TESTIMONY

OF

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"PREPARING FOR AND RESPONDING TO FUTURE PUBLIC HEALH SECURITY RISKS"

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Introduction

Chairs McMorris Rodgers and Guthrie, Ranking Members Pallone 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) efforts to prepare for the 2023 reauthorization of the Pandemic and All Hazards Preparedness Act.

The Department of Health and Human Services (HHS) had to overcome real challenges while responding to the once-in-a-century COVID-19 pandemic and other recent emergencies, including the infant formula shortage, mpox, and Hurricanes Ian and Fiona. Similar challenges in the future will be even harder to effectively address without appropriate additional authorities, flexibilities, and funding as requested in the FY 2024 President's Budget. Together, the proposals my colleagues and I will discuss today will help bridge key gaps and barriers to enable a robust and timely response to future emergencies—by enhancing early detection; safe, effective, and accessible Medical Countermeasures and other supplies; response and health system capacity; and recovery and other supports. These proposals complement the discretionary funding and $20 billion mandatory funding requested across HHS public health agencies to prepare for biological threats.

The last three years of the COVID-19 pandemic underscore 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. Our efforts are in close coordination and collaboration with our partners, both within HHS and across the federal government, to help facilitate the development, authorization, licensure, approval, clearance, and availability of critical, safe, and effective medical products and help ensure the continuity of the food supply to address current and future public health threats. We look forward to continuing work with you this Congress to ensure future readiness.

FDA's Public Health Emergency Preparedness and Response Mission

The Pandemic and All-Hazards Preparedness Act (PAHPA) contains key legal authorities to sustain and strengthen our Nation's preparedness for public health emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, as well as emerging infectious disease threats.

The law, including critical policies from both previous reauthorizations, recognizes the key role FDA plays in public health emergency preparedness and response. Its provisions further FDA's mission of fostering the development and availability of drugs, vaccines, and devices (also referred to as medical countermeasures, or MCMs) for use in these emergencies.

Together, these authorities for FDA have not only supported and facilitated government partners' pre-event planning efforts and pre-positioning of MCMs, but also helped to facilitate MCM development and the efficient and rapid deployment of these medical products in the event of a CBRN emergency or emerging disease health threat – including COVID-19. FDA has effectively used PAHPA provisions to support our nation's preparedness and response capabilities, and continues to provide the highest quality and most timely guidance possible to all stakeholders engaged in MCM product development.

One of the lessons learned from the COVID-19 pandemic was 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. From the beginning of the COVID-19 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 MCMs 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. Looking ahead, FDA is committed to continuing to use every tool in our toolbox to prepare for CBRN response activities, fight future public health emergencies, arm ourselves with the best available MCMs, and support U.S. response efforts.

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 instance, as it relates to the development of COVID-19 testing kits, since January 2020, FDA has engaged with over 1,000 test developers and worked interactively with them to support emergency use authorization (EUA) of over 500 tests for COVID-19, including 35 over-the-counter (OTC) tests. FDA has already been working to strengthen communication strategies and tools that have proved effective for ongoing collaboration with our private sector partners as demonstrated during the COVID-19 PHE, including town halls, webinars, a telephone hotline and email boxes for stakeholder inquiries, templates, and interactions with professional and trade organizations.[1] FDA entered into a memorandum of understanding (MOU)[2] with the Centers for Disease Control and Prevention (CDC) and laboratory stakeholders (including APHL and ACLA) in May 2022, a formal step in further building collaborative relationships with the lab community. The Agency is fully engaged with CDC and developers under this MOU with respect to mpox. FDA also continues working proactively with the National Institutes of Health (NIH) Independent Test Assessment Program (ITAP)[3] to support developers of at-home COVID-19 tests, including multiplex tests that can also detect influenza. The program is an extension of the NIH Rapid Acceleration of Diagnostics (RADx) Tech program, which supported development of several authorized tests, including the first OTC COVID-19 test. We have consistently seen shorter review times for such EUA requests due to our partnership with ITAP and we are continuing to work with this program to help provide additional testing options for patients.

[1] https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/emergency-use-authorization-covid-19-tests-independent-assessment-fdas-response
[2] https://www.fda.gov/about-fda/domestic-mous/mou-225-22-020
[3] https://www.hhs.gov/about/news/2021/10/25/new-hhs-actions-add-biden-administration-efforts-increase-access-easy-use-over-counter-covid-19-tests.html

In addition, 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. 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.

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 MCMs 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 MCMs can be rapidly and rigorously evaluated in preparation for pandemic response.

Facilitating Access to Safe and Effective Medical Products

As FDA prepares to combat future threats, ensuring access to safe and effective medical products continues to be of utmost importance. FDA can provide support to this mission through its work in several preparedness areas.

Drug Product Supply Chain

There is a need for greater transparency into the supply chains of our medical products to both improve resiliency and ensure continued access for critical medical products, including drug products. FDA works within its limited authorities to find ways to prevent and mitigate drug shortages, and worked with manufacturers to successfully prevent 222 shortages in CY 2022. 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 has relied on these notifications to help prevent supply disruptions. However, during the pandemic we also saw unprecedented *demand* for drugs and would benefit from similar notifications of supply disruptions based on *demand*.

Looking to future preparedness, and in accordance with the National Strategy for a 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. The authorities provided under section 3112 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) enhanced FDA's visibility into drug and medical product supply chains and the tools available to the Agency to help identify, prevent, and mitigate drug shortages. To increase patient access to critically needed medications in shortage or to prevent potential shortages, FDA leveraged available tools (including the authorities and requirements added by the CARES Act), including in CY 2022:

- Expedited reviews of approximately 200 submissions.
- Prioritized certain establishment inspections to address drug shortages
- Expedited assessments of manufacturing supplements to facilitate the manufacturing capacity for COVID-19 therapeutic biologics.
- Exercised regulatory flexibility and discretion in 87 instances to increase supplies of critically needed medications.

However, 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. 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 drug supply chain-related authorities could include:

- Requiring labeling of bulk drug substances to include the original manufacturer and requiring 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;

- Enhancing information that manufacturers must report with respect to the amount of listed drugs produced for distribution, 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;
- Ensuring FDA has an opportunity for a facility inspection or evaluation before distribution of certain non-application drug products. Under current law, for drugs that are not subject to premarket approval requirements, FDA typically does not have an opportunity to inspect the manufacturing facilities before such products are shipped to or distributed in the United States. Providing an opportunity for facility inspection would help enable FDA to identify potential safety issues related to manufacturing before a non-application drug product is distributed;
- Requiring facilities at which drugs are manufactured to create, submit, and maintain Site Master Files (SMFs). SMFs are internationally harmonized documents that typically contain specific information about the firm's manufacturing and product activities and quality management and quality control activities at the named site and identify any closely integrated operations at adjacent and nearby buildings. SMFs would improve Agency understanding of manufacturing activities and provide critical information on supply chain management, thereby providing supply chain transparency to reduce the risk of shortages.

Finally, as more manufacturers enter the vaccine and biotherapeutics industries, the ability of ORA's inspectorate to robustly respond to future pandemics will depend on operational readiness and surge capacity. For example, FDA could achieve more effective and efficient oversight if it had improved authorities for conducting remote regulatory assessments. This could include explicitly extending FDA's authority 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. In the fiscal year (FY) 2023 Omnibus, Congress recognized that such authorities were key to future preparedness 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 and the Agency was provided authority for mandatory remote interactive evaluations. Critical investments in this space are also needed, such as 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

U.S. preparedness and our national security depend on a strong domestic supply chain for medical devices. Under the CARES Act, FDA received new authority requiring medical device manufacturers to submit information related to a device shortage during a public health emergency[4]. As of December 2022, we have received over 455 potential and actual shortage signals, which translates to hundreds of thousands of device units that have been in shortage. We used the information we collected under these new authorities to help mitigate approximately 350 of the 455 shortages. FDA also used information gathered under these authorities to perform assessments that enabled us to:

- Expedite premarket reviews and inspections
- Issue guidance documents, letters to healthcare providers, and enforcement discretion;
- Publish communication products including conservation strategies to provide end users with information on device shortages; and
- Work with ASPR on Defense Production Act priority ratings and other actions by the U.S. Government – as ASPR, the Department of Defense, the Department of Transportation, and others all depend on the information from FDA to support companies who are trying to help support the U.S. response.

[4] Section 506J of FD&C Act (21 U.S.C. 356j)

Unfortunately, the requirement for manufacturers to provide this critical information is temporally limited as it is only required to be provided to FDA during or in advance of a PHE. However, medical device shortages occur in many situations that fall outside of or are unrelated to declared PHEs, including certain natural or human-made disasters, recalls, geopolitical conflicts, production shutdowns, and cybersecurity incidents. We know that these shortages most often impact our most vulnerable and underserved populations -- like children, rural populations, and our veterans and VA hospitals. As an example, rural hospitals often do not have the funding to purchase multiple types of critical equipment, such as X-ray machines and washers and sterilizers to clean and sterilize reusable medical devices. When these devices and equipment cannot be serviced or replaced because of a lack of parts or materials, patients may have to drive hours, if they can, to other areas to try to seek the care they need. Moreover, as we saw with the onset of COVID-19, by the time there is an emergency, it is often too late to prevent or mitigate shortages.

The FY 2023 Omnibus clarified FDA's ability to receive voluntary notifications from manufacturers about certain device discontinuances and interruptions, but this pandemic has demonstrated that relying on voluntary information-sharing deprives FDA and the public of critical supply chain information. To protect patients, build a more resilient domestic supply chain, and help reduce dependence on foreign sources, it is critical that Congress remove the temporal limitation that only requires manufacturers to notify FDA about interruptions or discontinuances in the manufacture of certain devices during or in advance of a PHE.

Furthermore, COVID-19 also 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. A good example of this was the recent tracheostomy tube shortage. The manufacturer was reliant on a single source for a critical raw material component (silicon)—the vast majority of which comes from China. Having a risk management plan in place could have helped the manufacturer and FDA to respond more swiftly to ensure redundancy in suppliers. Risk management plans are commonplace in all types of industries, and

mandatory for other medical product areas such as drugs, biologics, and critical foods (the latter of which Congress just enacted in the FY 2023 Omnibus). Providing FDA with statutory authority to require risk management plans would help ensure manufacturers have plans in place to improve resiliency and mitigate future supply chain disruptions -- and this includes minimizing reliance on products and components from any one foreign country. For example, the United States continues to import 45 percent of finished medical devices from China, and we are even more dependent on China for raw materials and components that are used to make medical devices.

Our supply chain is too vulnerable and the health care of our patients – our veterans, seniors, children, and underserved populations including those in rural areas and others who often suffer the most when there is a supply chain issue – is too important to rely on voluntary reporting of this critical information.

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.[5] 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

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

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 that there may be inaccurate laboratory developed tests, or LDTs, in use today.[6] 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 a supply disruption for other critical products can have an 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 FY 2023 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, help 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 in certain areas and fatigue. During COVID-19 we have seen that FDA staff need to be prepared to

[6] 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).

continue to address the current pandemic needs while also preparing for potential future pandemics and staying on top of our daily work to help 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 and other threats, the Agency would be well positioned to respond to emerging and identified 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: further accelerate the review of critical MCM product applications, provide recommendations and guidance to developers of vaccines and other medical products and to 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 applied 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. New provisions for the disclosure of non-public information to these agencies with complementary functions related to FDA-regulated products, and a federally consistent expectation for disclosure, 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.