Prepared Opening Statement of Ranking Member Richard Burr
Executive Session of S. 4348, S. 958, S. 4353, H.R. 1193, and S. 4053

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Thank you, Chair Murray.

Typically, the mark up of the FDA user fees is a technical, procedural exercise, funding the review of the products that save American lives every day.

It is usually a moment to thank our colleagues for their contributions to the bill, and today's FDA legislation and the three public health bills we are marking up have no shortage of these contributions.

Due to the work of Senators Paul and Booker, Collins and Kaine, Cassidy and Smith, Murkowksi, Braun, Casey, Scott, Romney, Marshall, and so many others, this FDA bill is in a better place than where we started.

For the first time, FDA listened to Congressional concerns as part of this agreement.

Dr. Jeff Shuren took steps to address concerns I raised to add accountability to the TAP program within the medical device agreements – these metrics will help measure the success or failure of the program.

It even has our own agreement, Senator Murray, on the extremely thorny issues of diagnostic test modernization, cosmetics reform, dietary supplements,

appropriate avenues for drug importation, and addressing the current infant formula crisis and preventing future ones.

We have wrestled with most of these issues for over a decade, and this is a significant result.

Our staffs have worked long hours over many months to bring forward landmark legislation for the Food and Drug Administration.

However, there is a dark cloud over shadowing our Committee work today.

These agreements and the bill we have before us give the FDA more resources and more authority, but it has become clear that the agency may not deserve our trust.

I have spent my career improving the FDA, and I have never seen an agency I value so deeply in such disarray.

I worked to confirm a Commissioner who I thought had a vision.

At his nomination hearing I advocated for his confirmation because I believed he had the experience and appreciation for the next generation of medical breakthroughs coming through the agency.

He started his second tour at the helm of an FDA that weathered a once-in-a-century pandemic, with a team that saved millions of lives.

I said as much during the agency's user fee hearing, praising Dr. Marks, Dr. Shuren, and Dr. Cavazzoni for their tireless efforts and that of Dr. Janet Woodcock and the many other professionals at the FDA.

I was able to secure five other Republican votes, in the closest confirmation of an FDA Commissioner in recent history, for a nail-biting 50 to 46 vote.

But when confronted with one of the FDA's biggest crises facing parents of babies and infants, the response was a casual shrug and a recognition that their performance was merely suboptimal.

Suboptimal?

Tell that to millions of parents desperately searching for formula. I can think of a few other words I'd use, but we're in polite company.

The food center has betrayed the trust of the American people and I will not sit idly by and pretend that major reforms aren't needed to fix this broken center. Two weeks ago, I listed just a few of the activities undertaken by the food center while the infant formula shortage escalated.

Chair Murray and I have taken 13 steps in this bill to fix the fundamental failures of the FDA that contributed to the infant formula crisis we're experiencing, and my colleagues have a few more ideas that will be offered by amendment.

I hope they are all adopted unanimously to demonstrate our shared outrage at the catastrophe that is the food center at FDA, and that accountability will become the most important word of the day.

Why do I emphasize accountability?

Dramatic failures at the food center.

A tobacco center that bans menthol cigarettes, but hasn't made a single effort to bring American menthol users a less harmful alternative.

Congress even had to step in and pass two different laws to try and bring more sunscreens to market, and FDA has still failed to act, almost a full decade later.

We rightly put warning labels on foods for allergens, I guess we need to add "lacks accountability" as a warning label on the front door of the FDA.

I am deeply torn over this legislation before us today.

Through our updates to the accelerated approval pathway, this bill would bring important reforms to many aspects of the FDA, bringing new hope to Americans battling diseases like Alzheimer's, ALS, and cancer.

It would encourage development in the generic and biosimilar drug industry, bringing down drug costs for Americans and injecting greater competition in the drug market.

It would help to advance innovation for rare diseases.

It would modernize the data that can be used to support medical product development, increase options for patients to safely dispose of opioid medications, and strengthen FDA's hiring capabilities and workforce planning so that the agency is better prepared for the future.

It would support the agency's inspection activities that need to return to normal as soon as possible.

And would provide greater transparency and accountability for the user fees FDA collects.

I am pleased that the Chair agreed to work with me to begin reforms to the FDA's food center and to the agency's leadership, so that we can turn the page on their failure. The changes addressing infant formula include:

- Creating a new Office of Critical Foods at FDA, bringing leadership and accountability to the oversight of foods for our most vulnerable Americans;
- Imposing new timelines on FDA to help bring new formulas to market;
- Requiring the agency to be more flexible and more nimble when a shortage may arise;
- Requiring the agency to work with industry to solve problems found during inspections in a more timely manner; and,
- Making the FDA's actions on infant formula more transparent to Congress and the American people.

We've also ensured that packages aren't 'lost' in the mailroom, that correspondence is logged, tracked, and responded to appropriately, and that the agency takes a strategic approach to improving its aging IT infrastructure.

I hope that this bill and the amendments that will be offered may be enough to get FDA to change its tune and do its job.

However, the bill also includes agreements negotiated by industry and FDA that substantially increase the user fees FDA is allowed to collect.

My friends, here's a fundamental truth: when industry has to pay more to the FDA, the cost of development increases – and those costs are passed along to patients.

This bill also grants substantial new authorities to the FDA, and expands the FDA's reach.

I acknowledge that I myself have asked for the diagnostic reform bill to be included that would clarify FDA's authority over diagnostic tests and provide certainty and predictability for test innovators, physicians, and patients.

But I worry that we are rewarding bad behavior.

Is this the time to expand FDA's authority in any space, including diagnostic tests, cosmetics, and dietary supplements?

When FDA fails to do their fundamental job on infant formula, can they be trusted with new responsibilities?

The baby formula crisis happened while the FDA was distracted by what food salmon could eat so they look more pink, or what ingredients go into yogurt.

What crisis will they miss next when they are determining whether to ban or allow the words "made with a smile" on certain food packaging?

We are also considering a number of amendments today about which I have significant concerns.

In multiple circumstances, FDA has acted in violation of the law, got sued, and lost.

Now FDA is coming to Congress requesting changes to the law to make it consistent with their interpretation. They aren't changing behavior to follow the law the way we wrote it, they want us to change the law to match the way they want it to read.

That's not how this works. FDA doesn't get to change the rules of the game, just because it lost.

This has become a pattern – a pattern that highlights the agency does not believe it should be accountable to the laws we write.

I urge my colleagues not to become complicit with FDA's desire to avoid accountability.

I look forward to discussing these issues with my colleagues, and avoiding adoption of amendments that would give FDA new authority to chill innovation or jeopardize the safety of American patients.

We still have a long way to this bill becoming law, and I will be watching the actions of the FDA all the way to the end to see if they will rise to the challenge.

And, decide whether they deserve an ounce of new authority.

I thank the Chair.

I ask unanimous consent to insert into the record these documents recording the actions of the FDA's food center from August 2021 until May 2022 into the record, so that the American people can see just what FDA was up to when they were ignoring the infant formula crisis.