consumers of the risks associated with its talc products and accuses the company of implementing a “racially targeted strategy” for selling Baby Powder after J&J became aware of health concerns. The company focused its marketing on “minority communities expected to be more likely to use the talc products,” Hood claims in the lawsuit.

J&J denied the allegations and last year filed a motion for summary judgment in the suit, arguing that the case involved matters of federal law, beyond the state’s purview. A judge in December denied J&J’s motion, a move the company has appealed. The case is scheduled for trial later this year.

In its response to Reuters’ questions, J&J said: “Suggesting that Johnson & Johnson targeted a particular group with a potentially harmful product is incredibly offensive and patently false.”

“DEEP, PERSONAL TRUST”

Sold continuously since 1894, Johnson’s Baby Powder accounted for less than 1 percent of J&J’s \$81.6 billion in revenue last year, but it is deemed critical to the company’s family-friendly

image. An internal J&J marketing presentation from 1999 refers to the baby products division, with Baby Powder at the core, as J&J's "#1 Asset," grounded in "deep, personal trust."

Beginning in the 1950s, however, a series of case studies published in medical journals pointed to the dangers of breathing in talc. Pediatricians took notice. By the late 1950s, a third of them were recommending cornstarch or oil to treat diaper rash and chafing "because there is no dangerous dust" in them, according to an internal J&J report.

A report in the June 1966 edition of the American Journal of Diseases of Children, citing the deaths of three children who inhaled large amounts of talcum powder, concluded there was "no justification" for using the product on babies because it has "no medicinal value."

By 1974, more than 60 percent of Johnson's Baby Powder sales were "attributable to adults" who used it on themselves, according to a J&J analysis.

Losing the connection to the product's namesake – babies – left J&J eager to cultivate other markets.

Beginning in the 1970s, J&J ran ads clearly intended to woo young women, in addition to its traditional marketing aimed at families with babies. "You start being sexy when you stop trying," was the line from an ad that appeared in Seventeen magazine in 1972. The photo shows a young woman stroking a young man's curly blond hair.

"It's a feeling you never outgrow," is how an ad in Family Circle magazine from the mid-1980s put it, with a photo of a bottle of Baby Powder next to a teddy bear alongside the mirrored reflection of a young woman.

In 1989, advertising firm Young & Rubicam submitted a plan to J&J to "initiate a high level of usage" among young women to "augment the weakening baby link." Under the plan, ads in style magazines like Seventeen, YM, Glamour and Mademoiselle would try to convince teen girls that Johnson's Baby Powder, "applied daily after showering, is a simple, feminine way to smell clean and fresh during the day." Young & Rubicam, now known as VMLY&R, declined to comment on the document and referred questions to J&J.

Baby Powder sales continued to fall throughout the 1980s and early 1990s. Since health professionals had already recommended against using talc on infants, a 1986 internal report warned, a "last straw" safety concern could lead consumers to abandon the product altogether.

As early as 1992, the company keyed in on the sales potential with minority women. A J&J memo that year mentions "high usage" rates for Baby Powder of 52 percent among African-Americans and 37.6 percent among Hispanic customers – and notes that women of both ethnicities use the product more than the general population.

The memo suggests investigating "ethnic (African American/Hispanic) opportunities to grow the franchise," while referring to "negative publicity from the health community on talc," including

“inhalation, dust, negative doctor endorsement, cancer linkage.” Portions of that memo were cited in reports from Bloomberg and the New York Times.

STAGNATING SALES

By 2006, the company was recognizing that “consumers do not see a need for powder,” according to a sales presentation that year. Baby Powder shipments had been “stagnating” in recent years, the presentation said, and it was essential to “find a new business model” that “strategically and efficiently targets high propensity consumers.”

Those groups, according to the presentation: African-Americans, nearly 60 percent of whom used Baby Powder by this time, compared to about 30 percent for the overall population; overweight people; and fitness-conscious people looking to lose weight.

It was also in 2006 that the International Agency for Research on Cancer (IARC), an arm of the World Health Organization, classified perineal use of talc as “possibly carcinogenic,” saying available research provided “limited evidence” it caused cancer in humans. That came about 20 years after IARC classified “talc containing asbestiform fibres” as “carcinogenic to humans,” its highest-risk classification.

After the IARC’s 2006 move, talc supplier Luzenac America started including a note about the agency’s latest classification on a chemical safety document accompanying shipments to all customers, including J&J. Under a heading that reads “carcinogenic status,” the document says IARC “has concluded that perineal use of talc-based body powder is possibly carcinogenic to humans.”

In a deposition for one of the ovarian cancer cases tried in St. Louis, a Luzenac America executive, Shripal Sharma, said the company felt it was important to add what he referred to as a warning to the safety document. Asked whether Luzenac knew that J&J did not pass on this warning, Sharma said: “It is not our job to tell our customers what to do with their products.”

In a statement to Reuters, Imerys Talc America Inc, as Luzenac is now known, said: “Talc’s safe use has been confirmed by multiple regulatory and scientific bodies,” echoing J&J’s response.

Through an Imerys spokeswoman, Sharma declined to comment.

Two years after the IARC classification, J&J sought proposals for an “African American agency” to develop marketing campaigns for the company’s baby products line. A 2008 document sent to prospective agencies summed up the situation: “Johnson’s Baby Oil and Baby Powder products, while traditionally used only on babies, are today primarily consumed by adult AA women for use on themselves.” One way to reverse the brand’s decline, it said, was by “speaking to AA consumers with a more relevant message with the most effective media vehicles.”

“ETHNIC CONSUMERS”

That year, the company contracted with a North Carolina marketing firm, Segmented Marketing Services Inc, which says it specializes in targeted promotions to “ethnic consumers.” The firm would distribute 100,000 gift bags containing Baby Powder and other Johnson’s baby products in African-American and Hispanic neighborhoods in Chicago, according to a contract with J&J.

Run by African-Americans who had been executives at Procter & Gamble Co and Quaker Oats, Segmented Marketing Services has said in past press releases and its own marketing publications that it hands out millions of free product samples and promotional offers through national networks of more than 10,000 African-American and Hispanic churches, and tens of thousands of “beauty salons, barber shops, entertainment venues and healthcare networks.”

The company published an advertorial in 2008 prepared for distribution with Johnson’s baby products in which the firm’s founders, Sandra Miller Jones and Lafayette Jones, said they “welcome” J&J as a partner.

“When caring rituals started in infancy continue through adulthood, a person’s self-confidence and even faith in the world are often strengthened,” the pamphlet said. “Whether in the gym, at work, at church or at the beach, Johnson’s Baby Powder helps grown-ups feel more comfortable in their own skin.” It came with a coupon for \$1 off Baby Powder.

Lafayette Jones and Sandra Miller Jones did not respond to calls, emails and LinkedIn messages seeking comment.

J&J also launched campaigns to boost sales of Baby Powder to “curvy Southern women” and athletic adults who want to smell fresh, according to company documents. It advertised in Weight Watchers magazine and offered promotions through the Lane Bryant clothing chain for plus-size women and Curves, a women’s fitness and weight-loss franchise. Marketing plans also included ads to run in Southern Living magazine and during the Style Network show “Ruby,” a reality TV series that documented an obese Georgia woman on a mission to lose weight.

A 2009 presentation laying out the “Powder media plan” highlights that it will reach 31 million people “in the South (hot climates/overweight states),” and that “43% of our plan will focus on the top 10 overweight states in the nation.”

A 2009 ad in Weight Watchers magazine suggests readers “bust stress with a midday workout” and then “stay fresh post-exercise by applying Johnson’s Baby Powder.”

Internal J&J marketing emails before the Weight Watchers campaign ran discuss whether the women featured are heavy enough to resonate with the intended audience. “Can you ask WW if they have any images of slightly bigger women? They don’t have to be super curvy, but a little bigger than the current image would be preferable,” wrote Grace Lee, a J&J brand manager, to others at the company and ad agency Lowe New York.

Weight Watchers, now known officially as WW International Inc, declined to comment on the campaign. Lee & Interpublic Group of Companies Inc, which owns the former Lowe New York, didn't respond to requests for comment.

SUMMER SUCCESS

The Weight Watchers campaign was successful, according to a 2009 internal J&J recap, which showed that sales of Baby Powder at Wal-Mart shot up as much as 9 percent during the summer months when the ads ran from the same months a year earlier, reversing a decline.

J&J's overall Baby Powder media advertising budget increased to a proposed \$495,000 for 2010, up 71 percent from \$288,000 in 2009, driven by more dedicated spending toward promotions for overweight women.

The company in 2010 launched a radio campaign in the South targeting "Curvy Southern Women 18-49 Skewing African American." A presentation from TMPG, a marketing agency that handles promotions with radio DJs, said the campaign made more than 18 million impressions on the target audience through ads and promotions on "urban adult contemporary" radio stations in Southern markets, including Dallas; Atlanta; Nashville; Mobile, Alabama; and Jackson, Mississippi.

The presentation slides feature some photos of plus-size African-American women holding Baby Powder samples at "targeted station events" that also included spa giveaways and "Baby Powder Stay Cool Cash." TMPG did not respond to requests for comment.

In a 2010 email, Debra DeStasio, a J&J promotions and marketing manager who oversaw the baby products line at the time, gave the green light to two proposed radio stations for the campaign in Dallas, saying "we are good with those general market stations that have good Hispanic reach and good AA reach." In another 2010 email, she said the DJs will be the Baby Powder "brand ambassadors," charged with "communicating our message, encouraging listeners to call in to talk about how they use Baby Powder and driving to retail where appropriate."

All the radio promotions would be "based on the weather," she wrote. "If it's hot and humid, we'll run that week. If it's rainy or colder, we won't."

DeStasio, who now works as a promotions and marketing manager at Bristol-Myers Squibb Co, did not respond to requests for comment.

J&J's spending on Baby Powder promotions – coupons, discounts, and samples – came to about \$1.2 million in 2008 and again in 2010, almost half of it directed at overweight and minority women. By 2011, the company cut back its promotional spending to \$752,000, mostly aimed at the general consumer market.

In 2013, a jury found J&J negligent in the first case ever to claim that regular use of Baby Powder for feminine hygiene caused ovarian cancer. The jury didn't award monetary damages, but the verdict spawned a cascade of similar lawsuits.

Of the eight ovarian cancer cases that have gone to trial so far, four have resulted in verdicts for plaintiffs and one for the company. Three other verdicts against J&J were overturned on appeal.




In 12 trials of cases claiming that asbestos in talc caused plaintiffs' mesothelioma, J&J was cleared of liability in five, and plaintiffs won three, resulting in a total of \$172 million in damages. Four others resulted in hung juries and mistrials.

J&J is appealing all the verdicts against it.

Meanwhile, J&J has pulled back from marketing specifically to minority and overweight women. A 2015 presentation makes no mention of minorities, suggesting the brand "target adults, with a focus on men."

Plaintiffs' lawyers and other advocates have become more vocal in criticizing the targeted marketing campaigns. In its most recent newsletter, the National Council of Negro Women, a women's leadership group with about 30,000 members, drew attention to the issue with an essay penned by civil-rights lawyer Ben Crump, who is representing some Baby Powder plaintiffs.

In an interview, Janice Mathis, the council's executive director, said: "Lots of products target African-Americans. That's marketing 101: Go where our customers are. What has me disturbed about this is that you didn't give any caveat to the customers, once you knew there was a possibility there was some danger."

<div>   </div> <div> JOHNSON'S® Baby Powder 2010 Promotional Radio Overview </div> <div>  </div>									
Owner: Curry Southern Wireless, LLC, 441 Standing African American GBPs: 480 General Market GBPs per market Flights: June 14 - 27, 2010 July 12 - 25, 2010 August 9 - 22, 2010									
All Stations Will Execute the Following Contesting Concept: Submit Your JOHNSON'S® Baby Powder® Tip to Stay Cool and Fresh We all have tips for staying cool in the summer, whether it's applying JOHNSON'S® Baby Powder when getting dressed in the morning, putting some in your sandals or sprinkling some on after taking a dip in the pool after work or on your sheets at night while you crank up the air conditioning. Listeners will be asked to call in or log on to the station website to submit their best Baby Powder tips to stay cool and fresh this summer. One winner will be awarded the Grand Prize.									
Market	Station	Dial Position	Format	Station Market Rank (AQR RTG) GM W 18-49	Rank (AQR RTG) AA V 18-49	DI Brand Ambassador(s)	Online Activity / Additional Exposure	Grand Prize	In-Market Events (For Possible Coupon Distribution)
Atlanta	WVEE-FM	103.3	Urban Adult Contemporary	1	1	Elle Duncan Midday	Client Logo / Hyperlink / Web Template Email Blast to Opt-In Listeners	\$250 JOHNSON'S Baby Powder Staying Cool Spa Gift Certificate	Event: V103 Car and Bike Show Event Date: July 10, 2010 at 12h - 8pm Approx. Attendance: 25,000 # Coupons Station can Distribute: 10,000 Event: Bonner Brothers International Hair Show Event Date: August 8, 2010 Approx. Attendance: 10,000 # Coupons Station can Distribute: n/a Event: For Sisters Only Event Date: September 11-12, 2010 Approx. Attendance: n/a # Coupons Station can Distribute: n/a
Dallas	KVUE-FM	103.7	Adult Contemporary	1	4	Lugh Ann PM Drive	Client Logo / Hyperlink / Web Template	\$250 JOHNSON'S Baby Powder Stay Cool Cash	Event: July 4th Event Date: July 4, 2010 Approx. Attendance: 30,000 # Coupons Station can Distribute: 2,000
Dallas	KXDA-FM	104.5	Urban Adult Contemporary	4	2	Suga Midday	Client Logo / Hyperlink / Web Template / Banner Email Blast to 53,000+ Opt-In Listeners Streaming Spots	JOHNSON'S Baby Powder Stay Cool Summer Fun - 2 Tickets to the Annual Summer Jam in the VIP Suite	Event: Summer Jam Event Date: July 31, 2010 Approx. Attendance: 8,000 # Coupons Station can Distribute: n/a Event: E! News Summer Concert Event Date: August 10, 2010 Approx. Attendance: 3,000 # Coupons Station can Distribute: n/a
Jackson, MS	WRBJ-FM	97.7	Urban Adult Contemporary	4	4	Tambura Cherie Midday	-----	\$250 JOHNSON'S Baby Powder Stay Cool Cash	Event: America's Next Top Model Event Date: July 17, 2010 at 10pm Approx. Attendance: 100 - 150 # Coupons Station can Distribute: n/a Event: Back to School Event Date: August 7, 2010 Approx. Attendance: 100 # Coupons Station can Distribute: n/a

Market	Station	Dial Position	Format	Station Market Rank (AQH RTG) GM W 18-49	Station Market Rank (AQH RTG) A3, W 18-49	DI Brand Ambassador(s)	Online Activity / Additional Exposure	Grand Prize	In-Market Events (For Possible Coupon Distribution)
Mobile	WBLX FM	92.9	Urban Adult Contemporary	1	1	Corney Hicks Midday	Client Logo / Hyperlink / Web Template Email Incentive / 12,000-Online Users Streaming Spots	Supply of JOHNSON'S Baby Powder Soothing Spa Gift Certificate	Event: Picnic in the Park Event Dates: TBD Approx. Attendance: 1,000 If Coupons Station can Distribute: n/a
Nashville	WUBT FM	101.1	Urban Adult Contemporary	1	1	Pamela PM Drive	Client Logo / Hyperlink / Web Template Streaming Spots	\$250 JOHNSON'S Baby Powder Stay Cool Cash	Event: Shoe Carnival Event Dates: August 14, 2010 12h - 2pm Approx. Attendance: 1,000 If Coupons Station can Distribute: n/a

*Station Appearance Dates / Times are NOT final and are subject to change.

JOHNSON'S® Baby Powder

2010 Promotional Radio Program Recap

The logo for Johnson's baby powder, featuring the brand name in a blue script font with a registered trademark symbol, and the words "baby powder" in a smaller, blue, sans-serif font below it.

September 22, 2010

Presented To:
Debbie DeStasio
Amanda Givens
Michael Haas



Program Objectives

- Create top-of-mind awareness and drive purchase of JOHNSON'S® Baby Powder
- Reinforce the key product attributes and benefits of JOHNSON'S® Baby Powder, while introducing the new Magnolia Petals scent
- Encourage consumers to stay cool and fresh this summer with JOHNSON'S® Baby Powder





Program Overview

- Demo: Women 18-49 (skewing towards curvy women)
- GRP Goal: 480 GRPs per market
- Flight Dates:
 - June 14th – 27th (2 weeks)
 - July 12th – 25th (2 weeks)
 - August 9th – 22nd (2 weeks)
- Markets: Atlanta, Dallas, Jackson, Mobile and Nashville
- Budget: \$300,000



Results

- Program ROI: 1.3 : 1
- Total Promotional Value:
 - On-Air Value: \$ 380,397
 - Off-Air Value: \$ 353,997
 - Off-Air Value: \$ 26,400*
- Total Promotional Announcements: 2,588
- Total W18-49 Gross Impressions: 18,492,100
- Online Activity:
 - Email Blasts: 115,000+
 - Streaming Spots: 1,500+

* Off-Air Value includes conservative estimates for digital activity, station supplied prizes, appearances, etc.



Delivery

Demo: Curvy Southern Women 18 - 49 Skewing African American
 GRPs: 480 General Market GRPs per market
 Flights: June 14 - 27, 2010
 July 12 - 25, 2010
 August 9 - 22, 2010

Market	Station	Promos Delivered	GRPs Delivered	Gross Impressions	On-Air Value	Off-Air Value	Total Promotional Value
Atlanta	WVEE-FM	534	576.7	7,239,200	\$156,862	\$6,250	\$163,112
Dallas	KVIL-FM	484	421.4	6,100,600	\$108,300	\$4,750	\$113,050
Dallas	KKDA-FM	430	129.6	1,798,900	\$33,307	\$4,750	\$38,057
Dallas Total		914	551.0	7,899,500	\$141,607	\$9,500	\$151,107
Jackson, MS	WRBJ-FM	504	559.0	614,500	\$11,180	\$2,750	\$13,930
Mobile	WBLX-FM	218	590.0	743,800	\$13,570	\$3,150	\$16,720
Nashville	WUBT-FM	418	580.7	1,995,100	\$30,777	\$4,750	\$35,527
Grand Totals		2,588		18,492,100	\$353,997	\$26,400	\$380,397

Source: Arbitron - Fall 2009 ARB / March 2010 PPM





Themed Contesting

- Brand-Themed Custom Promotion
 - Contesting gives DJ Brand Ambassadors more opportunities to talk about the brand, generate buzz and drive awareness for JOHNSON'S® Baby Powder
- Stations Conducted the Following Contest:
 - ***"Submit Your JOHNSON'S® Baby Powder Tips to Stay Cool & Fresh"***
 - DJs encouraged listeners to call in, or log online to the station's website to share their best JOHNSON'S® Baby Powder tips to stay cool and fresh this summer for a chance to win the Grand Prize!
 - Stations awarded prizes on behalf of JBP including \$250 Spa Gift Certificates, Tickets to KKDA-FM's Summer Jam, \$250 JOHNSON'S® Baby Powder Stay Cool Cash, Gift Baskets full of JOHNSON'S® and JOHNSON'S® products featuring JOHNSON'S® Baby Powder



Mobile WBLX-FM Contest Promotion



Jackson KFKF-FM Call-In Qualified Contestant




Online Exposure Added Value

- Stations provided prominent online exposure for the brand
 - Increased consumer interaction with the brand, while reinforcing the benefits of JOHNSON'S® Baby Powder to stay cool and fresh during the summer
- Station websites included:
 - JOHNSON'S® Baby Powder logo
 - Dedicated Contesting Pages
 - Hyperlink to www.babypowder.com
 - Email Blast to Opt-In Listeners



Click to view Dedicated Contest Pages →

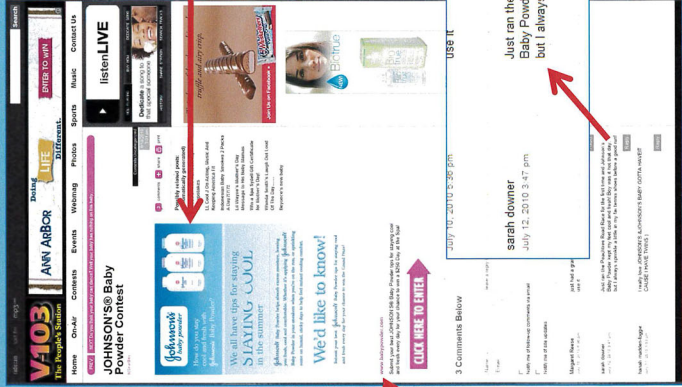



Dedicated Contest Page

Atlanta WVEE-FM

Contesting Web Template

Hyperlink to www.babypowder.com





Dedicated Contest Page

Nashville WUBT-FM

Rememembering Michael Jackson

Hyperlink to
www.babypowder.com

Contesting Web Template



In-Market Exposure

Added Value

Coupon Distribution

- Stations handed out JOHNSON'S® Baby Powder Coupons at various, targeted station events, giving the brand additional exposure and driving purchase of JOHNSON'S® Baby Powder products





In-Market Exposure Added Value cont...

Market	Station	Dial Position	Format	In-Market Events
Atlanta	WVEE-FM	103.3	Urban Adult Contemporary	Event: V103 Car and Bike Show on July 10, 2010 at 12n - 8pm Approximate Attendance: 25,000 (Distributed 3,100 Coupons)
				Event: Bonner Brothers International Hair Show on August 8, 2010 Approximate Attendance: 20,000 (Distributed 2,000 Coupons)
				Event: For Sisters Only on September 11-12, 2010 Approximate Attendance: 35,000 (Distributed 2,400 Coupons)
Dallas	KVIL-FM	103.7	Adult Contemporary	Event: July 4th on July 4, 2010 Approximate Attendance: 30,000 (Distributed 1,500 Coupons)
Dallas	KKDA-FM	104.5	Urban Adult Contemporary	Event: Summer Jam on July 31, 2010 Approximate Attendance: 6,000 (Distributed 3,400 Coupons)
				Event: KRNK Summer Concert on August 10, 2010 Approximate Attendance: 3,000 (Distributed 1,600 Coupons)
				Event: America's Next Top Model on July 17, 2010 at 10am Approximate Attendance: 100 - 150 (Distributed 50 Coupons)
Jackson, MS	WRBJ-FM	97.7	Urban Adult Contemporary	Event: Back to School on August 7, 2010 Approximate Attendance: 100 (Distributed 50 Coupons)
				Event: Picnic in the Lyons Park on August 14, 2010 4pm - 6pm Approximate Attendance: 1,000 (Distributed 500 Coupons)
Mobile	WBLX-FM	92.9	Urban Adult Contemporary	
Nashville	WUBT-FM	101.1	Urban Adult Contemporary	Event: Outside of Shoe Carnival, within Mall on August 14, 2010 12n - 2pm Approximate Attendance: 1,000 (Distributed 500 Coupons)



Thank you for partnering with TMPG on an
integrated promotional radio program for
JOHNSON'S® Baby Powder!

We look forward to building on the success of
this campaign and collaborating
on future programs!

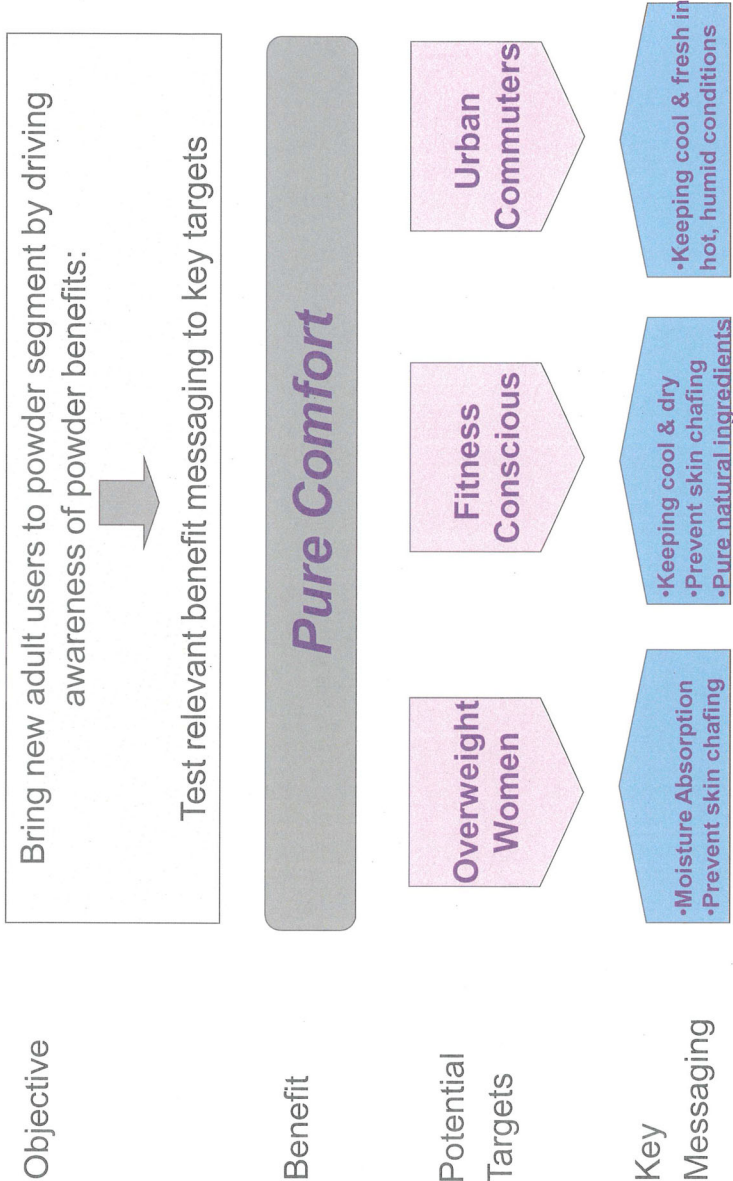
Cynthia Alecci Abramson
caabramson@tmpg.com
O.914.696.2385
M.917.620.0047

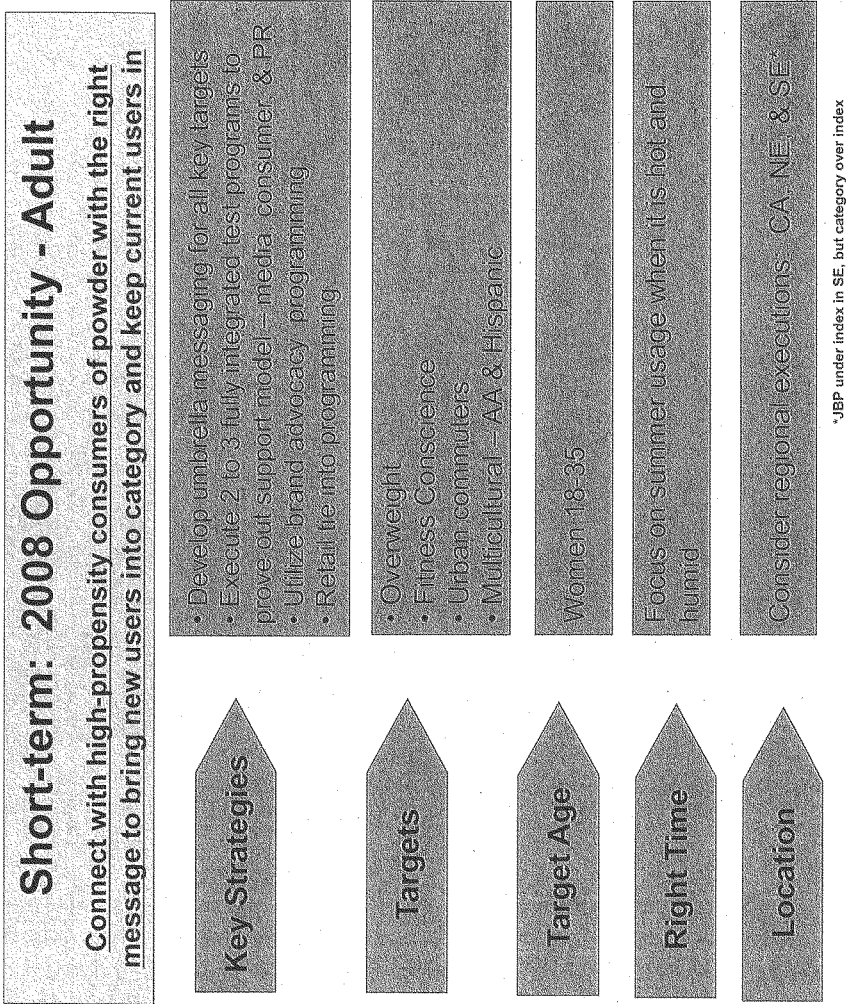




Johnson's Baby Powder Revitalization Plan

Project Pixie: JOHNSON'S BABY POWDER





*JBP under index in SE, but category over index

Umbrella Messaging: *Pure Comfort*

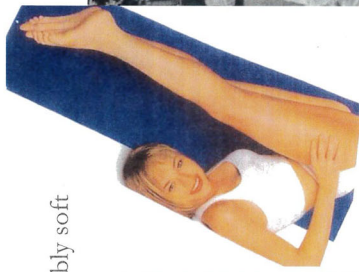
- Benefits most appreciated by both users and non users alike:
 - Staying fresh and dry,
 - Helping stay cool,
 - Fresh smell throughout the day,
 - Silky, soft and smooth skin,
 - Less chaffing and irritation between thighs and/or during exercise,
 - Keeping feet, shoes odor-free

- When we talked to users and non-users about what they liked most about powder – the benefit described always laddered up to comfort:
 - *“the comfort and confidence of feeling fresh”*
 - *“the comfort of staying cool and dry”*
 - *“skin comfort – i.e no chafing or irritation”*

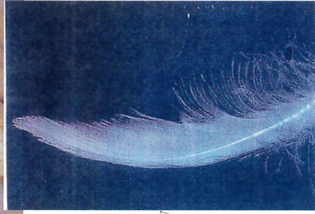
Images Chosen by Powder Users to depict how Powder made them feel



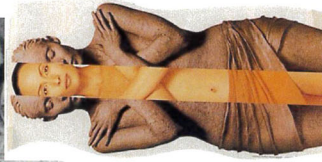
Clean, shower fresh, free, huggably soft



Comfortable, secure, safe, breaking free, natural and fresh



Light, gentle, soft, baby fresh



Images chosen by Users to depict how feel when not using powder: "Feel Less Comfortable When Not Use Powder"



Hiding, not want to be near people



Insights & Implications from Focus Groups

312

Focus Group Insights – Adult

Insight	Potential Implication
<ul style="list-style-type: none"> For current users first memories of powder usage tended to revolve around nostalgic, nurturing moments – it was a staple in their HH growing up 	<ul style="list-style-type: none"> Consider messaging that taps into this emotional connection to bring lapse users back into the segment.
<ul style="list-style-type: none"> Although lapse users had not used in over a year, they still had positive association of powder – many had simply forgotten the positive benefits of using 	<ul style="list-style-type: none"> Lapse users should be primary target as conversion will be much easier than non users
<ul style="list-style-type: none"> JBP users are very passionate about using powder – they grew up using and cannot imagine their life without it 	<ul style="list-style-type: none"> Current users are very loyal and use daily – growth opportunity is with lapse/non-users Should consider viral plan that taps into this passion for recruitment of non users

Focus Group Insights – Adult

2/28/2013 10:58:23 AM

Insight	Potential Implication
<ul style="list-style-type: none"> Many of the non-users had used powder on their baby, but did not think it was appropriate for them – “I don’t want to smell like a baby’s diaper” or “I don’t want to smell like a baby, I want to smell like a woman” 	<ul style="list-style-type: none"> Mom of baby is not the “way in” into households and just having in the house does not necessarily trigger adult usage
<ul style="list-style-type: none"> JBP users tended to use on other members of family – husband and children 	<ul style="list-style-type: none"> Consider family messaging and promotions where it makes sense
<ul style="list-style-type: none"> For adult non-users – a variety of fragrances broadened the appeal of powder 	<ul style="list-style-type: none"> In communication – consider highlighting different fragrances Consider tagging along with core fragrance play for 09

Focus Group Insights – Adult

Source: Focus Group Discussion

Insight	Potential Implication
<ul style="list-style-type: none"> Powder usage is very polarizing to non-users – need to have real need to add to current skin care regime 	<ul style="list-style-type: none"> Identify key targets that are likely to be receptive to messaging of cool, dry comfortable
<ul style="list-style-type: none"> Warm weather and/or conditions tend to be key triggers 	<ul style="list-style-type: none"> Maximize support timing & messaging to hit warm season
<ul style="list-style-type: none"> AA have high affinity for the category and tend to be heavy users 	<ul style="list-style-type: none"> Plan should have multicultural angle
<ul style="list-style-type: none"> “Long lasting” appeared to be desirable benefit to users and non user 	<ul style="list-style-type: none"> Consider line upgrade with long lasting technology

Focus Group Insights - Adult

Insight	Potential Implication
<ul style="list-style-type: none"> • People have no idea of what “medicated” is used for. 	<ul style="list-style-type: none"> • Potential repositioning; or renaming – give stronger reason for being
<ul style="list-style-type: none"> • Using puff appeared to be a way heavy users dealt with mess 	<ul style="list-style-type: none"> • Is there a way to do some type of promotion with tin and puff – maybe a contest?
<ul style="list-style-type: none"> • Mess continues to be a hurdle for non-users 	<ul style="list-style-type: none"> • Optimize packaging or form to minimize messiness factor

Johnson's Baby - Sampling

[illegible]

[illegible]

[illegible]

Congress of the United States

Washington, D.C. 20515

December 10, 2019

Mr. Alex Gorsky
Chairman and Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Dear Mr. Gorsky,

We are writing to express our deep concerns regarding the ingredients contained in some of your personal care products and their potential to cause harm, particularly to women, teenage girls, and people of color. Due to your failure to testify before Congress, you have significantly hindered our oversight of your company. Despite that, it is our constitutional responsibility to ensure that consumers are accessing safe and healthy products, especially cosmetics and personal care products that are used daily.

Currently, the average woman uses approximately twelve personal care products each day, resulting in exposure to one-hundred and sixty-eight unique chemical ingredients.¹ These exposures have been linked to cancer, infertility, miscarriage, poor infant and maternal health outcomes, obesity, asthma, and many other serious health concerns.² Women of color, who use a higher number of products daily, are disproportionately exposed to harmful chemicals through personal care products.³ A 2018 study released by the Breast Cancer Prevention Partners found that the most toxic product it tested was a children's shampoo from a hair-relaxing kit marketed to young black girls, containing carcinogens, hormone disruptors, and other toxins.⁴

More specifically, we have concerns about the health impacts of talc, as well as the fact that many talc products are contaminated with asbestos, a known carcinogen.⁵ As far back as 1987, talc-based cosmetic products containing asbestos have been classified as carcinogenic to humans by the International Agency for Research on Cancer (IARC), a branch of the World Health Organization. Subsequently, in 2006, IARC specifically confirmed perineal use of talc to

¹ "Personal Care Products Safety Act Would Improve Cosmetics Safety," Environmental Working Group, *available at* <https://www.ewg.org/Personal-Care-Products-Safety-Act-Would-Improve-Cosmetics-Safety>.

² "Why this matters – Cosmetics and your health", Environmental Working Group's Skin Deep, *available at* <https://www.ewg.org/skindeep/2011/04/12/why-this-matters/>; "Personal Care Products," Breast Cancer Prevention Partners, *available at* <https://www.bcphp.org/our-work/personal-care-products/>.

³ "Study: Women of Color Exposed to More Toxic Chemicals in Personal Care Products," Environmental Working Group, *available at* <https://www.ewg.org/enviroblog/2017/08/study-women-color-exposed-more-toxic-chemicals-personal-care-products>.

⁴ Right to Know: Exposing toxic fragrance chemicals in beauty, personal care and cleaning products, Breast Cancer Prevention Partners, *available at* https://d124kohvtz1951.cloudfront.net/wp-content/uploads/2018/09/26035904/BCPP_Right-To-Know-Report_Final-2_9.20.18.pdf.

⁵ IARC, Carbon Black, Titanium Dioxide, and Talc: Monographs on the Evaluation of Carcinogenic Risks to Humans, 2010.

Mr. Alex Gorsky
December 10, 2019
Page 2

be “possibly carcinogenic,” prompting talc-supplier Luzenac America Inc. to include that warning in its shipments to all customers, including Johnson & Johnson. However, the warning

was never passed on to consumers through your company’s product labels. Furthermore, the United States Food and Drug Administration (FDA) has repeatedly found cosmetics and personal care products marketed towards women and children were contaminated with asbestos—the most recent agency warning to consumers was released in October about a contaminated lot of your baby powder.⁶

As a result of the scientific evidence identifying asbestos-contamination in talc-based products and linking such contamination to increased cancer incidence, thousands of consumers have filed lawsuits against the manufacturers of personal care products containing talc.⁷ Juries around the country and several scientific studies have also found that exposure to baby powder causes increased risk of ovarian cancer and mesothelioma.⁸ More alarmingly, there have been repeated reports that you knew of the asbestos contamination for decades, yet continued to market and sell your talc-based products.⁹ Internal memorandums also show that after your company learned of asbestos contamination, marketing of talc-based products was specifically directed at Black and Latina women.¹⁰

In light of this troubling evidence, we ask you to provide the following documentation and answer the following questions no later than December 20, 2019:

1. Documents that your company filed in federal court revealed that in response to stagnating sales of baby powder, in 2008—two years after learning your talc-based products were possibly carcinogenic—Johnson & Johnson began a new marketing strategy aimed at Black and Latina consumers that involved direct ad buys and giveaways. One example of this strategy included 100,000 gift bags containing talc-based baby powder and other Johnson’s baby products that were distributed in Black and Latino neighborhoods in Chicago. In response to recent media reports around these practices, your company has said “we’re proud pioneers of the practice of multicultural marketing.”¹¹

⁶ FDA Alerts Consumers About Cosmetic Products Recalled due to the Presence of Asbestos, U.S. Food & Drug Administration, June 6, 2019, available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-alerts-consumers-about-cosmetic-products-recalled-due-presence-asbestos>; Baby powder manufacturer voluntarily recalls products for asbestos: FDA advises consumers to stop using affected products, October 18, 2019, available at <https://www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos>.

⁷ “Johnson & Johnson Has a Baby Powder Problem: More than 1,000 women are suing the company for covering up a cancer risk,” *Bloomberg*, March 31, 2016, available at www.bloomberg.com/features/2016-baby-powder-cancer-lawsuits/; Mesothelioma Cancer Alliance, Asbestos in Talcum Powder, March 29, 2019, Available at <https://www.mesothelioma.com/asbestos-exposure/products/talc-powder/>.

⁸ House Panel Takes Up Talc Safety, *Law.Com*, March 12, 2019, available at <https://www.law.com/2019/03/12/house-panel-takes-up-talc-safety/>.

⁹ “Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder,” *Reuters*, December 14, 2018, available at <https://www.reuters.com/investigates/special-report/johnsonandjohnson-cancer/>;

¹⁰ “Special Report: As Baby Powder concerns mounted, J&J focused marketing on minority, overweight women,” *Reuters*, April 9, 2019, available at www.reuters.com/article/us-johnson-johnson-marketing-specialrepo/special-report-as-baby-powder-concerns-mounted-jj-focused-marketing-on-minority-overweight-women-idUSKCN1RL1JZ.

¹¹ “Special Report: As Baby Powder concerns mounted, J&J focused marketing on minority, overweight women,” *Reuters*, April 9, 2019, available at www.reuters.com/article/us-johnson-johnson-marketing-specialrepo/special-report-as-baby-powder-concerns-mounted-jj-focused-marketing-on-minority-overweight-women-idUSKCN1RL1JZ.

Mr. Alex Gorsky
December 10, 2019
Page 3

- Please provide internal documents detailing your company's "multicultural marketing" strategy, including information on money spent, geographic communities targeted, and all advertising materials utilized.
2. While engaged in your targeted marketing campaign, you concluded the "right place" to focus were areas with a "higher [African American] population" and that "powder is still considered a relevant product among [African American] consumers. This could be an opportunity." You focused on "ethnic (African American/Hispanic) opportunities to grow the franchise." To expand sales among Black and Latina women, your company distributed samples in Black and Latino neighborhoods, ran print and digital campaigns, enlisted paid radio advertisements to reach "curvy Southern women 18-49, skewing African American," and enlisted third parties, including Weight Watchers.¹²
 - Please provide any materials related to this marketing campaign or any similar marketing campaign conducted by your company, including:
 - All marketing plans targeting Black and/or Latina women;
 - Contracts, cooperative agreements, or other documents by which your company engaged the services of third parties to promote talc-containing products to Black and/or Latina women, including Weight Watchers;
 - Print, radio, television, or digital advertisements that feature Black and/or Latina women and promote the sale of talc-containing products; and
 - Any other marketing materials which promote the sale of talc-containing products to Black and/or Latina women.
 3. Your company continues to contend that your products produced with talc are asbestos free.¹³ However, based on evidence and testimony received during the March 12, 2019 House Committee on Oversight and Reform's Subcommittee on Economic and Consumer Policy hearing entitled, "Examining the Public Health Risks of Carcinogens in Consumer Products," we are deeply troubled by this claim.
 - When you claim your products are asbestos free does this mean your baby powder contains absolutely no asbestos whatsoever; your testing of talcum powder does not show the presence of asbestos; your talcum powder may contain up to one percent asbestos; or something else entirely?
 - Please describe your protocol for testing talc for potential asbestos contamination and when these processes were put in place; specifically, the steps you have taken in the past and now take in order to guarantee that no asbestos, in any quantity, will ever be found in your talc-containing products. Please also provide written documentation demonstrating that these steps are indeed effective and support your claim.
 - Please include how frequently you test the talc you use to ensure it is not contaminated by asbestos at dangerous levels; what the quantities of talc that you

¹² "Special Report: As Baby Powder concerns mounted, J&J focused marketing on minority, overweight women," *Reuters*, April 9, 2019, available at www.reuters.com/article/us-johnson-johnson-marketing-specialrepo/special-report-as-baby-powder-concerns-mounted-jj-focused-marketing-on-minority-overweight-women-idUSKCN1RL1JZ.

¹³ "Johnson & Johnson CEO testified Baby Powder was safe 13 days before FDA bombshell," *Reuters*, October 22, 2019, available at <https://www.reuters.com/article/us-johnson-johnson-talc-ceo-insight/johnson-johnson-ceo-testified-baby-powder-was-safe-13-days-before-fda-bombshell-idUSKBN1X12GF>.

Mr. Alex Gorsky
December 10, 2019
Page 4

test are; and whether you test mined talc, processed talc, or the finished product itself for asbestos contamination.

- Please provide all test results from 2006 to present day, including information regarding what type of testing is done to certify your talc is not contaminated by asbestos. If you have destroyed these test results or refuse to provide any results, please provide your rationale for doing so.

It is imperative that cosmetics and personal care products receive additional scrutiny in order to better ensure their safety. Toward that end, the *Safe Cosmetics and Personal Care Products Act of 2019* (H.R. 4296), introduced on September 12, 2019, establishes a robust regulatory framework to ensure the safety of cosmetics and personal care products. This framework demands accountability and includes a strong safety standard for cosmetic ingredients that is protective of all consumers, and in particular, vulnerable subpopulations like women of color and professional salon workers. This bill was considered during the December 4, 2019 House Committee on Energy and Commerce Subcommittee on Health legislative hearing entitled, "Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety."

However, this bill and other proposed federal cosmetic safety legislation is currently under consideration by Congress. While we are encouraged that you recalled 33,000 bottles of your baby powder for the first time ever in October after FDA detected asbestos contamination, your recent press release about new safety tests that supposedly refute FDA's findings suggests that you intend to put these products back on the market.¹⁴ We urge you not to do so. Furthermore, until FDA is given more statutory authority to conduct cosmetic ingredient safety review and mandatory recall, we emphatically urge you to voluntarily warn consumers about the inhalation hazard and risk of cancer posed by your talc-based products. These warnings must be explicit and readily available on product labels so that consumers can make informed decisions about the products they put on their bodies. We also urge you to immediately halt all deceptive marketing practices specifically targeting women and young girls of color. *All* American women deserve personal care products that are safe.

Thank you in advance for your attention to this matter. If you have any questions or would like to further discuss compliance with this request, please contact Osaremen Okolo with Congresswoman Schakowsky at (202) 225-2111 or Lynese Wallace with Congresswoman Pressley at (202) 225-5111.

Sincerely,


 JAN SCHAKOWSKY
 Member of Congress


 AYANNA PRESSLEY
 Member of Congress

¹⁴"Johnson & Johnson Recalls Baby Powder Over Asbestos Worry," *New York Times*, October 18, 2019, <https://www.nytimes.com/2019/10/18/business/johnson-johnson-baby-powder-recall.html>; Company Investigation Confirms No Asbestos in Johnson's Baby Powder, Johnson & Johnson, December 3, 2019, available at, <https://www.jnj.com/company-investigation-confirms-no-asbestos-in-johnsons-baby-powder>.



January 28, 2019

The Honorable Frank Pallone
Chairman, House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Anna Eshoo
Chairwoman, House Subcommittee on Health
202 Cannon House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
Ranking Member, House Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Michael Burgess
Ranking Member, House Subcommittee on Health
2161 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Pallone, Chairwoman Eshoo, Ranking Member Walden, and Ranking Member Burgess:

We are writing to express our support for the Safeguard American Food Exports (SAFE) Act, H.R. 961, led by Rep. Schakowsky (D-IL) and Rep. Vern Buchanan (R-FL), on January 29th, and to thank you for holding a hearing on this important bill. Our team at Animal Wellness Action and Animal Wellness Foundation has advocated tirelessly in support of this bill for many years. This Congress, the bill has been on our priority list since day one, and we've met with over 350 offices since January 2019 to garner cosponsors for the bill.

Public opinion stands firmly against the slaughter of American horses, and most are shocked to know that tens of thousands of horses – racehorses, show horses, and even companion ponies – are sent across the border each year to be slaughtered for human consumption. Horse slaughter is nothing but cruelty and suffering, from the long grueling transport without food or water, to the slaughter process itself where these frightened, skittish animals suffer multiple blows to be rendered unconscious. Not only are domestic horses subjected to this, but now some groups have put forth a dangerous proposal to roundup 130,000 wild horses, putting

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them at great risk of slaughter. It's a horrific end and a deep betrayal to an animal that has served us throughout history and stands as a symbol of freedom and our country's heritage.

It's far overdue time to pass this bill. In 2006, a bill to ban horse slaughter passed the House but was never taken up in the Senate. Even Vice President Mike Pence, then a U.S. House Member from Indiana, voted in support of the bill. Over the last few years, we've seen congressional support grow for the bill, which now touts well over 200 cosponsors. Congress has also routinely included language in the final yearly spending bill to defund horse slaughter, thereby keeping horse slaughter plants closed in the U.S. – but that is a temporary, partial solution. Instead of dealing with this issue every single year, Congress should pass the SAFE Act to permanently defund horse slaughter and stop horses from being sent over the border.

Thank you for holding a hearing on the SAFE Act, and we are also thankful for the hearing on the Horseracing Integrity Act on January 28th. We hope you will move both of these bills to the full committee and floor for passage.

Please feel free to contact us at holly@animalwellnessaction.org should you have any questions.

All the best,



Marty Irby
Executive Director



Holly Gann
Director of Federal Affairs

reuters.com

Exclusive: Sri Lanka halts imports of Johnson & Johnson Baby Powder pending asbestos tests

Reuters Editorial

COLOMBO (Reuters) - Sri Lanka has halted imports of Johnson & Johnson Baby Powder until the company proves its product is free from cancer-causing asbestos, two government officials and the product's local distributor told Reuters.



A bottle of Johnson and Johnson Baby Powder is seen in a photo illustration taken in New York, February 24, 2016. REUTERS/Mike Segar/Illustration

Stocks of the product already in Sri Lanka can still be sold, but there will be no new imports of the talc, a popular healthcare product across Sri Lanka and much of Asia, until J&J India, from where Sri Lanka imports the product, provides fresh test results.

On Dec. 14, Reuters reported that the U.S. drugs and consumer products group knew for decades that asbestos lurked in its Baby Powder, leading to tests in several countries, including in India.

The report was based on thousands of pages of company memos, internal reports, and other confidential documents.

J&J has described the Reuters story as “one-sided, false, and inflammatory”.

Kamal Jayasinghe, chief executive of Sri Lanka’s National Medicine Regulatory Authority (NMRA), which is part of the health ministry, said it had informed the distributor, A.Baur & Co., that it would require further tests for it to continue importing the powder.

“We have held their re-registration and informed the distributor to submit quality reports from an accredited laboratory to ensure there is no asbestos in their products,” Jayasinghe told Reuters.

The license for A.Baur & Co to import the product expired in December, a second person at the NMRA said.

Shalutha Perera, head of consumer for A.Baur, told Reuters the firm has informed J&J in India of the suspension of the licensing process.

“J&J India directly handles all the regulatory matters,” he said.

Perera said the NMRA contacted A.Baur in December regarding new asbestos testing.

A spokeswoman for J&J India declined to comment on the halt of shipments to Sri Lanka but said the company “is in full compliance with current Indian regulatory requirements for the manufacturing and testing of our talc”.

“We are fully cooperating with the Indian government and are awaiting results from their testing,” she added.

The spokeswoman said the product was routinely tested by both suppliers and independent labs to ensure it is free of asbestos.

COVINGTON

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December 20, 2019

The Honorable Janice Schakowsky
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Ayanna Pressley
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Schakowsky and Representative Pressley:

On behalf of our client, Johnson & Johnson, and its subsidiary Johnson & Johnson Consumer Inc., this letter and the accompanying materials respond to your letter of December 10, 2019. Johnson & Johnson takes very seriously the issues raised in your letter regarding the safety of its personal care products, including Johnson's Baby Powder. Johnson & Johnson is deeply committed to the health of consumers and the safety of Johnson's Baby Powder. Decades of independent scientific testing have shown that Johnson's Baby Powder is safe and not contaminated with asbestos.

As you may know, Johnson & Johnson has dedicated significant resources to providing the public with open and transparent information regarding Johnson's Baby Powder, talc, and talc safety, including through a dedicated website, Facts About Talc (www.factsabouttalc.com), where the company has publicly posted more than 2,000 documents. Just this month, Johnson & Johnson posted information concerning the comprehensive investigation that it conducted in response to a report by the FDA finding sub-trace levels of asbestos (no greater than 0.00002%) in samples from a single bottle of Johnson's Baby Powder. Johnson & Johnson Consumer Inc. promptly recalled the entire lot as a precautionary measure. Over the course of the ensuing investigation, a total of 155 tests were conducted by two different third-party laboratories using four different testing methods on samples from (1) the same bottle tested by the FDA's contractor, (2) the recalled lot of Johnson's Baby Powder, (3) three lots manufactured before the recalled lot, and (4) three lots manufactured after the recalled lot. All of the 155 test results confirm no asbestos in Johnson's Baby Powder, as detailed on Facts About Talc.

As noted in your letter, the issue of talc safety has also been the subject of extensive discovery in civil litigation. We have drawn on these previously collected materials in an effort to respond to your letter quickly. Today's production provides materials in response to each of the requests in your letter. If you have additional questions or requests after reviewing the materials being provided today, Johnson & Johnson stands ready to work with you to address any additional questions or requests that you may have. Today's production, numbered JNJ_H_12_000001 to JNJ_H_12_027202, responds to your requests as follows.

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The Honorable Janice Schakowsky
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In response to the requests in items one and two of your letter, we are providing documents assembled by reviewing materials identified to plaintiffs in civil litigation as potentially relating to marketing plans that discuss various consumer segments. Additionally, we are producing documents that have been identified to plaintiffs in civil litigation as related to promotional advertisements for Johnson's Baby Powder. Please note that it is our understanding that not all of the advertisements contained in today's production were used in actual advertising.

Regarding the marketing issues raised in your letter, it is important to note that Johnson & Johnson's consumer products are marketed to all Americans. To reach consumers, Johnson & Johnson Consumer Inc. conducts market research to understand the consumers who use its products, and the company develops advertising that is meaningful to its customers. Marketing for Johnson's Baby Powder has included advertising that is multicultural and inclusive. The company believes in marketing to all communities that use its products, and it is proud to market its products in an inclusive manner, just as it promotes inclusion in its internal hiring and development. Johnson & Johnson and Johnson & Johnson Consumer Inc. believe that marketing to every community is a sign of respect, and are proud to embrace multicultural marketing. Johnson & Johnson and Johnson & Johnson Consumer Inc. seek to appeal to diverse audiences and advertise in media outlets that reach a broad range of communities. To the extent that anyone, including outside advertising consultants engaged in the past, has failed to show respect for all of the company's customers, the company rejects and repudiates such statements.

Regarding the questions in item three of your letter, the talc used in Johnson's Baby Powder is sourced only from carefully selected mines that are subjected to rigorous testing with respect to asbestos. For decades, Johnson's Baby Powder has been repeatedly tested and found not to contain asbestos, meaning that asbestos has not been detected using the best scientific methods available. The industry standard for testing, called CTFA J-41, requires the use of X-Ray Diffraction and, where necessary, Polarized Light Microscopy. The cosmetic talc used in Johnson's Baby Powder is tested through a combination of X-Ray Diffraction and Polarized Light Microscopy and, since the 1970s, the additional test of Transmission Electron Microscopy. Notably, by using Transmission Electron Microscopy, Johnson & Johnson Consumer Inc. has exceeded the industry standard for talc testing. The company's routine talc testing has several steps. Since the 1970s, samples of cosmetic talc have been taken every hour from Johnson & Johnson Consumer Inc.'s talc processing facilities for asbestos testing. Samples of ground talc ore are combined and tested regularly and that practice continues today, through testing conducted by the company's current talc suppliers. As an added safeguard, Johnson & Johnson Consumer Inc. requires additional quarterly testing by independent, third-party laboratories on its cosmetic talc. The company tests the sites where its cosmetic talc is mined, the raw ore taken out of the earth, and the milled powder before it is bottled. In total, Johnson & Johnson Consumer Inc., its suppliers, and independent labs have tested composites of hundreds of thousands of samples since the early 1970s, and the tests have consistently shown that Johnson's Baby Powder does not contain asbestos. In response to your request in item three, today's production includes certificates of analysis from approximately October 2009 to March 2017 reflecting asbestos testing of the talc used in Johnson's Baby Powder.

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Please note that today's production includes documents with redactions or notations of documents withheld for privilege as they appeared in the underlying litigation productions. Several of the documents additionally contain confidential indicators, again from the underlying productions in connection with litigation. These and other documents may contain confidential business information that Johnson & Johnson considers proprietary and competitively sensitive. Disclosure of such information could cause competitive harm to the company and distortions in the marketplace. Accordingly, Johnson & Johnson respectfully requests that the materials produced today be treated as confidential. If you should nonetheless consider the public release of these materials, we respectfully request that Johnson & Johnson be given advance notice and an opportunity to discuss the matter with you.

Johnson & Johnson appreciates the opportunity to address these important matters relating to the safety of its cosmetic talc products. Please let us know if you have any questions regarding the information and materials being provided today.

Sincerely,


Brian D. Smith

Attachments—Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Improving Safety and Transparency in America’s Food and Drugs”
January 29, 2020**

**Kao-Ping Chua, MD, PhD
Assistant Professor, Department of Pediatrics
University of Michigan**

The Honorable Ann Kuster (D-NH)

Dr. Chua, 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.

1. 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

Thank you for the opportunity to address these excellent questions. There are two main ways in which high prices can impede access to buprenorphine-based treatment of opioid use disorder. The first is that high prices may prompt insurers to not cover buprenorphine drugs or to enact barriers such as prior authorization. Some insurers, for example, refuse to cover Sublocade due to its high price.

The second is that high prices can increase the amount that patients have to pay out-of-pocket. For example, when insurance plans have deductibles for prescription drugs, patients often have to pay the full list price of drugs until they meet the deductible. Even after the deductible is met, patients often have to pay a percentage of a drug’s price through co-insurance. Recently, we analyzed out-of-pocket spending for buprenorphine among a national sample of privately insured patients with opioid use disorder (<https://www.healthaffairs.org/doi/10.1377/hblog20200302.846103/full>). In this analysis, we found that patients paid an average of \$48 every time they filled a Suboxone prescription and \$101 every time they had a monthly injection of Sublocade. This substantial out-of-pocket spending suggests that the high prices charged for buprenorphine products may deter initiation of buprenorphine treatment and/or adherence to treatment.

The question regarding how orphan drug policy has contributed to the high prices of buprenorphine products is an important one. U.S. drug prices are strongly correlated with

Kao-Ping Chua, M.D., Ph.D.
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market power. When there is a monopoly with no competitors, drug companies can charge whatever the market will bear. The 1994 orphan drug designation for Subutex and Suboxone, coupled with their 2002 orphan approvals under these designations, effectively gave their sponsor Reckitt-Benckiser a monopoly by providing seven years of orphan drug exclusivity. During this period, no competitors were able to make an alternative version of Subutex or Suboxone to treat opioid use disorder. Both of the 1994 designations for Subutex and Suboxone were granted via the “cost-recovery” prong because the drugs supposedly had limited sales potential, but both drugs ultimately had strong sales – particularly Suboxone.

Indivior’s Sublocade was grandfathered Subutex’s orphan drug designation upon approval in 2017. Consequently, Sublocade was entitled to orphan drug exclusivity. Had this exclusivity been granted, competitors would have been blocked from marketing alternative buprenorphine products to treat opioid use disorder until 2024, thus allowing Indivior to charge high prices for a prolonged period. Fortunately, because FDA revoked Subutex’s designation, Sublocade is no longer eligible for orphan drug exclusivity, and competing buprenorphine products will now be able to enter the market in December 2020 (including Braeburn Pharmaceutical’s extended-release buprenorphine injection product, Brixadi). Based on prior experience, the entry of competitors should decrease prices for extended-release buprenorphine products, facilitating access to buprenorphine-based treatment of opioid use disorder.

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 the monopoly established by the gaming of the Orphan Drug Act.

2. Dr. Chua, how might the entrance of new formulations of buprenorphine improve treatment in vulnerable populations?

This is a very important question. There are two major advantages of extended-release buprenorphine products. The first is that they can increase adherence to treatment. Most buprenorphine products must be taken daily. In contrast, Sublocade is given monthly, and Braeburn’s Brixadi is given either weekly or monthly. For some patients, it will be easier to receive an injection in an office every week or every month than to remember to take buprenorphine every day.

The second advantage is that extended-release buprenorphine products stay in the provider’s office, making them hard to divert. In contrast, immediate-release buprenorphine products such as Subutex and Suboxone are in the patient’s possession. While the majority of patients do not divert buprenorphine, increased reliance on extended-release buprenorphine products and decreased reliance on immediate-release products could decrease the risk of diversion among the few patients who engage in this behavior.

3. And is the legislation that we considered at this hearing effective in closing the loophole that has prevented other companies from entering the market with new formulations?

Yes. HR 4712 and its companion bill in the Senate would permanently close the loophole that allowed Sublocade to become an orphan drug. Under the legislation, sponsors of a new drug who apply for orphan approval under a previously granted cost-recovery prong designation would have to prove there is no reasonable expectation *at the time of approval* that the lifetime sales of the new drug would be sufficient to recover development and production costs. Under current policy, Indivior theoretically could develop a new formulation of buprenorphine-naloxone (Suboxone) and automatically obtain orphan approval under Suboxone's 1994 cost-recovery prong designation, just as it did for Sublocade under Subutex's cost-recovery prong designation. If the bills were enacted, Indivior would have to argue that the new formulation of Suboxone was unlikely to be profitable, but this would be challenging because Suboxone is a blockbuster drug with billions of sales to date.

Additionally, HR 4712 and its companion bill in the Senate would permanently block the possibility of Sublocade receiving orphan drug exclusivity even in the event of successful litigation by Indivior. Within 60 days of the legislation's enactment, sponsors of orphan drugs approved under a prior cost-recovery prong designation would be required to submit cost-recovery analyses proving that there was no reasonable expectation at the time of approval that lifetime sales of the drug would be sufficient to recover development and production costs. Under current policy, if Indivior successfully sues FDA for revoking Subutex's orphan drug designation, Sublocade would again be entitled to orphan drug exclusivity. If the bills were enacted, Indivior would not receive exclusivity for Sublocade unless the company could argue that the drug was unlikely to be profitable based on data available at the time of approval in November 2017. Such an argument would be difficult to make, as Indivior projected in February 2018 that Sublocade's peak annual sales would exceed \$1 billion.

Attachments—Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Improving Safety and Transparency in America’s Food and Drugs”
January 29, 2020**

**Rich Kaeser
Vice President, Global Brand Protection
Johnson & Johnson**

The Honorable Larry Buchson (R-IN)

In your testimony you discussed Johnson & Johnson's work in Bangladesh seizing counterfeit contact lenses.

1. Where are the most vulnerable points of entry in the legitimate supply chain for counterfeit contact lenses to enter?
2. Are these specific points of sale that are riskier or less regulated than others?

Response from Johnson & Johnson:

At Johnson & Johnson, our Vision Care company serves more than 50 million patients across 103 countries with the gift of clear sight through our ACUVUE® Brand contact lenses. While contact lenses are an everyday item for many patients, they are still complex medical devices. As you may be aware, in the United States, the FDA classifies contact lenses as Class II and Class III medical devices that require a prescription for dispensing. The authenticity of a contact lens brand is critical for patient safety, because each brand is designed based upon unique combinations of material and design properties to suit individual patient’s eye physiology, anatomy, and lifestyle needs. At Johnson & Johnson Vision, we’re dedicated to manufacturing high-quality products that meet or even exceed government standards, so patients not only feel safe, but have a consistent experience with their lenses every day.

To best serve our patients, we work to ensure that our global supply chain, which crosses six continents, is safe and secure. Our Global Brand Protection team monitors active complaints as well as proactively implements preventative measures. We also collaborate with regulatory, law enforcement agencies, industry, distributors, and patients to combat the threat of counterfeit devices and products. Currently, Johnson & Johnson Vision is not aware of counterfeit issues directly affecting its products in the United States.

However, despite these and other efforts, in today’s global marketplace, we are likely to continue to see counterfeit contact lenses become more prevalent and sophisticated. According to the

Mr. Rich Kaeser

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World Health Organization, the illicit trade of health care products is difficult to quantify but is growing. In fact, health care products are the 6th most targeted counterfeit category—and included in that, are contact lenses. Online marketplaces have made for ideal storefronts for selling counterfeit products, because in the e-commerce space, most of the time the seller is invisible. We're working to combat this threat by using programs that scan our products to make sure they're authentic and safe, and advanced analytics and algorithms to determine whether product images and listing information online are suspicious and might need further investigation. We're also constantly monitoring and taking down illicit internet sites and listings.

We look forward to continuing to work with our partners in industry, law enforcement, and Congress to address the threats posed by counterfeit goods sold online to patients and consumers.

Attachments—Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Improving Safety and Transparency in America’s Food and Drugs”
January 29, 2020**

**Tom Balmer
Executive Vice President
National Milk Producers Federation**

The Honorable Ann Kuster (D-NH)

I’ve visited family dairies around my district and heard from farmers about how important the DAIRY PRIDE Act is. Right now, they are being hit hard by tariff trade wars, more erratic weather and climate patterns, and other factors. The survival of these farms, some of them passed down in families for generations, is being challenged in ways never seen before. New Hampshire has less than 100 dairy farms with an average of 130 cows per farm. That represents a substantial decline in our state, even in just the last decade alone. That said, the perseverance and determination of these farmers is absolutely inspiring. And I’m proud to say milk remains the Granite State’s number one agricultural product. I think it’s very important to note that dairy producers are not trying to eliminate competition. Rather, they deserve to have their products accurately represented, just as consumers deserve transparency with what they are buying off the grocery store shelves. By definition, “milk” and dairy products come from cows and other animals. They contain a nutritional value that plant-based beverages do not. This distinction has public health implications, and it is important to correct the record on what is or isn’t milk.

1. With that in mind, Mr. Balmer, can you explain in detail the consumer confusion issue? Do you believe that consumers mistakenly think that plant-based products contain cow’s milk?

Thank you, Rep. Kuster, for this question and for your support of the DAIRY PRIDE Act. We fully agree with you regarding the importance of transparent labeling to provide accurate information to consumers as they make purchases in stores. To that point, we have argued that consumers do not have an accurate understanding of the nutritional profile of these alternative products relative to dairy products. Consumer survey data backs this up significantly. I noted in my testimony that a 2018 survey found that 73% of consumers surveyed have a false understanding of the protein content of almond-based beverages, mistakenly believing that such products have a higher protein content than milk when milk actually has up to eight times as much protein. A follow up survey found that half of consumers surveyed mistakenly believe that the main ingredient in a plant-

Mr. Tom Balmer
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based beverage is the plant itself, when in reality these drinks are mostly flavored water. Contrary to what others have stated, we have not alleged that most consumers believe plant-based products contain cow's milk.

Attachments—Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Improving Safety and Transparency in America’s Food and Drugs”
January 29, 2020**

**Melanie Benesh
Legislative Attorney
Environmental Working Group (EWG)**

The Honorable Ann Kuster (D-NH)

Unfortunately, communities in New Hampshire are all too familiar with the risks posed by exposure to PFAS chemicals. Parents already live in fear wondering whether or not their children are drinking water contaminated with these harmful forever chemicals. So, you can imagine how alarming it is to learn that these same chemicals are in food packaging like popcorn bags.

1. Ms. Benesh, what are food companies doing to respond to the risks of PFAS in food packaging?

Answer: Responsible retailers abandoning PFAS. Burger King reportedly stopped using PFAS-coated paper in 2002,¹ and McDonald’s pledged to move to PFAS-free coatings in 2006.² Panera has started the process for switching to PFAS-free baguette bags and will continue to transition to PFAS alternatives in 2020.³ Taco Bell will also phase out PFAS by 2025.⁴ In December 2018, both Whole Foods and Trader Joe’s stated that they were working toward PFAS-free packaging.⁵ Ahold Delhaize (parent company of Food Lion, Giant Food, GIANT/MARTIN’S, Hannaford, Peapod and Stop & Shop, and its U.S. services company, Retail Business Services) announced in September that it would put a restriction on PFAS and other chemicals.⁶ As of Jan. 1, 2020, the

¹ Callie Lyons, *Stain-Resistant, Nonstick, Waterproof, and Lethal: The Hidden Dangers of C8* at 113 (Praeger 2007), <https://epdf.pub/stain-resistant-nonstick-waterproof-and-lethal-the-hidden-dangers-of-c8.html>.

² Sara Schaefer Muñoz, *EPA Probes Safety of Key Chemical in Teflon*, Wall Street Journal (Jan. 31, 2006).

³ Mind the Store, Retailer Report 2019, Panera Bread <https://retailerreportcard.com/retailer/panera-bread/> (last visited Jan. 25, 2020).

⁴ Press Release, Taco Bell® Rings in 2020 With Bold New Commitments (Jan. 9, 2020), <https://www.tacobell.com/news/taco-bell-2020-commitments?selectedTag=&selectYear=2020>.

⁵ Mike Schade & Laurie Valeriano, *Whole Foods, Trader Joe’s Pledge Initial Action on Toxic PFAS*, Safer Chemicals Healthy Families (Dec. 12, 2018), <https://saferchemicals.org/2018/12/12/whole-foods-trader-joes-pledge-initial-action-on-toxic-pfas/>.

⁶ Press Release, Ahold Delhaize USA Brands Announce Commitment to Sustainable Chemistry, Transparent Products and Packaging (Sept. 19, 2019), <http://www.globenewswire.com/news-release/2019/09/19/1918074/0/en/Ahold-Delhaize-USA-Brands-Announce-Commitment-to-Sustainable-Chemistry-Transparent-Products-and-Packaging.html?culture=en-us>.

Ms. Melanie Benesh

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Biodegradable Products Institute will no longer certify any product as compostable if it contains intentionally added PFAS.⁷

2. Are states doing anything to address the problem of PFAS in food packaging?

Answer:

States are not waiting for Congress to take action. Washington state was the first to ban PFAS in 2018, which will take effect in 2022.⁸ Maine also passed a law authorizing the state Department of Environmental Protection to ban PFAS in food packaging as early as 2022.⁹ San Francisco has banned bowls that have been intentionally manufactured using PFAS.¹⁰ California is considering reviewing and regulating PFAS in food packaging under its green chemistry law.¹¹

Arizona, Connecticut, Illinois, Iowa, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Virginia, and Wisconsin are all considering bans on PFAS in food packaging.¹² New York and Connecticut both have procurement policies limiting or restricting PFAS in food packaging.

3. Lastly, could you confirm whether or not we really need PFAS chemicals in food packaging?

Answer: Food packaging is a non-essential use of PFAS.¹³ Several materials can be used as PFAS alternatives, polyethylene, bamboo, palm leaf, bio-wax, and polylactic acid (PLA) –which is a compostable bio-based material derived from renewable substances like potato, wheat and corn starch.¹⁴ In many cases, packaging materials can also simply be used without a coating material.

Grease-resistant food contact paper and paperboard free of PFAS has been available for more than a decade. When EWG and other groups tested paper food wrappers for PFAS in 2014-2015,

⁷ Biodegradable Products Institute, Fluorinated Chemicals, <https://bpiworld.org/Fluorinated-Chemicals> (last visited April 7, 2020).

⁸ H.B. 2658 (Wash. 2018).

⁹ H.P. 1043, 129th Leg. (Maine 2019).

¹⁰ City of San Francisco, Ordinance 201-18 (File No. 180519)(Aug. 10, 2018).

¹¹ Department of Toxic Substances Control, Safer Products & Workplaces Program, *Work Plan Implementation: Food Packaging with Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs)* (Oct. 24, 2019), https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/10/Food-Packaging_Perfluoroalkyl-and-Polyfluoroalkyl-Substances-PFASs.pdf.

¹² See Safer States, Bill Tracker, <https://www.saferstates.org/bill-tracker/FilterBills> (last visited April 7, 2020).

¹³ Ian T. Cousins et al., *The Concept of Essential Use for Determining When Uses of PFAS Can Be Phased Out*, 21 *Env't'l Science: Processes and Impacts* 1803 (2019),

<https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h#divAbstract>.

¹⁴ See, e.g., Center for Environmental Health, *Avoiding Hidden Hazards: A Purchaser's Guide to Safer Foodware* (January 2018), <https://www.ceh.org/wp-content/uploads/2019/05/CEH-Disposable-Foodware-Report-final-1.31.pdf>

Ms. Melanie Benesh

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tests detected no fluorine in more than half of the paper.¹⁵ This indicates that the PFAS-free paper is readily available and competitively priced.

The Biodegradable Products Institute, as of January 2020, no longer certifies food service products as compostable if they contain any intentionally added PFAS.¹⁶ Even so, there are dozens of companies offering clamshells, plates, coffee cups, pizza boxes, takeout containers, and other food packaging materials in BPI's catalog.¹⁷

¹⁵ Laurel A. Schaidt et al., *Fluorinated Compounds in U.S. Fast Food Packaging*, 4 *Env'tl Sci. and Technology Letters* 105 (2017), <https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.6b00435>.

¹⁶ Biodegradable Products Institute, Fluorinated Chemicals, <https://bpiworld.org/Fluorinated-Chemicals> (last visited April 7, 2020).

¹⁷ Biodegradable Products Institute, Catalog, <http://products.bpiworld.org/> (last visited April 7, 2020).

