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Memo: Hearing on "Improving Safety and Transparency in America's Food and Drugs"

House Energy and Commerce Committee, Health Subcommittee
1/29/2020

Panel 1 Witnesses

- **Jeff Allen,** Friends of Cancer Research
- **Richard Kaeser,** Johnson & Johnson
- **Fernando Muzzio,** Rutgers, the State University of New Jersey
- **Kao-Ping Chua,** University of Michigan Medical School

Panel 2 Witnesses

- **Melanie Benesh,** Environmental Working Group
- **Tom Balmer,** National Milk Producers Federation
- **J. David Carlin,** International Dairy Foods Association
- **Douglas Corey,** American Association of Equine Practitioners
- **Talia Day,** Patient Advocate
- **Paul C. DeLeo,** Integral Consulting
- **Mardi Mountford,** Infant Nutrition Council of America
- **Nancy Perry,** American Society for the Prevention of Cruelty to Animals
- **Sara Sorscher,** Center for Science in the Public Interest

Standards of Identity and DAIRY PRIDE Act

- Rep. Bucshon (R-IN-08) asked why the FDA has not addressed dairy labeling since the first complaint was filed in 1979. Mr. Balmer said the labeling issue was not a matter of public health concern when the first complaint was filed, which is why the FDA did not address it then. It has since become a public health issue as there are reports of child malnutrition with parents buying alternative milks under the presumption that it is a dairy product. Plant-based beverages do not have the same nutritional benefits as milk. For example, "almond milk" only has 2 grams of protein compared to the 8 grams found in dairy milk.
    - Rep. Buschon believes the mislabeling issue is because companies want market share, and they know using these terms on their products will create a higher demand for them.
- Rep. Welch (D-VT-AL) wondered if standards of identity are a violation of the First Amendment. Mr. Balmer said it is not. The government has imposed food labels, such as the nutrition facts panel and food allergies, therefore, standards of identity can also be added.
- Mr. Balmer repeatedly mentioned that other countries do not allow the term "milk" to be used on plant-based beverage labels. He provided an example of a company that makes an almond beverage and successfully markets and sells it in three countries. The US

labels it as “almond milk,” and the other two use alternative terms. Implementing the DAIRY PRIDE Act will not disrupt the market in the US.

- Members discussed “natural cheese” less frequently than milk alternatives. Rep. Long (R-MO-07) and Rep Schrader (D-OR-05) both asked about if the term would confuse consumers. Mr. Carlin said it will not because consumers already know the difference between “natural” and “processed” cheeses.
    - The FDA threatened the term “natural cheese” when they began the process of allowing food labels to use the claim “all natural.” “Natural cheese” is not a product claim; rather it defines a category of cheese.
    - Ms. Sorscher of Center for Science in the Public Interest (CSPI) opposed this bill, saying that “processed” cheese is already clearly labeled, therefore, “natural cheese” does not require a label. Her argument is that artificial ingredients and additives can be added to “natural cheeses,” and it harms the integrity of the “natural” product claims that FDA is working on defining.

Food Allergens and the FASTER Act

- The FASTER Act would make sesame one of the major food allergens, requiring food manufacturers to include sesame on all food labels. The bill also authorizes the FDA to update and review the list of major allergens and continue to research food allergies, treatments, and cures.
- Ms. Day said in her testimony that hospitalizations from food allergies are up 400% from 2007 to 2016. This rapid increase demonstrates the importance of the bill and the need for research on food allergies.
- Rep. Griffith (R-VA-09) and his family also have food allergies, and not all of them are shared among them, making family meals difficult and expensive. He asked Ms. Day if they could redo the language of the bill to specify the complexities of food allergy research. He wants to ensure the research acknowledges the economic costs associated with the number of family members with food allergies and what allergies they have.

Continuous Manufacturing

- Many members raised the topic of continuous manufacturing, directing questions at Mr. Muzzio, the only witness that testified for H.R. 4866, the “National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2019.”
    - The **bill** defines “continuous manufacturing” as “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.”
- Four brand pharmaceutical companies have approved drugs on the market that use this technology. Another half dozen brand companies are working hard to implement the technology, and a few generic companies have tried, but failed, at using the technology.
    - The cost of entry companies to implement this technology is high. Not only is the financial cost of the initial investment high, but the resources needed are more than what these smaller companies have access to.

- Mr. Muzzio says that it could take as short as a couple months to expand access to continuous manufacturing technology if they created shared spaces for companies to access the product and learn how to implement the technology.
- This technology would also help decrease response times to disease outbreaks, such as the recent coronavirus. Continuous manufacturing could reduce the time it would take to create drugs to respond to outbreaks to a few days, rather than the weeks and months it currently takes.
- Mr. Muzzio believes the US is significantly behind on implementing continuous manufacturing compared to the EU, which has billions of euros of grant money for institutions that are researching and using the technology.

Other Topics

- A common theme throughout the hearing is the length of time these issues have been waiting to be addressed by FDA. A complaint on Dairy Labeling was first submitted to FDA in 1979, and Ms. Day's first complaint on sesame allergies was seven years ago.