TESTIMONY

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SUBCOMMITTEE ON HEALTH
AND
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
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U.S. HOUSE OF REPRESENTATIVES

THE FEDERAL RESPONSE TO COVID-19

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Introduction

Chairs McMorris Rodgers, Griffith, and Guthrie, Ranking Members Pallone, Castor, and Eshoo, and distinguished members of the Committee, thank you for the opportunity to testify before you to discuss the Food and Drug Administration's (FDA's or the Agency's) coronavirus disease 2019 (COVID-19) response and our preparedness efforts moving forward. Our efforts are in close coordination and collaboration with our partners, both within the Department of Health and Human Services (HHS) and across the federal government, to help facilitate the development, authorization, licensure, approval, and availability of critical, safe, and effective medical products to address current and future threats.

The COVID-19 pandemic underscores the need to continue to optimize our preparedness and response capabilities. The Agency's continued preparedness for, and capabilities to respond to, public health emergencies and disease threats such as COVID-19, mpox, respiratory syncytial virus and pandemic influenza have been strengthened by Congress' support of our work. We look forward to continuing work with you this Congress to ensure future readiness.

COVID-19 response efforts

This testimony is just a snapshot of the Agency's extensive work to address this pandemic. From the beginning of this public health emergency (PHE), FDA has taken a leadership role in the all-of-government response and continues to focus on facilitating the development and availability of medical countermeasures to diagnose, treat, and prevent COVID-19; surveilling the medical product and food supply chains for potential shortages, disruptions, and contaminated or fraudulent products; and helping to mitigate or prevent such impacts. FDA is committed to continuing to use every tool in our toolbox to fight this pandemic, including pivoting as the virus adapts, to arm ourselves with the best available medical countermeasures to fight this virus.

Data show the current vaccines remain highly effective at preventing serious clinical outcomes associated with SARS-CoV-2 infection, including hospitalization and death. Staying up to date on COVID-19 vaccinations is the best thing Americans can do right now, in addition to other precautions, to help protect themselves and their families.

Biologics, Including Vaccines: FDA's Center for Biologics Evaluation and Research (CBER) continues to facilitate the development and availability of vaccines and other biological products to combat the COVID-19 pandemic expeditiously and safely. Through our transparent scientific evaluation, FDA has issued Emergency Use Authorizations (EUAs) for four monovalent COVID-19 vaccines: the Pfizer-BioNTech COVID-19 Vaccine for use in individuals six months of age and older; the Moderna COVID-19 Vaccine for use in individuals six months of age and older; the Janssen COVID-19 Vaccine for use in certain individuals 18 years of age and older; and the Novavax COVID-19 Vaccine, Adjuvanted for use in individuals 12 years of age and older. FDA has also approved Comirnaty (known as Pfizer-BioNTech COVID-19 Vaccine under the EUA) for use in individuals 12 years of age and older and Spikevax (known as the Moderna COVID-19 Vaccine under the EUA) for use in individuals 18 years of age and older. Additionally, FDA has authorized two COVID-19 vaccines that have a bivalent composition (original and Omicron BA.4/BA.5) as a booster dose: Pfizer-BioNTech COVID-19 Vaccine, Bivalent; and Moderna COVID-19 Vaccine, Bivalent. Pfizer-BioNTech COVID-19 Vaccine, Bivalent was also authorized as a third dose in the 3-dose primary series in individuals six months through four years of age. On January 26, 2023, FDA held a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to consider whether and how the composition for primary doses of the currently available COVID-19 vaccines should be modified and how and whether the composition and schedule for booster doses should be adjusted moving forward. By a unanimous vote, the committee recommended harmonizing the vaccine strain composition of primary series and booster doses used in the United States to a single composition, e.g., the composition for all vaccines administered currently would be a bivalent vaccine (Original plus Omicron BA.4/BA.5.).

We have relied on the Agency's rigorous standards for safety, effectiveness, and manufacturing quality. These COVID-19 vaccines were developed without cutting corners or compromising our regulatory and scientific standards. As part of each EUA, manufacturers and vaccination providers are required to report certain information, including serious adverse events, even if it is unclear whether the vaccine was the cause, including those that result in hospitalization or death to the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program jointly run by FDA and the Centers for Disease Control and Prevention (CDC). Vaccine safety is a top priority for the federal government, and we take reports of health

problems following COVID-19 vaccination very seriously. FDA and CDC have implemented a coordinated and overlapping approach for continuous safety monitoring of all COVID-19 vaccines using state-of the art technologies.

Drug Products: FDA's Center for Drug Evaluation and Research (CDER) continues its successful work to facilitate the development and availability of diverse therapeutics for use by patients, physicians, and health systems. FDA accelerated the development and publication of guidance and other information for industry and researchers on developing COVID-19-related treatments. Further, FDA created an emergency review and development program for possible therapies for COVID-19, the Coronavirus Treatment Acceleration Program, or "CTAP." Under CTAP, FDA is using every available authority to facilitate the development of safe and effective products to treat patients with COVID-19. As of January 22, 2023, there are more than 720 drug development programs in the planning stages and the Agency has reviewed more than 440 trials of potential therapies for COVID-19.[1] These therapies include antivirals, immunomodulators, neutralizing antibodies, and combinations of these products, as well as cell and gene therapies regulated by CBER. The diversity of therapeutic approaches being investigated rapidly expands our understanding of the effect of different categories of potential treatments. As of January 22, 2023, FDA has approved three drugs to treat COVID-19 and there are currently fourteen EUAs for COVID-19 therapies.

Medical Devices: FDA's Center for Devices and Radiological Health (CDRH) has also worked to meet the unprecedented demand for medical devices including tests, personal protective equipment (PPE), and ventilators, while continuing to fulfill the Center's mission to protect public health and facilitate medical device innovation.

CDRH staff also utilized vital EUA authorities and interacts frequently with test developers and other device manufacturers through the pre-EUA process, including through rolling reviews to further expedite emergency use authorization of critical medical devices. This interaction included working closely with these developers and adapting CDRH's policies to addressing public health needs, as those needs changed. These efforts resulted in increased testing capacity and broadened public access to rapid tests, including those purchased over-the-counter (OTC), as

[1] https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

well as assuring access to other critical devices. CDRH prioritized at-home tests since the beginning of the pandemic, authorizing 30 OTC at-home tests, resulting in hundreds of millions of additional OTC tests available monthly to American consumers. Since January 2020, FDA has engaged with over 1,000 developers and authorized over 443 tests.

CDRH continues to issue EUAs as appropriate for other types of devices and has taken various actions to help facilitate the availability of critical devices and supplies for health care providers and patients. To date, we have issued EUAs or provided traditional marketing authorizations to over 2,800 medical devices for COVID-19, which is 15 times more EUAs than all other previous emergencies combined. In total, CDRH has reviewed 510(k)s for and cleared over 1,900 devices that can be used for COVID-19 and certain similar diseases, including future pandemics. CDRH also issued 28 guidance documents (as well as 21 revisions) outlining policies to help expand the availability of medical devices needed in response to COVID-19.

As we look to transition from the COVID-19 PHE to normal operations, FDA has worked on guidances[2] for transitioning devices that fall within enforcement policies issued during the COVID-19 PHE or that received EUAs to help facilitate a clear and predictable path to market for interested developers. FDA intends to facilitate continued access to devices for patients and health care providers during the transition and while marketing submissions are under review.

Human and Animal Food: As a key part of FDA's mission, a safe and accessible food supply is critical to the health and well-being of families across the United States. As such, FDA has worked with federal, state, local, and industry partners to help ensure a safe and adequate food supply for humans and animals. We have seen that the broad supply chain imbalances impacting so many products are also impacting food, including infant formula, for which COVID-19 had caused supply chain tensions well in advance of the February 2022 recall of certain Abbott infant formulas. To help mitigate the shortage, FDA worked to facilitate the importation of millions of cans of infant formula. Overall, food production and manufacturing in the United States has been remarkably resilient, but we continue to monitor the food supply and apply mitigation strategies for products impacted in part by pandemic-related issues.

[2] https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2023-fy2023

In response to the pandemic, FDA's Foods Program developed *21 Forward*, a food supply chain data management tool, to help identify where risks for interruptions in the continuity of the food supply may be greatest. As part of this tool, FDA conducted targeted outreach to the food industry to offer additional resources and technical assistance in addressing challenges, including monitoring and supporting the infant formula supply chain.

Imports, Inspections, Compliance and Protecting the Medical Supply Chain: Throughout the pandemic, import investigators have been on site protecting the medical supply chain at our ports of entry, courier facilities, and the international mail facilities (IMFs), with uninterrupted support from the Office of Regulatory Affairs (ORA) laboratories. Through continued vigilance, FDA has helped prevent pharmaceuticals and other medical products that do not meet import requirements from entering the country. Since March 2020, with the cooperation of and in coordination with U.S. Customs and Border Protection, FDA has refused and destroyed more than 148,904 drug products, totaling over 28,521,139 capsules, tablets, and other dosage forms of violative drugs shipped via international mail. FDA has maintained pre-pandemic levels of screening for products offered for import and refused approximately 202,746 medical product lines offered for import. FDA has focused examinations on COVID-19 relief supplies to ensure that reviews of compliant products are expedited while maintaining our commitment to refusing medical products that appear to be misbranded, unapproved, counterfeit, or otherwise violative.

Throughout the pandemic ORA continued to conduct mission critical foreign and domestic inspection and investigations including those in support of EUAs for critical medical countermeasures (MCMs) as well as to ensure the quality and availability of medical products. Since October 1, 2021, FDA has been performing domestic inspections at normal operational levels and in April 2022 began to conduct foreign facility inspections, including surveillance and other inspectional work. As FDA works through the inventory of postponed surveillance inspections, the Agency is prioritizing higher-risk establishments. The ORA inspectorate also continues to partner with foreign regulators to conduct inspections and share information to increase global access to medical products.

FDA's Public Health Emergency Preparedness and Response Mission

The Administration's National Biodefense Strategy and Implementation Plan on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security describes in detail a set of transformative capabilities the U.S. government aims to build to defend against future pandemics and biological threats. These include the capability to develop and safely deploy medical countermeasures against novel pathogens much more rapidly than is possible today. These capabilities will require additional resources and scientific breakthroughs. FDA is playing a key role in this effort, to ensure that medical countermeasures can be rapidly and rigorously validated to ensure their safety and efficacy for pandemic response.

The COVID-19 pandemic underscores the importance of a swift and agile response coordinated across all levels of government and in collaboration with the private sector. Through effective communication, dexterity, and innovation, we were able to mitigate the impact of the pandemic and prevent innumerable illnesses and deaths. Preparation for future PHEs depends on utilizing the many strategies that led to a successful response as well as the establishment and refinement of authorities and flexibilities that allow the Agency to identify and mitigate risks while promoting innovation. This includes continuing to proactively leverage existing relationships with entities outside of FDA in emergency response situations. For example, FDA leveraged an ongoing partnership with U.S. veterinary diagnostic laboratories to strengthen COVID-19 testing at the height of the COVID-19 pandemic. In ordinary times, this partnership, the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), helps the U.S. animal health infrastructure rapidly respond to animal health incidents, but during the critical need for COVID-19 testing, it successfully increased capacity to accurately test both human and animal samples for COVID-19. FDA's capacity to drive future PHE responses depends on maintaining and further building collaborations with regulatory, academic, and industry partners even in the absence of a crisis.

Facilitating Access to Safe and Effective Medical Products

As FDA prepares to combat future pandemics, assuring access to safe and effective medical products continues to be of utmost importance. Several areas can provide support in this mission.

Drug Product Supply Chain

The COVID-19 pandemic served as a reminder that the drug supply chain is extremely vulnerable to supply disruptions and surges in demand. Prior to this pandemic, most shortages were due to manufacturing issues that disrupted supply, for which manufacturers of drugs and active pharmaceutical ingredients (API) are required to notify FDA. This notification requirement provides FDA more time to mitigate or prevent a shortage, and the Agency used this authority often during the pandemic to prevent supply disruptions. However, during the pandemic we also saw unprecedented *demand* for drugs for which the Agency cannot require notifications.

Looking to future preparedness, and in accordance with the National Strategy for Resilient Public Health Supply Chain, it is critical for the U.S. government to have visibility into the end-to-end supply chain data access. We believe there are several areas where Congress could build on our current authorities to improve our visibility into the supply chain, strengthen our ability to oversee the drug supply chain, and ensure continued access to critical drug products. As noted, the ability to require drug manufacturers and distributors to report surges in demand to FDA could help the Agency prevent or mitigate shortages, including their severity and impact on patients. Additional improvements in the drug supply chain include:

- Requiring labeling of bulk drug substances to include the original manufacturer and labeling of finished drug products to include additional supply chain information to help identify sources of APIs, thereby providing greater insight into the supply chain; and

- Enhancing information that manufacturers must report, including the suppliers they relied on to manufacture the listed drug and the extent of such reliance, to provide more complete supply chain insight. Having this information would allow the Agency to work more proactively to diversify the supply chain and reduce the risk of shortages.

Finally, as more manufacturers enter the vaccine and biotherapeutics industries and as we face future pandemics, a robust response by ORA's inspectorate will depend on operational readiness and surge capacity. For example, FDA could achieve more effective and efficient oversight through enhanced authorities for conducting remote regulatory assessments. This could include

explicitly extending the ability to request records or other information, in advance of or in lieu of inspections, to all FDA-regulated products, as well as authorizing mandatory remote interactive evaluations. Congress recognized these authorities were key to future preparedness in the fiscal year (FY) 2023 Omnibus by expanding FDA's authority to request records and other information, in advance of or in lieu of an inspection, to devices and to sites or facilities subject to bioresearch monitoring inspections. However, the Agency could achieve even greater regulatory compliance if this records request authority were expressly extended to all FDA-regulated products. Critical investments in this space also include increasing the inspectorate's workforce capacity for oversight of medical products and funding training and continuing education of the inspectorate's workforce.

Medical Device Supply Chain and Safety

Shortages: In the COVID-19 pandemic, CDRH has worked with manufacturers, health care providers, suppliers and our U.S. government partners to mitigate over 350 reported medical device shortages, which equates to thousands of medical devices. Using the new device shortages authority we received through the CARES Act, we were able to facilitate device availability for patients across the United States. This is a vital authority, as our most vulnerable populations are those most often impacted the greatest by critical device shortages.

Based on our experience with this pandemic, as well as with shortages and supply chain disruptions that occur outside a PHE, we believe the public health would benefit from removing the temporal limitation in statute that only requires manufacturers to notify FDA about interruptions or discontinuances in the manufacture of certain devices *during or in advance of a PHE*. The FY2023 Consolidated Appropriations Act (FY23 Omnibus) added voluntary notifications from manufacturers about certain device discontinuances or disruptions, but an effective device supply chain program requires a more comprehensive and consistent flow of information between manufacturers and FDA, similar to what is required for drug products. Without this, the Agency remains limited in its ability to collect information that can mitigate or prevent medical device shortages, protecting U.S. patients and health care providers.

Critical shortages occur in many situations that are outside of or unrelated to PHEs, including natural or human-made disasters, recalls, geopolitical conflict and production shutdowns, and

cybersecurity incidents, among other triggering events for which device shortages can still significantly impact patient care. Furthermore, by the time there is an emergency, it is often too late to mitigate or prevent shortages. For example, supply chain disruptions began even before COVID-19 cases were identified in the United States, as other nations had outbreaks and needed PPE, testing supplies, and other equipment in excess of supply.

Another important aspect of supply chain preparedness are risk management plans. The ability to require a risk management plan for critical devices would help ensure manufacturers have plans in place to ensure resiliency and mitigate future supply chain disruptions. COVID-19 showed us that manufacturers are not always prepared for situations where their ability to manufacture product may be disrupted or may be insufficient to meet increases in demand, especially where they are dependent on one source for a critical raw material or component that was in shortage. Risk management planning that occurs even outside of an emergency will result in greater resiliency in the critical device supply chain.

In Vitro Diagnostics: The past few years have also highlighted the critical need for a modernized regulatory framework that applies to all in vitro diagnostics. The COVID-19 pandemic underscored the importance of both test access and test accuracy. Beyond COVID-19, tests are used for many different purposes and are based on many different types of technologies, and they are becoming increasingly important to our entire health care system. According to CDC, 70 percent of health care decisions are based on clinical lab test results.[3] Some of those tests are the sole determinant of a patient's treatment. A modern oversight framework that is specifically tailored to assuring tests work is critical to position ourselves for the future – whether it is to prepare for the next pandemic or to realize the full potential of diagnostic innovation.

Such a system can balance innovation with assurance of accuracy and reliability for tests. For example, a technology certification approach could provide assurances for most tests without individual FDA review of the tests. These assurances are critical. We have seen many examples of tests that do not work – from COVID-19 tests marketed during the pandemic, to tests that are the sole determinant of which treatment a cancer patient receives. In particular, we are concerned

[3] https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html#print

that there may be inaccurate laboratory developed tests, or LDTs, in use today.[4] This puts patient health at risk, undermines our health care system, and hinders the country's ability to effectively address PHEs.

We look forward to continuing our work with Congress and stakeholders to create a modern framework for all tests and to strengthen supply chain authorities. In the meantime, we intend to move forward using our current regulatory authorities to offer providers and patients confidence in the diagnostic tests that they use.

Overseeing Products Critical to Public Health and Fostering Medical Countermeasure Development

We have also seen that during a PHE or a supply disruption that other critical products can have immense impact on families, as we saw in the infant formula shortage. Preventing food shortages is critical to public health and we are grateful that Congress included a provision in the FY23 Omnibus to require manufacturers of infant formulas and certain medical foods to notify FDA of potential shortages. Looking forward, parallel authority to require notifications of anticipated interruptions in the supply chain of additional categories of foods designated by FDA during a declared PHE could help prevent future shortages in the food supply.

Further, enhancing FDA's regulatory capabilities and readiness to respond to emerging pathogens, ensure blood safety and availability, and expeditiously review new vaccines, existing vaccines and other medical products, is vital to the Agency's continued success in PHE preparation and response. Our staff have had to be pulled off other work and have been working relentlessly on pandemic issues for the past three years, leading to a significant backlog and fatigue. During COVID-19 we have seen that FDA staff need to be prepared to continue to address the current pandemic needs while also preparing for potential future pandemics and staying on top of our daily work to ensure blood safety and availability and regulate vaccines and other medical products. Through the creation of a specialized program within CBER to defend against emerging pathogens, the Agency would be well positioned to respond to identified

[4] For example, see: Case studies of 20 LDTs that may have caused patient harm (http://wayback.archive-it.org/7993/20171114205911/https:/www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm472773.htm) and FDA's analysis of 125 EUA requests for COVID-19 tests from labs that found 66 percent were not designed or validated appropriately (https://www.nejm.org/doi/full/10.1056/NEJMp2023830).

threats of concern and focus experienced resources to work quickly on MCM development to address these concerns. In consultation with HHS partners, the program could: provide recommendations and guidance to developers of vaccines and other medical products and relevant federal partners; use real-world data or real-world evidence to study the safety and effectiveness of products for addressing biological incidents and identify which products may be best suited for specific pathogens or for use in different populations; and facilitate product development including advances in manufacturing. It could also support scientific research within CBER that contributes to development and review of biological products to counter biological incidents and emerging pathogens.

FDA's ability to monitor the safety of vaccines would also benefit greatly by a coordinated federal public health data reporting authority. Through the Biologics Effectiveness and Safety (BEST) Initiative, part of the FDA Sentinel Initiative, FDA can analyze information occurring in millions of health insurance claim submissions or electronic health records (EHR) recorded in large data systems. FDA's contractors assist with this program and analyze the data itself behind their firewall as part of data privacy protections. While the BEST Initiative has been essential for our work and provided us with a robust picture of safety data, our ability to analyze claims information is limited by the fact that some vaccinations are not recorded in health insurance claims data. Further, when insurance claims databases or EHRs detect an adverse event, FDA often needs to quickly verify information or access additional information to evaluate the adverse events of interest. When we request records to verify adverse events detected by the BEST Initiative databases it has taken FDA around 8-12 weeks in some cases to receive voluntary access to these records. Additionally, coordinated federal public health data reporting authority would help the Agency to more swiftly identify adverse event patterns and trends associated with the use of vaccines or other MCMs, and swiftly be able to communicate with health care providers and patients about safety signals.

Finally, across all these areas, FDA's partnerships with state, local, and U.S. territorial governments continue to play an important role in the protection of public health, particularly as FDA partners with them in the regulation of products, helping to ensure the safety and integrity of supply chains, and assisting in enforcement against products that are being unlawfully sold. Allowing for disclosure of non-public information to these agencies with complementary

functions related to FDA-regulated products could achieve faster and more effective action to protect the public health during national public health emergencies, other state/local disaster declarations, outbreaks or other public health events, and for routine regulatory oversight.

Conclusion

FDA continues to advance its mission to protect and promote public health by helping to ensure the safety of human and animal food, and the safety and effectiveness of medical products in the COVID-19 pandemic. The Agency is continuing to monitor its policies, the marketplace, and national needs, and will continue to adapt as the circumstances of the pandemic evolve. We take our public health mandate very seriously and will continue to work each day to help end this pandemic and prepare for the next one. We look forward to continuing to work with the Committee on the Agency's public health emergency preparedness and response mission and strengthening FDA's authorities to continue building a resilient supply chain for critical medical products, foods, and medical countermeasures. Thank you again for the opportunity to testify.