TESTIMONY OF DAVID KESSLER
April 9, 2025
House Committee on Oversight and Government Reform
"Restoring Trust in FDA: Rooting Out Illicit Products"

Chairman Comer, Ranking Member Connolly, and Members of the Committee:

My name is Dr. David Kessler. I have had the privilege of working for both Republican and Democratic presidents. I was appointed by President George H. W. Bush and reappointed by President Bill Clinton as Commissioner of the U.S. Food and Drug Administration (FDA or the Agency). Under my leadership, FDA was responsible for establishing accelerated approval, user fees, Nutrition Facts food labels, and regulation of tobacco products. In January 2021, I had the privilege of returning to federal service and co-leading Operation Warp Speed.

Mr. Chairman, I am in full agreement with you regarding significant concerns about the safety and efficacy of illicit, and sometimes licit, drug products originating from overseas, particularly China. Counterfeit drugs, devices, and precursor substances are reaching our shores and pose a serious health risk. As this Committee knows, e-cigarettes, that have never been authorized, are easily available.

But if we are serious about these concerns, we have to discuss the loss of critical functions and missions due to the radical reductions to staff at FDA. Given the lack of transparency and accounting, it is difficult to even see the full scope of impact. But we do know a few concrete examples of how these reduction in force (RIF) actions will cripple key functions and missions at FDA, particularly regarding oversight of illicit and counterfeit products. Let me give you a snapshot of how some of these FDA Centers and offices and key personnel supported critical public health oversight and what we, as a nation, will miss.

Licit, illicit and counterfeit imported products

As you can see from Figure 1, only four percent of active pharmaceutical ingredients (API)—the key component of a drug—are produced in the United States. In my opinion, we have been conducting a reckless national experiment with compounded new weight loss drugs (GLP-1s). It is my understanding that there are not routine FDA surveillance testing of the GLP-1 products that are being imported into the United States from China for compounding to assure what is in the product. We cannot have full confidence in imported compounded GLP-1 drugs.

We need to take enforcement actions on illicit products. While we have heard that no inspectors were eliminated, it takes more than inspectors to ensure safe products enter this country. As we have seen, bad actors are frequently using or modifying their tactics for importing illicit products

into the U.S. Strengthening enforcement against illicit products often requires analyzing the Agency's authorities and enforcement tools against these tactics. In many cases, this has required modifying or proposing new policy to better enable FDA to deter or prevent these products from entering the U.S.

For example, to address the avalanche of flavored vapes, FDA officials with decades of experience came up with a plan to enable regulatory action on products like "Iced Lemonade" e-cigarettes. Industry objected, and FDA fought all the way to a victory at the Supreme Court last week. Key staff at FDA's policy shops and the Center for Tobacco Products, including Center Director Brian King who led this strategy, were all cut last week.

I agree that we need to improve–and yes, streamline–FDA's oversight and response to illicit products. But the cuts last week are not streamlining. They are not improving. If you remove the people doing the work to ensure the safety of products entering this country's supply chain, it is not hard to project that more illicit and counterfeit products will enter this country as a result of last week's haphazard cuts.

Infant formula and food safety

If we want to talk about the safety of imported goods, we also need to talk about food safety. Food safety experts at FDA identified salmonella in cucumbers that sickened 551 Americans as well as raw pet food that infected pets. We have had lead in applesauce traced to imported cinnamon. I think we all agree we do not want lead in baby food. Secretary of the Department of Health and Human Services (HHS), Robert F. Kennedy, recently launched Operation Stork Speed, which will be testing infant formula for heavy metals, among other actions.

At the same time, FDA's food testing laboratory in Alameda, California was cut. This lab was testing for contaminants in baby food and for avian flu in other food products.
Again, how does FDA address food safety, and what is the impact of last week's cuts?

For any food safety threat, FDA has to identify the crisis. This can mean responding to whistleblower complaints, such as the four infants that died in 2022 at the outset of the infant formula crisis. This can also mean using data to track and detect outbreaks, including partnering with the Centers for Disease Control and Prevention (CDC) or states to integrate their data signals. But you need staff to receive the whistleblower complaints and data. You need experts and teams to review those whistleblower complaints and data. You need staff to sample products and identify the source of contamination. We are all still trying to understand who was cut last week, but it appears that key staff at the Human Foods Program (HFP) who work on food safety

were lost. Some of the experts who would support a food outbreak response were housed in policy offices, and data experts in the "Office of Digital Transformation".

FDA also has to communicate with the public, industry, and government officials to address a crisis. For many outbreaks, this means a team of scientists and communications specialists work, often weekends or overnight, to issue advice and warnings to the public, including recalls and notifications to Congress. Members of these interdisciplinary teams have specialized experience and are not interchangeable. Much of these communication and legislative teams are gone.

The Agency also sometimes needs to create policy in the midst of crises to address the emergency. For infant formula, FDA policy experts worked nights and weekends to issue new enforcement discretion policy to enable importation of formula from around the world. That imported formula – over six million pounds – helped alleviate the shortages of formula on the shelves. It appears that HFP's Office of Policy and International Engagement was cut by more than half. Among other things, this office works on rules and policy documents related to food safety, infant formula, "generally recognized as safe", nutrition, and chemical safety. Key staff that write food safety rules and guidances are gone, including staff that work on international regulatory partnerships and other key policy initiatives.

Avian flu response and Center on Veterinary Medicine

The recent RIFs also seem to have unknowingly dismantled the FDA's avian flu (also referred to a H5N1) response.

The staff in the Office of the Director at Center on Veterinary Medicine (CVM) was cut drastically. This includes the FDA's Chief Veterinary Officer, who was co-leading the Agency's response to avian flu, and another senior veterinarian working to coordinate lines of effort and data between state and federal partners. They were put on administrative leave with no plan for transition of this important work.

As noted above, critical to any Agency action is communicating with consumers, manufacturers, and local officials. Communications staff who made sure recall notices about pet food contaminated with avian flu linked to cat illness and deaths reached consumers and veterinarians were cut, as were key staff who communicated ways the pet food industry can keep products safe from avian flu.

Senior veterinary leadership responsible for making tough decisions to keep animals and humans safe from growing threat of avian flu were also cut, including veterinarians who designed the first studies that tested retail milk, showing that pasteurization works against avian flu.

All these teams have been affected by the cuts –communications, policy, as well as veterinary teams, laboratories, and food safety regulatory experts working on critical reforms. We have heard that inspectors were not cut. But inspectors are highly trained in sciences, not trained logistics experts to support trips to China or other foreign facilities. Without key support staff, they will have less time to do inspections. Travel cards were limited to $1 without clearance. Laboratories—the ones that remain open—cannot purchase the products they need to test if the food is safe. Imagine if all the staff of Congress were dismissed and every expense over $1 needed to be approved.

Let me tell you about one committed public servant at FDA – Dr. Elise Ackley – who was sent a RIF notice. She is a veterinarian working on chemical safety and contamination in food – supporting the current Administration efforts including reforms of the "generally recognized as safe" framework. Dr. Ackley is a military spouse married to an active-duty Army veterinarian, both grads of Louisiana State University. The loss of her expertise in support of FDA and its mission to make sure our food system is safe poses risk that we are just now beginning to fully understand.

Product approvals

One of the reasons we have been able to lead the world in health sciences is due to a strong FDA and its rigorous standards. One of my goals as Commissioner was to ensure that if you needed access to a life-saving drug and you lived in the United States, you would have access to it before anyone else in the world. We saw that in COVID-19, for example, with monoclonal antibodies. This new treatment appears to have saved President Trump's life back in October 2020. Dr. Peter Stein, who led FDA's Office of New Drugs, made that drug available to the president and thousands of others. Dr. Stein was removed from his office in the recent round of cuts, as were thousands of others. It is no way to restore trust in FDA when you cut the person who may have saved the president's life.

Dr. Stein is but one of the people FDA fired last week. We lost thousands of FDA employees last week. Each of those employees brought years or decades of experience and knowledge on how to execute FDA's mission. That is thousands of years of experience and capabilities that we have lost, including a wealth of experience that could help us root out illicit and counterfeit products.

The scientific independence of FDA – paired with the best scientists in the world who earned that independence – has been the key to FDA's gold standard status around the world. We are losing both.

We have lost key scientists. The departure of Dr. Peter Marks, the former director of the Center for Biologics Evaluation and Research (CBER), was widely reported, but key deputies at FDA's Oncology Center of Excellence (OCE) also resigned, in part because an entire division was

decimated by departures even before last week's RIF actions. These were talented, brilliant scientists who helped make life-saving medicines available for someone's mother, father, or child.

I also want to say a couple more words on Dr. Marks – his letter and concerns have been widely reported – but I want to talk about what FDA has lost as an Agency. Dr. Marks is a hematologist-oncologist and, under his leadership, CBER approved the first genetically modified cell therapy for children with leukemia who had no other treatment options. This approval occurred during the first Trump Administration. This whole category of cell and gene therapy is a vibrant new class of innovative treatments that did not really exist before Dr. Marks – and his support has been critical.

The scientific independence of FDA has been a bipartisan value, one that industry and consumers alike have fought for and defended. We heard last week about a hold on the Novavax application. I have no idea whether or not Novavax should be approved – but I can tell you this should be a decision by scientists and physicians within the Center for Biologics.

FDA has depended on transparency to help the public understand and have confidence in its decision making. However, the administration also cut the communications and policy staff, which undermines a longstanding practice of regulatory independence. I fear these cuts may enable more political interference. This could delay regulatory actions or undermine the public's ability to get science-based information.

I was hopeful when Secretary talked about "radical transparency". But press reports suggest that advisory committees may not meet because the staff to support them were fired. The very people who support a public process of analyzing data to determine a recommendation about whether a product should be approved. These firings will lead to less, not more, transparency. And equally as important, this radical change in the process will deprive developers of the predictability of the process they have come to depend on. Ultimately, by creating chaos in the system, it will be American patients who suffer.

Industry knows this matters. Biotech stocks fell four percent with the departure of Dr. Marks. Analysts at Cantor Fitzgerald were deeply concerned at Dr. Marks departure, saying that "pushing out one of the most trusted leaders of the FDA to promote an anti-science agenda is a step too far for us…", and highlighting the "disruptive, destructive and chaotic decision-making" of this current HHS.

Other senior Agency officials at CBER were also cut— this team was working on a policy framework for accelerated approval for gene therapy for rare diseases such as muscular dystrophies and other pediatric neurodevelopmental conditions. This team was also working on

fully standing up FDA's Rare Disease Innovation Hub, and issuing guidance on platform technologies, as well as development of policy on the use of artificial intelligence in regulatory decision making. To be clear, these individuals were enabling innovations in science and technology, and, with their departures, we may lose that edge.

The current processes at FDA rely on user fees to ensure timely review and consideration of lifesaving technology and innovations. According to Politico's AgencyIQ, about half of those individuals who were negotiating and overseeing implementation of the user fee commitments have left the Agency, including key senior leaders. And even more concerning, the cuts to FDA-funded staff could cause FDA to miss negotiated triggers necessary to collect user fees from industry. If the federal government is not paying for their share of funding, FDA will be required to refund industry's share to them as well – compounding the losses well beyond the cuts already. If that happens, all medical product reviews could be dramatically slowed – we could go back to 2-3 years for review rather than the six months we see right now for groundbreaking drugs and biologics.

Now, in a world where Congress committed to replacing that $3.3 billion in user fees, you could argue that having full public funding for the Agency might be a good bipartisan policy goal. But if that were the goal, this should go along with an appropriations package with a radical increase in FDA funding.

Conclusion

The conventional wisdom is that illicit cheap copies coming from China are a major threat to our health and safety. The more significant threat, Mr. Chairman, is that China is attempting to surpass the U.S. in the sciences. As shown in Figure 2, the highly respected Nature Global Index reveals that eight of the top 10 universities in terms of impactful research in the natural sciences are located in China. Specifically in chemistry, all 10 of the highest ranked universities are in China. Only in the health sciences does the U.S. hold the lead.

I was fortunate to grow up at a time when, following the launch of Sputnik, the United States recognized the need to invest heavily in the sciences.

I know this is a committee that has strong views on both sides of the aisle. Still, I hope that we can come together and recognize that China is poised to surpass us in the sciences, and we need to act quickly to make the necessary investments to shore up our competitiveness and avoid putting our nation at risk.

I recognize that there are limitations to those rankings and that China may have been citing papers in a way that increases its standing. Increasingly, U.S. scientists I have spoken to see

much higher quality work coming out of their country. Refer to Figure 3, which illustrates their increasing investment in research and development, currently at approximately $500 billion as of last year. In contrast, from 2004 to 2016, our investment in the National Institutes of Health (NIH) increased only slightly. Whatever needs to be fixed, let's fix it, but we need to make a marked increase in our investment—this is Sputnik 2.0, but with China.

These recent cuts to federal science workforce and investments appear to me as devastating, haphazard, thoughtless, and chaotic.

We need to be clear-eyed about the threat that China poses to American exceptionalism, especially in the sciences. We cannot afford to be haphazard in our support of the American scientific enterprise – not when China's commitment to the sciences is more real than it has been in the past.

The competition – America's real competition – in the sciences is China. We simply cannot afford to lose our focus. It is important that President Trump and this White House, as well as Congress, understand the nature of that competitive challenge, and respond strategically, thoughtfully, and with appropriate strength.

Thank you for your attention to making sure FDA continues to be a strong scientific and regulatory agency serving the American people.

Referenced Figures

Figure 1:

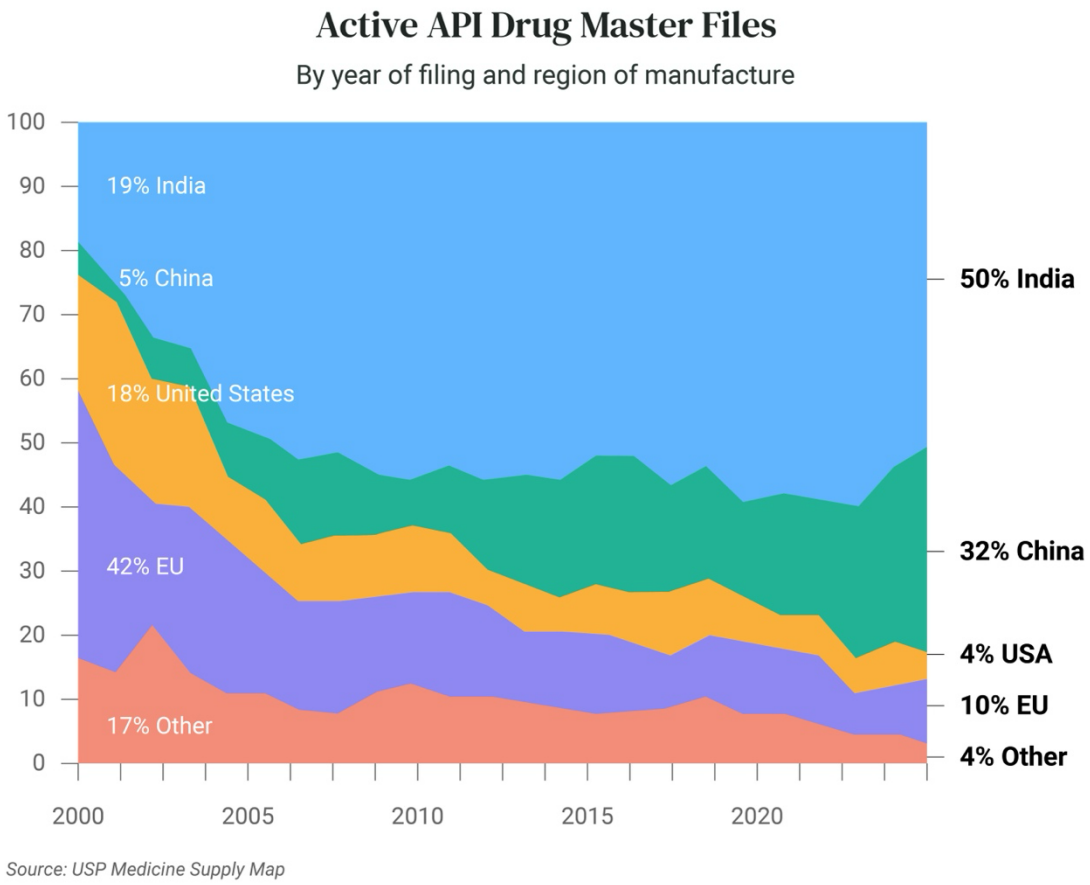


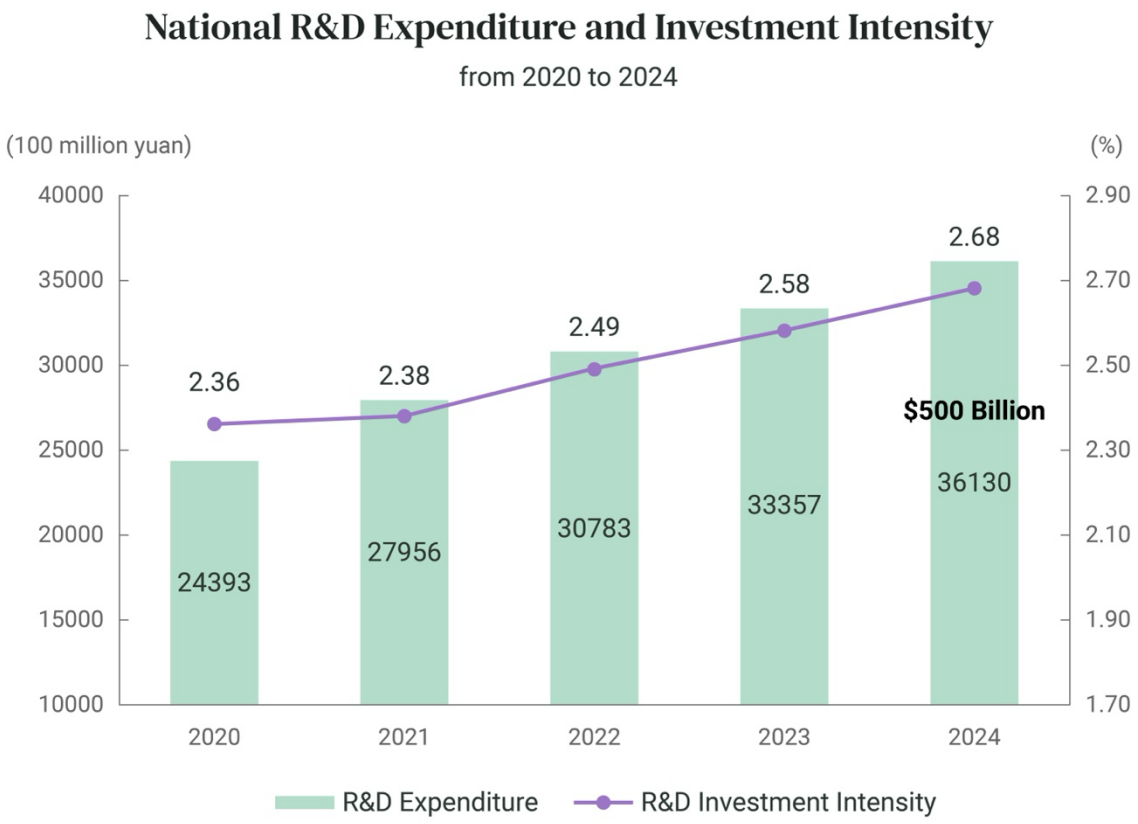
Figure 2:

Nature Index 2024

Global Ranking Natural Sciences

Position	Institution	Count	Share
01.	Chinese Academy of Sciences (CAS)	9364	2795.8
02.	University of Science and Technology of China (USTC)	2575	847.2
03.	Zhejiang University (ZJU)	2015	793.19
04.	University of Chinese Academy of Sciences (UCAS)	3880	788.45
05.	Tsinghua University	2443	772.23
06.	Peking University (PKU)	2864	768.76
07.	Harvard University	2561	750.33
08.	Nanjing University (NJU)	1830	746.91
09.	Max Planck Society	2735	744.74
10.	Shanghai Jiao Tong University (SJTU)	1770	663.17

Figure 3:


National R&D Expenditure and Investment Intensity
from 2020 to 2024
(100 million yuan)
(%)
40000
35000
30000
25000
20000
15000
10000
2.90
2.70
2.50
2.30
2.10
1.90
1.70
2.36
2.38
2.49
2.58
2.68
$500 Billion
24393
27956
30783
33357
36130
2020
2021
2022
2023
2024
R&D Expenditure
R&D Investment Intensity