Opening Remarks for the Honorable Brett Guthrie

Hearing on "Evaluating FDA Human Foods and Tobacco Programs."

September 10, 2024

- Today's hearing is an opportunity to learn more about how two of the U.S. Food and Drug Administration's Centers are improving their regulation of products that have an impact on millions of American families.
- Between foodborne illness outbreaks, the infant formula crisis, and the FDA's failure to authorize tobacco harm reduction products, the FDA's Center for Food Safety and Applied Nutrition and the Center for Tobacco Products have repeatedly tripped over their own feet to the detriment of the American people.
- It's been over a decade since Congress gave new authorities to the FDA to strengthen the Agency's ability to regulate tobacco and food.

- Yet over the past few years, I have personally heard gut-wrenching stories about Kentucky moms not being able to access formula for their newborns and from parents concerned about illicit nicotine products flooding their communities.
- Families have also had to deal with food recalls such as lead contamination in applesauce pouches. Additionally, we have lost 9 American lives to a listeria outbreak just this year, which also resulted in nearly 60 hospitalizations, and over 7 million pounds of deli meat being taken off the market.
- I believe that many of these problems are the direct result of misaligned priorities and culture at the FDA, rather than a lack of resources and authorities.
- A Reagan-Udall report published in December 2022 on the Center for Food Safety and Applied Nutrition states, “FDA has dedicated staff who are committed to protecting public health, but the current culture of the FDA Human Foods Program is inhibiting its ability to effectively accomplish this goal.”

- One example is the fact that it took almost 6 months for issues identified in an Abbott baby formula manufacturing facility to reach the highest levels of the FDA. Quicker action and stronger communication could have avoided this catastrophic crisis that endangered the lives of millions of infants across the United States.
- Another Reagan-Udall report published in December 2022 outlines challenges facing the Center for Tobacco Products and provides recommendations to improve how the center functions. The report recommends that the CTP should be proactive and engage more with stakeholders and the public. It also mentions that the Center should "make process improvements and identify and address the policy and scientific questions that underpin its regulatory framework."
- Manufacturers filing premarket tobacco applications with the goal of meeting the standard of "appropriate protection of public health" still have no clear guidance and are waiting hundreds of days for any outreach on their applications.

- More importantly, these products pending at FDA could present an opportunity to improve public health by providing less harmful alternatives to traditional cigarettes.
- This lack of transparency has consequences. First, because the FDA hasn't set a clear criterion for the science by which it will measure products, the Department of Justice has been forced to litigate on behalf of the Center, wasting millions of taxpayer dollars and causing even greater uncertainty.
- Second, because of the FDA's failure to approve new products and expand the legal market, people are turning to illicit products coming in from China instead. Without clear rules of the road and a robust authorized market known to consumers, wholesalers, and sellers, the CTP won't be able to enforce fast enough to keep harmful products out of the hands of unknowing consumers.

- To those that claim all of these issues can be addressed through more taxpayer and user fee dollars alone, I want to be very clear that Members of this subcommittee need to know exactly how the significant authorities and hundreds of millions of dollars provided by Congress have been deployed and exactly why they have fallen short in preventing widespread food-borne illness outbreaks or the ability to authorize products.
- Until we know better how dollars are prioritized and have agreement on those priorities, it is premature to provide any more funding.
- I am looking for clear results from a more transparent and predictable regulatory process, rather than more academic exercises and public awareness campaigns.
- I want these critical centers to succeed in their mission to protect and promote public health. I hope that today's hearing can shed light on our shared objectives and how your centers are making improvements to how your programs operate.