Remarks by the Commissioner of Food and Drugs

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Good morning. I'm I pleased to have this opportunity to speak with you again. Few groups can match the level of experience and understanding of the work of the FDA as the Food and Drug Law Institute. While the FDA is a science-based organization with a profound public health mission, we are also, of course, a regulatory agency, and I've been reminded over and over in the year since I've been back that regulators (often lawyers such as yourselves) play an essential and much discussed role in shaping and strengthening the diverse and rapidly changing environment in which we work.

We have our own group of expert food and drug lawyers at the agency who have committed themselves to public service and to both defending the role and work of the FDA and recommending legal pathways that can improve the public health. And these days, they seem to be extra busy. But we also often rely on many of you—as a sounding board, a source of knowledge and understanding of current legal and regulatory issues including the impact of potential changes, as well as in promoting understanding and support for the fundamental structural basis for our work, which is essential not only for the public, but also for many of your clients.

Your wisdom is particularly important these days, as the agency faces some significant, even unprecedented challenges that go to the heart of what we do. This morning I want to focus on a few of the underlying challenges we face, and hope that you will redouble your efforts to not only serve your clients but also reaffirm the role of the FDA and the system of government that has served us well overall in terms of channeling industries into producing and distributing safe and effective medical products and safe foods, while also protecting people, particularly youth, from the death and disability produced by tobacco products.

It's now been a little over a year since I returned to the FDA. (Although, given how much happens here every day, I sometimes think the proper calculation should be similar to how we determine the age of a dog—seven days for every regular human day.) Needless to say, it's been a busy and productive time for the FDA, filled with the privilege of regulating a multitude of amazing medical and scientific achievements, truly heroic responses to public health challenges, and, of course, something that I know gives many of you a warm feeling, a variety of legal conflicts. In short, it's just another day at the office in the FDA's efforts to protect and promote the health of the American public.

In many ways we are like referees at the FDA—we don't make the products and we adjudicate by a set of rules that are codified in laws, rules, and guidances. Of course, we have an influence on interpretation of the rule book through guidance, and we provide technical assistance as Congress writes the laws. Much like good referees in sports, we cheer on a competitor who makes a great product and plays by the rules,

and we have an obligation to penalize poor play and dishonest avoidance of the rules. But much like the umpires depicted in the author Michael Lewis's podcast "Ref, You Suck" in a series entitled "Against the Rules," our society is increasingly suspicious of those who make the calls by the rulebook and often downright antagonistic.

This audience understands, perhaps better than most, just how important the mission of the FDA is, and the importance of playing by the rules, not to mention how exciting and rewarding working at the FDA can be. You have a grasp of the real-world benefits to patients and consumers as a result of the work we do, not to mention an understanding of the risks for patients and consumers when we make the wrong call or when product manufacturers fail to fulfill their responsibilities. And, of course, you have a unique knowledge of the ways in which FDA policies, rules, and regulations can be interpreted, deciphered, and deliberated over.

The relevance of the FDA, not just to your clients, but to the nation as a whole, is obvious from the plethora of news stories—both positive and negative—highlighting our activities—from reports of products we've approved and the resulting benefits for patients, or of products that failed to meet the standard for pre-market approval or cause harm to people under our watch, or to criticism (or compliments) for a decision that we made too quickly or for ones that we took too long to make. You get the idea.

But that prominence—not to mention the middle ground between advocates and critics—is exactly where we should be, and the tension reflects how our system is designed to safeguard the process from the inappropriate influence of politics, politicians, and courts.

By nearly any measure, it has been an extraordinary year for the FDA. For example, even as we continued to respond effectively to the COVID-19 pandemic, we approved a wide variety of safe and effective new therapies in 2022, including thirty-seven novel drugs never before approved or marketed in the U.S., and numerous drugs for new uses and patient populations.

I am proud that more than half of the novel drug approvals last year were for patients with rare diseases. But even with this success, we recognize that thousands of rare diseases still do not have approved treatments. We are committed to supporting rare disease research, engaging patients and caregivers, and continuing to enhance our review processes to help advance medical products for rare disease patients.

In 2022, we approved the 40th biosimilar, a significant achievement in biosimilar product development. We also approved two interchangeable biosimilars, biological products that may (subject to state law) be substituted without the intervention of a prescriber, similar to how generic drugs are substituted for brand name drugs. There are now four approved interchangeable biosimilars.

I also call your attention to two areas that are shaping up possibly to be major game changers in our ongoing battle with chronic diseases that are causing the vast majority of death and disability in our country. We are awaiting final submissions, but if the submitted data matches up with the press releases, it is possible that we could see significant reductions in rate of progression in Alzheimer's disease. In addition, whole new classes of drugs appear to be having a major impact on obesity and diabetes with major implications for a number of associated chronic diseases. I want to stress again, that we have to wait on the data, but both of these areas will raise major questions about the interface between approval by FDA for an intended use and broader use for tens of millions of Americans. This is a good problem to have, and we are having productive discussions with our CMS colleagues, for example, but we all need to be working on these issues.

Our Center for Biologics Evaluation and Research (CBER) also had a busy and productive year with eight novel approvals; six products receiving breakthrough therapy designation, four receiving orphan designation, and three receiving fast track designation. CBER also continued its incredible work in response to several public health emergencies.

It's worth special note that of the novel approvals by CBER, five were for gene therapy products. This development underscores that one of the areas offering the greatest promise, not just in the rare disease space, but across the entire spectrum of humans, animals, and plants, involves the explosion in genetics and gene editing. This has profound implications for the development of new treatments and cures for human disease, as well as for the advance of environment-friendly and predictable food in the face of climate change and supply chain stresses. Because this involves work across the entire FDA, I've asked Dr. Namandjé Bumpus, our Chief Scientist, to coordinate our experts across the agency to make sure we're sharing knowledge in a way that reinforces regulation that supports innovation, enabling the benefit and preventing avoidable risk as the science continues to grow.

In the food safety area, we had a number of major accomplishments, including implementing the Food Safety Modernization Act through nine foundational rules and more than seventy guidances that have set the foundation of a modern regulatory framework. One of the last major pieces of FSMA—the food traceability rule—was finalized in 2022, and will facilitate faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths.

In the nutrition space, CFSAN oversaw the first major update to the iconic Nutrition Facts Label that included labeling of added sugars, the implementation of legislation requiring calories to be listed on restaurant and similar food establishment menus, as well as launching initiatives to help industry gradually reduce sodium in the food supply.

We also issued a new proposed definition of the "Healthy" nutrient content claim that consumers can see on the front of food packages, updated to align with current nutrition science and the Dietary Guidelines for Americans. Food labeling can be a powerful tool for change by empowering consumers to help them make informed choices about the products they are eating and by encouraging manufacturers to reformulate their foods to create healthier products, thereby helping to foster a healthier food supply.

Our Center for Devices and Radiological Health (CDRH) continues to foster timely patient access to safe medical devices, with a goal of spurring innovation in device safety and ensuring that new products are able to address unmet medical needs. In 2022, 135 devices were designated as breakthrough devices, more than nineteen submissions designated as breakthrough devices received marketing authorization, and eighty-four novel devices received marketing authorization.

We are increasingly focused on supporting digital health technologies, which play an increasingly significant role in today's health care system, and Artificial Intelligence and Machine Learning, which are powering important advancements in this field. The FDA has already authorized more than 500 AI/ML-enabled medical devices, and more are under development. In 2022, CDRH's Digital Health Center of Excellence (DHCoE) made significant strides to advance health care by fostering responsible and high-quality digital health innovation.

And CDRH continues to lead the development of new regulatory frameworks tailored to digital health technologies, while promoting consistent application of digital health policies. I probably don't need to tell you that large language models are evolving exponentially, and I personally believe that this technological advance will cause revolutionary disruption that could either yield dramatic benefits or serious risks. We will be working with CDRH on both the regulatory scheme for LLM's and potential new pathways for the types of complex integrated device and digital systems that could revolutionize clinical care.

While there have been many other exciting developments across the agency, I want to mention just a few, starting with our work in the area of food and nutrition, which has been an area of particular focus for me this past year.

Over the past decade, the FDA has made enormous strides in our efforts to make the American food supply as safe as it's ever been. Indeed, the most recent Global Food Security Index published by *The Economist*, which considers food affordability, availability, quality and safety, and sustainability and adaptation, across 113 countries, noted that the U.S. has moved up twenty-five positions for the food safety indicator since 2012 and is ranked a joint first for the most recent year, 2022.

That doesn't mean we haven't faced significant challenges in this work. Of course, the infant formula recall, which happened to occur on the day I was confirmed, has been an enormous challenge.

Our response to this recall and subsequent shortage involved wide-ranging collaboration within FDA and across the federal government, coordination with U.S. partners and domestic and international manufacturers and retailers, and innovation to increase flexibilities and develop new approaches. Importantly, our response also played a key role in stimulating a wider review and reorganization of the FDA Human Foods Program, catalyzing a growing understanding, both inside and outside the agency, that this area needed more attention, resources, and support.

Earlier this year we announced our vision for a unified Human Foods Program that will combine previously distinct parts of the FDA into a new organization under the guidance of a Deputy Commissioner for Human Foods. In addition, we are creating a Center for Excellence in Nutrition, which will elevate and strengthen FDA's nutrition portfolio. We will finalize the vision by this fall, and we will continue to engage with stakeholders throughout this process.

One other example of some tough waters to navigate over the past year is the regulation of tobacco products. The nation has made notable inroads in this area, with current cigarette smoking among U.S. adults having declined from 20.6% of the population in 2009 to 11.5% in 2021—the lowest levels recorded since 1965.

But we continue to face daunting challenges as we seek to regulate this evolving marketplace involving both combustible tobacco and the industry's shift to vaping. For example, our Center for Tobacco Products continues to respond to hundreds of thousands of product applications remaining among the over 26 million applications that were submitted, as well as dealing with enormous complexities in enforcement. And the growth in youth vaping, which is producing another generation plagued with addiction to products with unknown long-term health consequences, remains a continuing challenge.

But I am optimistic that the work we our doing—including our proposals to eliminate flavored cigarettes and cigars and reduce nicotine in cigarettes—offers a real opportunity to play a major role in dramatically reducing the toll of almost 500,000

Americans who still die every year from cigarette smoking and longstanding disparities in tobacco product use if the current patterns persist.

During this meeting you'll hear from Brian King, our new CTP director, as well as other Center directors about other areas in which the FDA is demonstrating important achievements, innovating, and responding to daily responsibilities and challenges. There are certainly plenty of kudos to be bestowed across the agency. But we also have a lot of work to do. Even though the FDA continues to operate at a high level, there are a number of serious challenges that we need to respond to and that I hope you will play a role in.

Make no mistake . . . the U.S. continues to be the number one innovator in medical products, producing drugs, biologics, tests, and devices that fuel health care around the world. But to retain this leadership we need to strengthen our structures, methods, data collection, and science to allow us to be even more efficient, flexible, and effective in the exercise of our regulatory responsibilities.

Let me offer one small but important example—the evolving role of advisory committees. The FDA has nearly fifty advisory committees and panels, which are convened to provide FDA with independent scientific, medical, and public health advice. While regulatory decision-making ultimately rests with FDA's full time civil servants, the breadth and complexity of our responsibilities make the use of advisory committees an important tool for obtaining independent advice regarding scientific, technical, or policy questions to inform our critical work.

As a former long-term advisory committee member, I believe strongly in the value of interchange among our experts at the FDA and experts who work outside the agency. For certain complex issues, seeking the advice of an advisory committee not only makes our decisions better, but it also adds an element of transparent societal discussion that is important. But I also believe that our advisory committee system can be improved, to enable our experts to get the best advice possible. Stay tuned for developments in this area.

One of the biggest challenges we continue to face does not involve refinement of internal processes but rather how we respond to dangerous and corrosive external factors. I'm referring of course to the continuing and growing challenge of misinformation and disinformation. Since I raised this issue with you last year, there's been an increasing understanding of the problem across government and the nation, but little in the way of real solutions.

That lack of traction is due in part to the very nature of misinformation, which involves unaccountable or unreliable sources, often coming through unattributable social media sources. One of the most basic responsibilities of the FDA is to disseminate facts about science and medicine to the public, in order to help Americans make informed choices about their health. But by undermining confidence in science, purveyors of misinformation make this much more difficult by weakening faith in governmental and other institutions, including the FDA and, in turn, endangering the American public.

The American public is not an abstract concept—these are our family members and friends. The extraordinary tragedy that the vast majority of Americans dying from COVID are not up to date and vaccinated and/or were not treated with an authorized antiviral is only the tip of a much larger iceberg at the core of our decline in life expectancy from drug overdose, suicide, gun violence and chronic diseases.

The FDA is working to aggressively combat this, but we can't do it alone. For instance, we recently relaunched a new updated FDA Rumor Control web page, which

provides a place for people to find the facts on hot topics and learn more about how to spot and address misinformation. I encourage you to stop by our table at this meeting and take a look at the page so you can help disseminate these and other facts that counter misinformation. As members of the food and drug community and bar, you not only can play a role in doing something about misinformation but also, I would suggest, have a special responsibility to do so.

As you well know, the role and mission of the FDA to protect public health was created, defined, delineated, and mandated by Congress. The agency has made an extraordinary difference in the health and safety of American patients and consumers. And today, it is under attack like never before. Indeed, our fundamental authority to regulate the safety and efficacy of products is being challenged.

I'm not going to discuss any specific cases—I'm sure many of you follow them closely. What I want to ask you to do—as lawyers intimately familiar with, and occasionally advocates for the crucial role the FDA plays—is to stand strong for the work and principles of FDA—to not let them be distilled or destroyed through misinformation, disinformation, or partisan legal challenges.

Many of you have worked at the FDA, often in key positions. Some of you have litigated on behalf of the agency. I've participated in many discussions about the revolving door for biomedical scientists, but I've heard little discussion about the revolving door for lawyers, and while the considerations are not identical, there are significant similarities that deserve more attention and debate.

I'm not asking you not to be advocates for your clients; my hope, however, is that in your current work you go beyond simply abiding by the ethical rules governing lawyers who leave federal government practice for the private sector and seek to strengthen the environment in which we all operate.

Each of you have the ability to help shape the debate and discussion, to promote communication and collaboration, and to work productively to reinforce the importance of our institutions to progress, no matter which side of a legal proceeding you're on. In taking this honorable path you can help to make sure that facts win out over misinformation and disinformation, that the principles we stand for are not eroded, and that our ability to protect patients and consumers is reaffirmed and preserved.

Thank you.