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House Committee on Energy and Commerce

Improving Safety and Transparency in America's Food and Drugs

January 29, 2020

10:00 am, 2322 Rayburn House Office Building

Purpose

The purpose of this hearing is to examine and discuss 10 pieces of legislation; H.R. 961, the "Safeguard American Food Exports Act of 2019", H.R. 1769, the "Defending Against Imitations and Replacement of Yogurt, Milk, and Cheese to Promote Regular Intake of Daily Everyday Act" or the "DAIRY PRIDE Act", H.R. 2117, the "Food Allergy Safety, Treatment, Education, and Research Act of 2019" or 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", H.R. 4487, the "Codifying Useful Regulatory Definitions Act" or the "CURD Act", H.R. 4712, the "Fairness in Orphan Drug Exclusivity Act", H.R. 4866, the "National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2019", H.R. 5663, the "Safeguarding Therapeutics Act", H.R. 5668, the "Making Objective Drug Evidence Revisions for New Labeling Act of 2020" or the "MODERN Labeling Act of 2020"

Members Present

Chairman Eshoo, Ranking Member Burgess, Representatives Guthrie, Dingell, Walden, Schrader, Upton, Matsui, Welch, Kuster, Griffith, Bucshon, Kelly, Bilirakis, Barragan, Brooks, Blunt-Rochester, Carter, Engel, Shimkus, Schakowsky, Long,

Witnesses

Panel I

Jeff Allen, Ph.D., President and CEO, Friends of Cancer Research
Richard Kaeser., Vice President, Global Brand Protection, Johnson & Johnson
Fernando Muzzio, Ph.D., Distinguished Professor, Chemical and Biochemical Engineering Rutgers, the State University of New Jersey
Kao-Ping Chua, M.D., Ph.D., Assistant Professor, Department of Pediatrics University of Michigan Medical School

Panel II

Melanie Benesh., Legislative Attorney, Environmental Working Group
Tom Balmer., Executive Vice President, National Milk Producers Federation
J. David Carlin., Senior Vice President of Legislative Affairs and Economic Policy, International Dairy Foods Association
Douglas Corey, D.V.M., Past President, American Association of Equine Practitioners
Talia Day., Patient Advocate
Paul C. DeLeo, Ph.D., Principal, Integral Consulting, Inc.
Mardi Mountford., President, Infant Nutrition Council of America
Nancy Perry., Senior Vice President, Government Relations, American Society for the Prevention of Cruelty to Animals
Sara Sorscher., Deputy Director of Regulatory Affairs, Center for Science in the Public Interest

Opening Statements

Chairman Eshoo said that 20 cents out of every dollar spent by consumers goes towards food and products that have been approved by the FDA. Today this committee examines 10 pieces of bipartisan legislation to improve food safety and access in the United States. These pieces of legislation range from bills to improve allergy warnings on food labels to ensuring food containers are non-toxic and non-pollutant. This committee is committed to working with the FDA to ensure that food in America is not only safe but accessible.

Ranking Member Burgess said that the FDA is the oldest consumer protection agency in the United States. In recent years, the responsibilities of the FDA have grown considerably. Today, this committee will continue its tradition of working in a bipartisan manner to improve the lives of Americans. Many of the bills discussed today seek to protect American consumers from counterfeit products, scams and predatory practices by corporations. It is vital for American consumers to know what products are in their food and to feel that the FDA is transparent.

Rep. Guthrie said that the bills introduced today will take significant steps in protecting American consumers.

Rep. Dingell said that H.R. 2827 is an important piece of legislation that ensures that food containers cannot continue to contaminate the environment and poison consumers.

Rep. Walden said that the bipartisan pieces of legislation in front of the committee today expand protections to American consumers. It is crucial to bring more transparency to the pharmaceutical market place and prevent counterfeit products from entering the market. Safeguarding the pharmaceutical supply chain is one of the most important tasks congress can take on. It is critical for American consumers to feel that they can trust that the medicine they take is safe and effective. Furthermore, pharmaceutical companies should not be able to block competition.

Testimony

Panel I

Dr. Chua said that he strongly supports passing H.R. 4712. Over the past decade, opioid use disorder has taken the life of countless individuals. When the FDA granted orphan approval to sublocade, they effectively prevented any competition or innovation for nearly seven years. This approval happened due to an outdated policy which allowed the manufacturer of sublocade to mislead the FDA about their ability to recoup money spent on research and development. Recently, a competing manufacturer filed a citizen's petition to the FDA asking to revoke the approval of sublocade and block their period of exclusivity. Soon after, the FDA ruled in favor of the petition and buprenorphine products can enter the market. This story speaks to the need to pass H.R. 4712.

Dr. Muzzio said that continuous manufacturing is the most efficient way to manufacture pharmaceuticals. This process minimizes quality failures and leads to safer products for

American consumers. Continuous manufacturing requires a significant amount of expertise. Luckily, the United States has a significant amount of experts who are ready to take on the challenge of continuous manufacturing. This process could reduce the United States reliance on imported drugs and increase the amount of high paying jobs. The United States must ensure that Europe does not dominate the continuous manufacturing market.

Mr. Kaeser said that counterfeit drugs are the biggest market in the United States at $200 billion a year. Johnson and Johnson (J&J) believes that consumers must have absolute faith in the products they are taking. This is why &J is dedicated to safeguarding our products and working with lawmakers and regulatory agencies. J&J is very pleased to support H.R. 5663. This is because it will make it more difficult for counterfeit products to enter and remain on the market. Currently, it is too easy for counterfeit markets to enter the US market. This puts not only patients at risk, but also providers.

Dr. Allen said that when kept up to date, drug labeling is the most comprehensive drug related information available to prescribers. However, it is easy for drug labeling to become outdated. Manufacturers have an ongoing responsibility to ensure the accuracy of their labels, but few regulations exist mandating this practice. Generic drugs are supposed to be materially similar to the brand name drugs. However, after old brand name drugs are withdrawn from the market the generic drugs are still required to have their label match the old brand drug. This creates a significant problem to consumers and providers. Labeling is the sole source of information to inform consumers of the ingredients and FDA approval process.

<u>Panel II</u>

Ms. Day said that all three of her children have food allergies. The Faster Act will have a positive impact on all families and individuals living with allergies. When individuals have an anaphylactic reaction, it is a remarkably traumatic experience for everyone involved. Roughly two children in every class room have a serious food allergy. Today, sesame remains the most common food allergy not required to be labeled on products. It is impossible to keep children safe if companies are not required to label their allergens.

Mr. Carlin said that U.S. cheese makers have used the term natural cheese to describe a particular type of cheese that is different from processed cheese. Unfortunately, the use of the term 'natural cheese' may no longer be able to be utilized due to new FDA restrictions. Defining the term 'Natural Cheese' in statue would create a carve out for cheese manufacturers to continue to use this term. The "Curd Act" is supported by cheese manufacturers and consumers. This bill does not change the ingredients that are approved for use in cheese products. The "Curd Act" will provide consistency in the market place.

Ms. Sorscher said that recent studies have shown that sesame allergies are more prevalent than most of the top 8 major food allergens. Furthermore, adults with sesame allergies report more visits to the emergency room due to their allergy than other individuals with a food allergy. This fact emphasizes that this is not just a youth problem. The Center for Science in the Public Interest supports H.R. 2117, but opposes the "Curd Act". This

opposition is founded in the fact that there is evidence that consumers may be misled by claims of "natural cheese". This bill would create a carve out only for the cheese industry.

Ms. Perry said that the ASPCA believes horse slaughter presents serious food safety concerns and is itself a form of equine cruelty. Historically, bans on horse slaughter have received bipartisan support over many years. Horses are not raised for food, and should not enter the food market place. Horses are often given therapeutic chemicals that are expressly banned by the FDA for meat intended for human consumption. This represents an obvious public health risk, and ignoring it would be irresponsible. Humane euthanasia is supported by ASPCA, but horse slaughter is not humane euthanasia.

Dr. Corey said that there is little evidence to suggest that horse meat raised in the United States presents a health threat to consumers. The meat is tested in the same way that beef, pork and sheep are tested. There is significant concern that horses used for slaughter will be left neglected and abandoned. The intention behind banning horse slaughter is commendable. However, the United States does not have the infrastructure to provide adequate care for all of the horses in the country. It is crucial to enhance efforts to improve rehoming facilities for horses. We must address the root cause of unwanted horses.

Mr. Balmer said that the Dairy Pride Act is a bipartisan bill intended to finally compel the FDA to enforce its existing standards of identity for dairy products. At its core, the Dairy Pride Act would ensure the accurate and appropriate labeling of nondairy foods utilizing standardized dairy terms, an issue with significant implications for consumers. 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. The National Milk Producers Federation does not oppose the sale of imitation dairy products, but instead oppose their use of dairy terms in violation of provisions specified in the Code of Federal Regulations.

Ms. Benesh said that Contamination from Per- and Polyfluoroalkyl Substances (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. The EPA has stated that food is a significant source of PFAS exposure. 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. Congress should quickly pass H.R. 2827 and remove PFAS from food contact substances.

Dr. Deleo said that H.R. 2827 is unnecessary, overly broad, and contrary to well-established scientific processes for the pre-market evaluation of chemical safety in the United States. Currently, 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. H.R. 2827 is overly broad because it would apply to any PFAS used as a food contact substance. 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 consequences such legislation might precipitate.

Ms. Mountford said that 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. 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. Today we have the opportunity to establish statutory measures to ensure expired infant formula is not sold at retail. The Infant Nutrition Council of America (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

Questions and Answers

Chairman Eshoo asked what the status of continuous manufacturing is in the United States. **Dr. Muzzio** said the technology for continuous manufacturing is robust. Furthermore, about 10 to 15 brand name companies have adopted this practice. It is crucial to extend this ability to generic manufacturers. **Chairman Eshoo** asked which companies utilizing continuous manufacturing. **Dr. Muzzio** said most brand name companies have the capability to do this.

Ranking Member Burgess asked what the role of J&J is in the process of notifying consumers of a counterfeit product and removing the product form circulation. **Mr. Kaeser** said after being alerted to the counterfeit product, J&J worked with the FDA to identify the counterfeiter and alert consumers. There were arrests made due to the investigation. **Ranking Member Burgess** asked is continuous manufacturing plays a role in preventing drug shortages. **Dr. Muzzio** said yes, a large portion of drug shortages are caused by quality issues.

Rep. Schrader asked how continuous manufacturing can bring back drugs that are experiencing a shortage. **Dr. Muzzio** said that continuous manufacturing is not a magic bullet to cure all shortages. However, the technology can be adapted to manufacture many kinds of drugs with the proper investment.

Rep. Upton asked if the FDA has asked to update labeling requirements. **Dr. Allen** said that there have been initiatives by FDA that have begun to identify old drug labels that are no longer accurate. However, these labels cannot be updated without legal action. **Rep. Upton** asked how it is true that over 1 million people across the world have died due to counterfeit products. **Mr. Kaeser** said most of these deaths occur in developing countries, and unfortunately he does not have information on which specific drugs have led to a majority of the deaths.

Rep. Matsui asked if generics can make updates to their label on their own. **Dr. Allen** said if the original brand name is removed, then the generic cannot update their labels. **Rep. Matsui** asked if off label uses are wide spread and accepted, why is it important to update the drug label. **Dr. Allen** said that drug labels are the most comprehensive non-biased way to present accurate information to consumers.

Rep. Burgess asked what happens once counterfeit products are discovered under current law. **Mr. Kaeser** said that under current law, the products are shipped back to whoever sent it. In this way, products may remain in the supply chain. **Rep. Burgess** asked what a combination product is. **Mr. Kaeser** said that a combination product is a product that combines a medical device and a drug or biologic.

Rep. Welch asked if it is the view of J&J that the orphan drug program was intended to be used 10 different times for one drug. **Mr. Kaeser** said that that question is out of his scope of practice. **Rep. Welch** asked what the best way to address the abuse of the orphan drug status is. **Dr. Chua** said that this is a very complicated problem. There are serious questions surrounding whether the orphan drug program creates perverse incentives. **Rep. Welch** asked if pharmaceutical companies will exploit any loophole in order to charge the highest price possible to consumers. **Dr. Chua** said that if rules allow, pharmaceutical companies will do whatever they can to maximize profit.

Rep. Walden asked how J&J typically becomes aware that a counterfeit product has hit the market. **Mr. Kaeser** said that they have a team that monitors the market place and alerts the proper officials. **Rep. Walden** asked how these products enter the market. **Mr. Kaeser** said through the internet and mail. **Rep. Walden** asked if H.R. 5663 would help curb the counterfeit market. **Mr. Kaeser** said yes.

Rep. Kuster asked how the cost of buprenorphine is a barrier to Opioid Use Disorder treatment. **Dr. Chua** said that the cost does two things. First it makes insurers more hesitant to cover the cost or at the very least implement prior authorization. Second, it imposes high cost sharing on patients. **Rep. Kuster** asked how the entry of new formulations of buprenorphine could affect new populations. **Dr. Chua** said they can promote adherence due to different delivery methods. **Rep. Kuster** asked if the orphan drug program allows manufacturers to prevent competition from coming to market. **Dr. Chua** said yes, it grants exclusivity.

Rep. Griffith asked if continuous manufacturing would allow the United States to deal with a disease outbreak. **Dr. Muzzio** said that continuous manufacturing would allow for the rapid development of some products to treat an emerging disease.

Rep. Bucshon asked why the private sector has not adopted continuous manufacturing. **Dr. Muzzio** said that technology wise this could have happened 30 years ago. Furthermore, it took Universities to demonstrate that the technology would work. 20 years ago, companies said the FDA would never let companies use this technology. **Rep.**

Bucshon asked what the greatest barrier to adoption is. **Dr. Muzzio** said the greatest barrier is the know how to implement continuous manufacturing.

Rep. Kelly asked how the abuse of the orphan drug program affects consumers. **Dr. Chua** said that once granted orphan drug approval status, manufacturers are awarded exclusivity. This prevents new products from coming to the market. **Rep. Kelly** asked if H.R. 4612 would harm innovation. **Dr. Chua** said no.

Rep. Bilirakis asked if the rise in ecommerce has made it more difficult to track counterfeit goods. **Mr. Kaeser** said yes, the internet provides the perfect playground for bad actors. **Rep. Bilirakis** asked if brands are working with e commerce businesses to crack down on counterfeit goods. **Mr. Kaeser** said yes. **Rep. Bilirakis** asked if all products have the same risk of being victim to counterfeit. **Mr. Kaeser** said the products that hold the most monetary value are at the highest risk of being victim to counterfeit.

Rep. Barragan asked what the most common medical products entering the market are. **Mr. Kaeser** said there is a wide range of medical products that enter the market. **Rep. Barragan** asked if more resources should be given to ports to improve their inspection process. **Mr. Kaeser** said he is not an expert on that. But yes, ports need more resources.

Rep. Brooks asked why manufacturers are relying on universities to accelerate continuous manufacturing. **Dr. Muzzio** said that historically, universities have the ability to build a unique relationships with regulators and stake holders.

Rep. Blunt-Rochester asked how access to buprenorphine is impacted by requirements by prescribing physicians to obtain a waiver. **Dr. Chua** said that obtaining the waiver is one of the largest barriers to accessing buprenorphine. Eliminating the waiver would greatly increase access. **Rep. Blunt-Rochester** asked if there are any limits on the amount of direct payments manufacturers can make to physicians. **Dr. Chua** said no.

Rep. Carter asked who communicates label updates to providers and pharmacists. **Dr. Allen** said the basis of communication is the label. The updates can be actively communicated by the manufacturer. **Rep. Carter** asked if the counterfeit market is evolving and becoming more complex. **Mr. Kaeser** said yes.

Rep. Engel asked how continuous manufacturing is more efficient in responding to drug shortages. **Dr. Muzzio** said that batch manufacturing is inefficient, because you have to make many batches under different conditions to determine the best way to do it. This takes a significant amount of time. Continuous manufacturing can produce different batches in mere minutes.

Rep. Schakowsky asked if sales of J&J products fall under Mr. Kaesers' job description. **Mr. Kaeser** said no.

<u>Panel II</u>

Chairman Eshoo asked how long the environmental working group has been petitioning the FDA on PFAS regulations. **Ms. Benesh** said for about 15 years. **Chairman Eshoo** asked if the FDA should be an independent agency. **Ms. Benesh** said that the FDA has been very slow to act, so that is a potential. **Ms. Sorscher** said the FDA should remain impartial.

Rep. Shimkus asked how long it takes to determine if a chemical is safe. **Dr. Deleo** said it can be done in a matter of months. However, sometimes new questions and new data can delay the process. **Rep. Shimkus** asked if there is specific short chain PFAS in food packaging that have gone through FDA review. **Dr. Deleo** said that all PFAS used in food packaging has gone under the FDA review. **Rep. Shimkus** asked if the FDA has sufficient staff resources. **Dr. Deleo** said yes.

Rep. Matsui asked what major food allergens must be displayed on food labels. **Ms. Sorscher** said that only the top 8 food allergens have to be displayed on a food label. **Rep. Matsui** asked if food allergens outside of the top 8 can be disguised with misleading labels like "flavors and spices". **Ms. Day** said yes. **Rep. Matsui** asked why there is such a rapid increase in hospitalizations due to food allergies. **Ms. Day** said more research around this matter needs to be conducted.

Rep. Bucshon asked why the FDA has refused to crack down on deceptive labeling on imitation dairy products. **Mr. Balmer** said that the FDA does not consider it a public health problem.

Rep. Schrader asked if horses are injected on a daily basis with chemicals that can be toxic to humans. **Dr. Corey** said that over the life span of a horse, they may be injected with medication. **Rep. Schrader** asked if it is appropriate to inject these horses with medication. **Dr. Corey** said yes.

Rep. Carter asked if consumers would be wary of formula that is classified as 'adulterated'. **Ms. Mountford** said yes. Consumers may be more likely to try homemade or unapproved formulas. **Rep. Carter** asked if it is common for formula to be sold after its use by date. **Ms. Mountford** said it does not occur very frequently but it still happens. **Rep. Carter** asked who is responsible for removing these products from the shelf. **Ms. Mountford** said the retailer is responsible.

Rep. Welch asked if enforcing standards of identity violates the first amendment. **Mr. Balmer** said there is enforced language on almost every food package. The government does have the ability to impose food labeling regulations. **Rep. Welch** asked why nondairy beverages may want to associate themselves with milk. **Mr. Balmer** said, since milk is so healthy most products want to align themselves with the health benefits.

Rep. Burgess asked if products past their use by date should be considered adulterated products. **Ms. Mountford** said no.

Rep. Griffith asked what the result was of the effective ban on horse slaughter in the United States. **Dr. Corey** said that there were severe unintended consequences including horse abandonment and neglect.

Rep. Dingell asked if the FDA has a safety threshold for PFAS. **Ms. Benesh** said no. They are using safety thresholds of other chemicals. **Rep. Dingell** asked if food labels need to include PFAS levels. **Ms. Benesh** said no. **Rep. Dingell** asked if the FDA has every pulled a product off the shelf for PFAS levels. **Ms. Benesh** said no.

Rep. Long asked why there is a need to define natural cheese. **Mr. Carlin** said that processed cheese is officially defined, while natural cheese is not. This could not be used for product claim purposes, only for consumer communication. **Rep. Long** asked if Mr. Carlin has worked with the FDA to develop this statue. **Mr. Carlin** said yes. **Rep. Long** asked if this would create inconsistencies between the USDA and FDA. **Mr. Carlin** said no.

Rep. Schakowsky asked if the FDA has banned the use of phenylbutazone in horse meat intended for consumption. **Ms. Perry** said yes.