Remarks by the Acting Commissioner of Food and Drugs

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Thank you, Daniel [Kracov]. It is a pleasure to join you once again for FDLI's annual conference. I know we all look forward to meeting in person.

The good news is, we're getting closer.

Last year at this time, our nation faced an uncertain future.

Since then, we've made enormous progress in combatting COVID-19. I'm especially proud of the work that the FDA has done.

And yet, thousands of people are still being infected daily, and new variants continue to pose a threat. Most tragically, many are still dying.

It reminds us that we must continue to be safe and vigilant and work to ensure everyone has access to a vaccine and gets vaccinated.

Even as we continue to respond to the pandemic, I believe we are at a critical inflection point—a time to more closely examine our response to this crisis, gauge what has worked, and formulate and implement plans to effectively transition to what comes next.

Today, I will highlight some of the FDA's accomplishments of the past year, but I also want to discuss how the FDA is using this experience to build for the future.

THE FDA'S COVID-19 RESPONSE

The effort by the FDA's workforce over the past year and a half has been nothing short of monumental.

Certainly, at the top of that list is supporting the development, authorization, and distribution of three vaccines that have met FDA's robust standards for safety and effectiveness, including one that can be used in adolescents.

Our Drugs and Biologics Centers also established the Coronavirus Treatment Acceleration Program (CTAP), to move new, safe, and effective treatments to patients as quickly as possible. The numbers are revealing.

As of the end of April there were:

- More than 610 COVID-19 drug development programs in the planning stages;
- More than 450 trials reviewed by the FDA;
- Nine COVID-19 treatments currently authorized for emergency use; and
- One COVID-19 treatment approved by the FDA.

Our Center for Devices and Radiological Health has issued more than 400 Emergency Use Authorizations covering nearly 800 medical products, including molecular diagnostic, antigen and serology tests, sample collection devices, personal protective equipment (PPE), and ventilators.

And our Office of Regulatory Affairs helped facilitate access to necessary and effective PPE, diagnostics, therapies, and vaccines by implementing strategies and operational policies to streamline and clarify the import process for industry.

PROTECTING CONSUMERS BY PREVENTING FRAUD

ORA also helped lead the way on FDA's expansive efforts to protect consumers from products that could be dangerous or that are sold with fraudulent claims to prevent or treat the virus.

To date, the FDA has identified more than 1,300 fraudulent and unproven medical products related to COVID-19. We've issued more than 170 warning letters to companies and individuals selling unproven products, with nearly seventy percent of the recipients taking voluntary action in response.

FDA also worked with the Department of Justice to obtain injunctive relief against several companies that did not take appropriate voluntary action. In some cases, our Office of Criminal Investigations has worked with DOJ to prosecute companies and individuals engaged in fraudulent COVID-related conduct.

Our Operation Quack Hack team has also reviewed thousands of websites, social media posts, and online marketplace listings, leading domain registrars and online marketplaces to review and take down nearly 300 websites and well over a thousand listings selling unproven COVID-19-related FDA-regulated products.

We advised consumers not to use certain hand sanitizer products, including some hand sanitizers that contained dangerous ingredients, and we've coordinated with manufacturers and distributors on the voluntary recall of more than 170 such products.

Our Center for Veterinary Medicine warned consumers about certain veterinary products, like chloroquine phosphate and ivermectin, which were being improperly redirected for human treatments and potentially causing significant adverse effects, even death.

It also worked with industry to set up forecasting and voluntary reporting for COVID-impacted supply chains for veterinary medicines, and livestock and pet food.

The FDA foods program developed a data analysis tool called 21 Forward to track the forecasted incidence of COVID-19 across the country and identify areas in which its spread could impact the food system, potentially disrupting food supply chain continuity. It also provides information to federal and state partners to help support the vaccination of food and agriculture workers by helping them determine how many food and agriculture workers they have in each county at various times. This brief summary shows how the FDA team quickly pivoted, applying its experience, preparedness, and expertise to respond to this crisis.

MEETING NON-COVID RESPONSIBILITIES

Just as important has been how the FDA workforce continued to fulfill the agency's regular and critical responsibilities to protect the public health.

Our Center for Tobacco Products has continued to apply a science-based approach to regulating an evolving tobacco landscape and protecting the public—especially kids—from the addiction, death, and disease caused by tobacco products.

Most recently, with the full support of the Administration, we committed to advancing two regulations that will dramatically change the landscape of combusted tobacco products, specifically, one proposed product standard banning menthol in cigarettes and another banning all flavors (including menthol) in cigars to publish as proposed rules within the next year.

In April, the FDA's foods team released the Closer to Zero action plan, identifying what the agency will do to reduce exposure to toxic elements from foods eaten by babies and young children.

And last month we took two important steps to advance the safety of leafy greens, which has posed a public health challenge—the release of the report from our investigation into a Fall 2020 E. coli outbreak and an updated version of the Leafy Green Shiga-toxin producing E. coli (STEC) Action Plan.

Our Center for Veterinary Medicine continued to support innovation in the animal drug industry. In December, it approved an intentional genomic alteration in a product called the GalSafe pig, which is the first alteration in an animal that the agency has approved for both human food consumption and potential therapeutic uses. Our human medical product centers acted on non-COVID products, approving hundreds of new drugs and biologics, and authorizing a record number of novel medical devices last year.

Opioid deaths have spiked during the pandemic, and the opioid crisis remains front and center for the FDA. Currently, most fatalities are caused by illicit synthetic opioids, particularly fentanyl and its derivatives and heroin, although deaths from prescription opioids remain high. Additionally, misuse of other psychoactive drugs, particularly stimulants, has also spiked over the past year.

In response, the FDA has worked to accelerate development of safe and effective drug overdose reversal agents as well as pharmacological treatment for stimulant use disorder. This is on top of our efforts to facilitate safe prescribing practices and reduce exposure and preventable harm through safety labeling changes, professional guidance development, and communications.

The FDA's One Health initiative is another example of an area where the pandemic brought existing work to the forefront.

One Health embraces the understanding that the health of people, animals, and their shared environment are interconnected. The FDA's Office of the Chief Scientist and Center for Veterinary Medicine have been leading our efforts in this area, which includes a focus on the possible animal origins of the pandemic—and the potential for future ones to arise from zoonotic disease.

One Health also overlaps with important work we are doing to counter antimicrobial resistance. We are collaborating with stakeholders and other partners in our continuing efforts to support responsible stewardship of antimicrobials in both human and veterinary settings.

BUILDING A STRONGER FDA FOR THE FUTURE

Our work in each of these areas (as well the countless efforts I haven't had time to mention) will have a profound impact on the health and safety of the American public for years to come.

But they share another quality as well. They are informed by the best available science and most rigorous data.

Put simply, good science and data are the DNA of the FDA.

One of the FDA's greatest assets is our ability to respond quickly and effectively to public health emergencies while applying what we learn to future crises. The COVID-19 pandemic has tested us, but it also has afforded us an opportunity to be smarter, more efficient, and better prepared.

To be an effective health and consumer protection agency for the 21st Century, we need to expand our scientific and data capabilities.

We need systems that do a better job talking to one another; enterprise platforms that we can use across the agency for multiple purposes. Many of the platforms we use today, which were groundbreaking when they were put in place, are sorely in need of updates.

To help achieve this, we have launched the Technology Modernization Action Plan (TMAP) and Data Modernization Action Plan (DMAP).

The TMAP is designed to help us modernize our approach to the use of technology in support of regulatory mission. But technology is only half the puzzle.

As it has become more sophisticated and our world more connected, we need more and better data from new sources.

We're working on this already.

For example, during the pandemic we've built on efforts to optimize the design and conduct of clinical trials, diversify who is included, and add new data sources, such as digital health data.

This past year, our Oncology Center of Excellence began Project Equity and Project Silver, which focus on increasing minority and geriatric patient enrollment in clinical trials and bringing the voice of under-represented populations to the world of drug development. And the Office of Minority Health and Health Equity and the Office of Women's Health continued to raise awareness and advance efforts to increase the participation of minorities and women in clinical trials.

We also continue to expand our use of real-world evidence and real-world data in our regulatory decision-making, which can strengthen clinical trials and transform the efficiency of product reviews and post-market surveillance.

For example, the FDA and the National Center for Advancing Translational Sciences collaborated on the development of the CURE ID app, which gathers information from the clinical community on novel uses of existing drugs for difficult-to-treat infectious diseases via a website, smartphone, or other mobile device. And our Office of Women's Health funded the expansion of the CURE ID app to gather real-world information on the use of medications for oncology and infectious diseases in pregnancy.

How data is made available is also important. The automation of processes, use of mobile technologies, and easier access to computing resources can support increased capabilities to track and trace medical and food products across the supply chain.

The FDA's New Era of Smarter Food Safety initiative aspires to equip FDA with important new ways to apply available data sources, including leveraging the use of artificial intelligence to identify products that may pose a threat to public health.

It will enable us to apply modern analytics to determine risks, pinpoint problems, and speed our capacity to trace back outbreaks, helping prevent foodborne illness through faster and more effective identification of contaminated foods.

Better technology and data can also help us address recurring problems such as shortages of human and animal drugs, and supply chain disruptions, a key issue during the pandemic.

We engaged with hundreds of drug manufacturers to understand supply chain problems, discover early warning signs of potential manufacturing discontinuances or interruptions, and help develop ways to mitigate risk of shortage. And we're also collaborating with our international partners.

In today's global environment, with individual products sourced in many different countries, we often lack the necessary information, data, or visibility to know if production will be disrupted. Building new systems that provide better data and greater communication is one solution.

Another is modernizing production systems using advanced manufacturing. We recently established several research and regulatory programs for advanced manufacturing, building on existing work.

The goal is to help lower production costs, increase access to critical medical products, and decrease the risk of supply disruption.

Finally, I want to briefly mention how we are building on experience gained during the pandemic regarding our inspections.

One of the most significant decisions we made was to pause most foreign and domestic inspections, with the exception of mission-critical inspectional work. The FDA resumed prioritized domestic inspections in July of 2020.

We recently released a "Resiliency Roadmap for FDA Inspectional Oversight" that discusses the impact of these actions and our plans for moving forward. It is an important report and our Associate Commissioner for Regulatory Affairs, Judy McMeekin, will be discussing it when she speaks with you.

In closing, I'll reiterate that we are only as good as the data we have to analyze, and the science we have to apply it. Or, as Sherlock Holmes once said— "It is a capital mistake to theorize before one has data."

Each day brings new scientific advances. The FDA needs to stay ahead of the curve.

You can look to us to be laser-focused on building the modern technology and data platforms we need to most effectively meet our daily challenges and achieve our public health mission.

Thank you.