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Ranking Member Jamie Raskin
Opening Statement as Prepared for Delivery
"Oversight of the U.S. Food and Drug Administration"
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Thank you very much, Mr. Chairman, and thank you to Commissioner Dr. Califf for being with us here today.

FDA regulates everything from bottled water to infant formula and meat, poultry and egg products, prescription and non-prescription drugs, vaccines, medical devices, microwaves, personal care products, and tobacco.

During the Biden-Harris Administration, FDA has made critical progress to ensure that we have access to safer food and to effective drugs. For example, last fall, FDA acted quickly to investigate reports of lead appearing in children's cinnamon applesauce packets for their school lunch. The cinnamon was adulterated with lead which was added by the manufacturer in order to increase the weight of the product to make it more profitable in the process.

However, the apple sauce contamination issue could have been completely prevented if end-product inspections for food were required. FDA asked Congress to amend the *Food, Drug, and Cosmetic Act* as part of the FY 2024 Budget Request to require that industry conduct testing of final products exactly for such contaminants and provide FDA immediate access to those results. This would greatly help to ensure the safety of all of our food products, for kids and for everyone else. But FDA needs these additional authorities to make that happen.

And, Mr. Chairman, I was very pleased to hear your opening comments, and I hope you would join me in supporting giving FDA additional regulatory authority, precisely to address the kinds of problems that both you and I have identified. FDA itself has proposed multiple solutions that would address the problems we're talking about today. The Democrats support greater and more refined regulatory authority to make our food and drugs safer, and we hope our colleagues will join us.

In the wake of infant formula and prescription drug shortages, FDA also advanced legislative proposals earlier this year to strengthen notification requirements and data sharing. Right now, they don't have any authority to tell drug manufacturers to produce more drugs.

One proposal they've offered would require manufacturers to notify FDA, dealing with this first problem of the applesauce, would require manufacturers to notify FDA about pathogens that are discovered in certain critical foods. In the case of infant formula, this authority would help FDA prevent contaminated infant formula from reaching any more consumers and babies. A second proposal they've suggested would expand FDA's authority to gather data from industry about potential drug shortages and supply chain disruptions.

FDA has improved access to contraception, and protections for medication abortion access. In 2021, FDA advanced the accessibility of medication abortion by removing the in-person dispensing requirement for mifepristone and allowing it to be distributed by mail through retail pharmacies.

In July 2023, FDA approved the first over-the-counter birth control pill, Opill. As a result, consumers' access to contraception is improved at a critical time when many states are enacting increasingly draconian and oppressive abortion restrictions.

FDA has also made advancements to combat a range of life-threatening diseases. In March of last year, FDA approved the first OTC opioid overdose reversal medication (naloxone) nasal spray, a critical step towards reducing opioid overdose deaths in our districts. FDA also recently approved new genome editing technologies to treat sickle cell anemia, a disease that has ravaged a lot of communities, primarily African Americans. This advancement is a crucial step towards treating sickle cell anemia and represents a breakthrough in gene therapy. FDA also secured additional supply chains in the wake of cancer drug shortages.

It is crucial that FDA continue to carry out its mission and create meaningful regulations based on sound science and not conspiracy theories or ideological programs. Public attacks on FDA without any corresponding legislative solutions simply undermine its ability to effectively protect public health.

Anti-abortion activists brought a case against FDA over its updated guidance on mifepristone, the first of a two-pill medication abortion. The activists claimed that FDA did not properly collect data on drug risks and complications. However, this claim is contrary to FDA's review of "extensive research showing that mifepristone is safe, including to take at home." FDA followed its standard procedure in reaching that conclusion. And, according to FDA, it must "act reasonably based on the information available," rather than "act based on perfect data, which seldom exists."

If the objective of anti-abortion activists is to undermine FDA's authority, the consequences will be devastating to public health. An FDA that bases its decisions on political science rather than actual science is not in the best interest of consumers. Congress must ensure FDA is empowered to rely on the facts, rather than bend to the will of people pushing an ideological agenda.

Thank you, Mr. Chairman, and I yield back.

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