Remarks by the Commissioner of Food and Drugs

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Good morning. I'm delighted to be with you again, albeit virtually, for this important conference. It's just one of the bonuses of my being back at the FDA.

I will tell you that more than a few people have asked me why I might want, at age 70, to immerse myself again in the stress and anxiety produced by Washington policy, personnel issues, and congressional funding battles, not to mention the regular demands and responsibilities of the FDA, which on a good day is pretty tough, let alone when we're responding to a pandemic or working around the clock to increase the supply of infant formula and distribute it equitably.

I would have been quite happy continuing my life in the private sector, living near the Golden Gate Bridge, being with my grandchildren, and having plenty of time to focus on my love for sports like Duke basketball and golf.

And yet, here I am, talking with a bunch of attorneys and other experts on FDA law.

I returned to FDA because we are at pivotal moment—for our nation's public health, for the future of our contribution as a nation to global health, and for the future effectiveness of the FDA.

Developments in science, medicine, agriculture, and technology have created enormous opportunities to help make the American public safer in each of the areas we regulate—from the development of new treatments and cures for disease, to new ways to make our food supply safer, to the chance to further limit the dangers posed by tobacco products and opioids, to name just a few. But to do so requires us to respond to challenges that go to the very essence of our agency.

I already was aware of many of these from my earlier experience at FDA. Indeed, as I was preparing for, and going through my confirmation hearings, I heard from many well-informed people about how the FDA needs to address its persistent lack of resources, an outdated organizational structure, and a profound need for data, technological and informational modernization, to name just some of the challenges.

I want to be clear that acknowledging these needs is not in any way an indication that the agency is not doing what it needs to do to protect the public. One of my greatest pleasures in returning to the FDA is the opportunity to work with a world class workforce that does an amazing job and is completely committed to the mission and the work it engenders.

It is, however, a recognition of changes that are needed to support the human effort required to keep up with, or really, to stay ahead of, the industries we regulate, and the technology, science, and communications those industries employ.

I am old enough now to say this with some confidence: After years of working in both the public and private sector, I believe that success follows proper attention to structure, function, leadership, and resources that support the people who do the

work—in this case our FDA workforce. The tendency in Washington is too often to point only to leadership, a foundational requirement for sure, but not enough by itself. In the almost four months since being confirmed, I've focused on a number of priorities that address these needs, and that cut across the agency and the breadth of our responsibilities.

RESTRUCTURING THE FOOD PROGRAM

One issue that's been front and center, highlighted by the recent challenges related to the supply of infant formula, is the need to adequately fund, revamp, and restructure our food program.

I want to be clear: the infant formula shortage on our shelves was multifactorial, including loss of focus on quality by a major company, market concentration, supply chain resilience issues, and inadequate federal authorities to assure vital supply chains. However, the crisis also reveals shortcomings at the FDA, including structural and organizational deficiencies, process insufficiencies, communication barriers, technological inadequacies, chronic underfunding, and in some cases a lack of congressional authority to allow us to do what is needed to assure an adequate supply of safe and nutritious infant formula.

We are currently conducting both a focused after-action review on infant formula and a comprehensive review of the entire food program to determine the best course of action. And when these reviews are completed, we will make whatever changes are necessary and that we have the ability to do.

But other changes will require congressional action. A good model is the 21st Century Cures legislation, passed by Congress a few years ago. That law made a dramatic difference on the medical product side, providing FDA with important resources and changes in regulatory authority that strengthened our ability to support innovation without sacrificing our standards of safety and efficacy.

It's time that the food side got a similar shot in the arm. The needs are clear, significant, and run the expanse of our food safety work, from more inspectors to more funding to better data and technology.

SUPPLY CHAIN MANAGEMENT

One piece of this, which goes beyond our food work to all of the industries we regulate, is the need for improved supply chain management. For example, there is no technical reason why the critical supply chains are not digitally integrated so that the system can be stress-tested, preemptive action can be taken, and reaction to problems can be swift. The authority granted to us by Congress in this regard is very limited. Consequently, we often find ourselves reacting to shortages after the fact in every single industry—for example, there were over 300 drug shortages last year and significant restriction of contrast agents affecting my specialty of cardiology.

Across the industries we regulate, the requirements for notification of impending shortages are variable and mostly inadequate. In the food arena, there is not even a requirement that a firm needs to let us know if they find a contaminant in a sample in their facility that has not yet been shipped out.

A big part of the problem is that each firm manages its own supply chains, but there is no composite view that enables anyone to understand the complete picture. When one firm, as in the case of infant formula, goes down, the ability to adapt is impaired. What we need is a national system that allows some entity, perhaps the FDA, to see

what's going on, make sure the supply is getting where it needs to go, do stress testing, and anticipate where there may be shortages. I am a fan of the benefits of the market, but when it comes to health, a market failure can lead to death and loss of dignity and physical function for those affected. So, the system should monitor, but not intervene except when necessary to prevent harm.

But to do this will require transparency about the information manufacturers have about each of their individual supply chains. The industry has considered this proprietary and has fought prior efforts for the government to gain access. This needs to change, so that we can prevent shortages from happening rather than waiting until they happen when it is often too late to prevent serious harm.

INFORMATION AND DATA MANAGEMENT

A third, related priority concerns virtually every area of our work—the need for improved information, data management systems, and evidence generation.

Throughout my career, I've focused on strengthening systems for generating and gathering new and better data and analyzing those data to provide reliable evidence to inform and improve the many decisions that we make as consumers, patients, families, clinicians, and regulators. This kind of information supports the nuts and bolts of the FDA's work.

The ultimate goal of gathering all of this data and evidence is to better inform our knowledge about a product's potential benefits or risks, additional treatment implications, and potential limitations. This, in turn, supports our regulatory decisions about medical therapies, food safety, tobacco products, or all of the other products we regulate. In fact, I'd say that the amount of societal heat generated by an FDA decision is inversely related to the quality of the evidence we have to support that decision. All too often we have tough issues with a required date for decision and the evidence is simply inadequate—this is a shame given the technological capability we now have to get the right evidence.

After all, we are in the midst of the fourth industrial revolution in which digital information is giving us access to data that would have been unimaginable in the past.

Having come to FDA from a place with the best technology in the world, I'm acutely aware of the technology gap that we face. Digitization and insertion of machine learning and other types of mathematical algorithms into everyday life is making a profound difference, but government agencies are lagging private industry. By the way, I will offer no opinion on whether Google's current AI algorithms are in fact sentient.

At the start of the pandemic, we asked for funding for a system to track outbreaks and shortages but did not get it. As a result, we had to take money from other things to build a system which gives us some, but not all, of the data we need. It also means that other things are not getting done.

In one of my recent appearances before Congress, I asked them to imagine the life of an FDA investigator, or any FDA employee, in a world in which digital technology optimally supports their work, and how much more efficient and effective, not to mention happy, those employees will be. I hope we can realize that day sooner rather than later.

COMBATING MISINFORMATION

One last priority I want to mention is our focus on countering the growing dissemination of misinformation and disinformation about science, medicine, and the FDA, which is putting patients and consumers at risk.

As lawyers, you understand the importance of courts getting the facts correct when applying the law. You also know that while you can and should be zealous advocates, you are not allowed to misrepresent the facts.

Increasingly today, however, people are being distracted and misled. Not in courts, but in the course of decision-making in everyday life. The constant stream of information, opinion, and, too often, disinformation being produced has eroded trust in societal institutions, including the FDA—and, regrettably, in the science upon which our decisions are based. This affects the scope of our work, and it is causing harm to patients and consumers.

Because trust in government has fallen to a low level, we can't fix this alone. That's why I'm appealing to all of you. The best way to correct misinformation is personal interaction; with your professional and personal connections you can help break through the disinformation echo chamber, promote reliable information, and discredit misinformation or disinformation that is intentionally designed to harm people.

WORKING WITH DEVELOPERS

I want to mention one final point that is relevant to many of you in your work that is a critical and often underappreciated element of the FDA's role—the importance of our engagement with industry and product developers.

There are some who question whether an independent regulatory agency like ours, which reaches its decision based on the best available scientific data, should communicate with businesses during the development process. That skepticism is premised on a profound misunderstanding of the value these communications provide to product development and scientific innovation that can help patients and consumers.

The FDA's primary and critical role in the medical product arena is in evaluating the promise and risk of new products and technologies and ensuring the responsible development of innovative medical products—while providing regulatory clarity to industry. Of course, that evaluation must be done independently, based on a comprehensive review of available evidence.

But regulation can also be a key driver of innovation in the laboratory and across society. And it is an essential aspect of the FDA's mission to protect and promote public health to engage in appropriate conversations with developers to help direct, support, and advance the development of groundbreaking new therapies and products.

Similarly, food safety would be a lost cause without a vibrant, constant dialogue between FDA, state agencies, businesses, farms, supply chain entities, and eating establishments, just to name some of the many components of this ecosystem.

While the FDA does not reveal confidential commercial information or trade secrets, the aggregate knowledge of agricultural FDA staff who know the field and who have seen all the products in development—both the successes and the failures—can be critical to guiding developers to the best and most efficient pathway, helping developers save time and money, prevent wasted or duplicative efforts, and ensure speedy development of the best and most effective products.

We aim to continue effectively fulfilling our responsibilities to protect and promote public health—as we have for more than a century. But to do so will require us to make changes.

I did not return to FDA to preside over business as usual. And I look forward to working with, and relying on, the expertise of FDLI and its members to help us in this effort.

Thank you.