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The End of an Era: How Will Terminating the COVID-19 Public Health Emergency Affect Life Sciences Companies?

The Biden Administration recently announced that it would allow the COVID-19 public health emergency ("PHE") to expire on May 11, 2023. Coming more than three years after the Secretary of the U.S. Department of Health and Human Services ("HHS") declared the PHE, the decision not to renew the emergency declaration will directly affect multiple stakeholders in the health care system, including life sciences companies. This alert discusses key points that life sciences companies need to know regarding the planned end of the PHE, including that:

- Emergency use authorizations ("EUAs") issued by the Food and Drug Administration ("FDA") are not directly affected by the end of the PHE.
- Various FDA enforcement discretion policies related to COVID-19 will terminate at the end of the PHE, but certain others, including for in vitro diagnostic ("IVD") products, will remain in effect until further notice from FDA.
- The Public Readiness and Emergency Preparedness ("PREP") Act, which grants immunity from liability for manufacturers of certain COVID-19 medical countermeasures, as well as for health care providers, is not directly affected by the end of the PHE and will continue until either October 1, 2024 or until HHS formally revokes such immunity, whichever comes first.

Background

Shortly after initial reports of the COVID-19 outbreak, the Secretary of the U.S. Department of Health and Human Services issued a determination that a public health emergency existed related to the virus causing COVID-19 (the "PHE Declaration").[1] Since then, the declaration has been repeatedly renewed, most recently on January 11, 2023.[2]

The PHE Declaration was key to unlocking access to funding and other legal authorities to help combat the pandemic. Among other things, it permitted HHS to expedite processes to make grants or enter into contracts, waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program ("CHIP") provisions, and modify the requirements surrounding the practice of telemedicine.

Following the original PHE Declaration, then-HHS Secretary Azar also issued a determination that the PHE had created circumstances that justified FDA issuing expedited regulatory authorizations, referred to as EUAs, for certain COVID-19-related medical devices – including IVD products – as well as vaccines, drugs, and biologics (collectively, the "EUA Declarations").[3] The PHE and EUA Declarations allowed FDA to establish enforcement discretion policies and issue EUAs that were crucial to increasing the availability of personal protective equipment, ventilators, and other medical supplies, establish diagnostic testing capabilities, and expedite the development of and access to vaccines and therapeutics.

With the impending termination of the PHE, many of the policies and protections issued thereunder will expire as well. Understanding what will – as well as what will *not* – come to an end as FDA transitions into a post-PHE world will help to ensure ongoing compliance with existing laws and regulations.

EUAs

EUAs have been necessary to expedite the development, distribution, and use of critical tools to manage the public health crisis. Since the start of the COVID-19 pandemic, FDA has issued more than 650 individual EUAs. While a significant majority of these have been issued for COVID-19 IVDs,[4] EUAs have been granted for other product types including COVID-19 vaccines,[5] therapeutics,[6] and other medical devices.[7]

Because FDA's EUA authority is tied to the EUA Declarations rather than the PHE Declaration, termination of the PHE does not automatically affect EUAs. Rather, termination of EUA Declarations requires a separate determination that the circumstances justifying the emergency use no longer exist, and advance notice must be provided when an EUA Declaration is terminated.[8] FDA can also terminate individual EUAs while leaving the broader EUA Declarations in effect and has already done so in a number of cases. For example, FDA has terminated EUAs when there were technical or performance concerns with a product,[9] where the manufacturer requested withdrawal due to business considerations,[10] and where full approval was granted to either the EUA-authorized product or a substantially equivalent product, such that the criteria for issuance of an EUA were no longer met.[11] While there is no sign that HHS intends to terminate any of the EUA Declarations immediately, manufacturers of products marketed under EUAs should be aware of FDA plans for transitioning away from such products at some point.

- FDA's Transition Plan for Medical Devices Issued EUAs: In December 2021, FDA issued a Draft Guidance entitled Transition Plan for Medical Devices Issued EUAs During the COVID-19 Public Health Emergency (the "EUA Transition Plan").[12] For an in-depth look at the contents of the EUA Transition Plan, *see* a prior Ropes & Gray analysis of the draft guidance document. While acknowledging that the continued validity of EUAs and EUA Declarations is not contingent on the continued existence of a PHE, the EUA Transition Plan contemplates terminating "device-related" EUAs, outlining the framework for doing so. Currently, the EUA Transition Plan exists only in draft form. However, during the notice-and-comment period for the Draft Guidance, the EUA Transition Plan received relatively few comments, and, as such, we have no reason to anticipate significant changes from the draft form.

  Manufacturers and distributors of medical devices that were issued EUAs should begin reviewing and familiarizing themselves with FDA's EUA Transition Plan, if they have not done so already.

- Non-Device EUAs: As described above, termination of an EUA Declaration and the attendant EUAs requires a separate termination declaration by FDA. To date, FDA has not made any statement regarding its policy or intentions for non-device-related EUAs, including those for COVID-19 vaccines and therapeutics. By law, any such statement would require sufficient advance notice to allow manufacturers of affected products to appropriately dispose, return, amend the labeling of, or otherwise remedy non-compliant products.[13]

- *Although FDA has terminated certain EUAs, it seems unlikely from a policy standpoint that FDA would terminate the broader EUA Declarations for vaccines, drugs, and other biological products before a sufficient number of COVID-19 vaccines and therapeutics have received full approval.*

FDA Guidance Documents and Enforcement Policies

To help alleviate the difficulties faced as a result of the COVID-19 pandemic, including drug and device shortages and other pressures on the drug and device supply chains, FDA developed policies to facilitate access to necessary drugs and devices. Typically issued in the form of guidance documents, such policies covered a wide variety of topics, including amending FDA's inspection practices, altering FDA's supply chain disruption reporting requirements, and exercising enforcement discretion to permit the marketing of certain unapproved or otherwise non-compliant products during the PHE. These policies will automatically expire at the termination of the PHE. However, FDA has indicated that it does not intend all of its policies to be impacted in the same way by the end of the PHE. To address potential confusion surrounding which guidance documents will terminate with the end of the PHE, FDA published an update on its website stating that "[t]he FDA intends to issue a *Federal Register* notice regarding how HHS' determination to end the COVID-19 public health emergency declared under the Public Health Service Act will impact the Agency's COVID-19-related guidances and which of those guidances it is temporarily extending or letting expire."[14] Until FDA offers such clarification, the impact of the PHE termination on enforcement discretion policies can be understood as follows:

- IVD Enforcement Discretion Policies: FDA issued enforcement discretion policies related to IVDs and COVID-19 testing, but chose to distinguish the scope of these policies from the scope of its medical device enforcement

policies; whereas the medical device guidance documents are only intended to remain in effect during the PHE, FDA has tied the existence of its IVD-focused enforcement policies to the IVD EUA Declaration.[15] As such, FDA's enforcement discretion policies related to the distribution and use of IVDs will not terminate with the expiration of the PHE.

Entities engaged in the manufacture, sale, marketing, or distribution of products impacted by enforcement policies should watch for FDA's upcoming statement regarding the impact of the PHE termination on its various guidance documents, which is expected to occur through a Federal Register *notice.*

- Medical Device Enforcement Discretion Policies: Many of these policies were focused on products that diagnose, treat, and prevent COVID-19 and associated conditions, or that facilitate the continued provision of safe and effective health care within the context of the COVID-19 pandemic. Therefore, these enforcement discretion policies are explicitly intended to remain in effect only for the duration of the PHE; the termination of the PHE in May 2023 will mean the discontinuation of these policies as well, if they are not finalized. FDA has gone into additional detail as it relates to medical device enforcement discretion policies, offering insight into the particular types of guidance documents that it intends to have terminate immediately at the end of the PHE. FDA issued a Draft Guidance in December 2021 entitled Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency (the "Medical Device Transition Plan").[16] This policy identifies various enforcement discretion policies that are intended to terminate at the end of the PHE unless finalized before that date, including the policies related to, among other things, remote digital pathology devices; non-invasive remote monitoring devices to support patient monitoring; infusion pumps and accessories; and face masks, face shields, and other personal protective equipment. It also provides general recommendations for a phased transition process with respect to the devices that fall within the scope of such policies. For an in-depth look at the contents of the Medical Device Transition Plan, *see* a prior Ropes & Gray analysis of the draft guidance document. Ultimately, FDA's Medical Device Transition Plan anticipates a 180-day buffer to permit manufacturers of medical devices covered by certain of the COVID-19 enforcement discretion policies to come into compliance with FDA's standard laws and regulations. Currently, the Medical Device Transition Plan exists only in draft form. However, relatively few comments were submitted to FDA during the notice-and-comment period, and many of those that were submitted by industry groups and actors that would be directly impacted by the transition offered support for FDA's general framework.

  Manufacturers and distributors of medical device products covered by existing FDA COVID-19 enforcement discretion policies should begin reviewing and familiarizing themselves with FDA's Medical Device Transition Plan, as the "implementation date" triggering the transition period is the date that the PHE expires – May 11, 2023.

- COVID-19 Operational Policies: In addition to the enforcement discretion policies related to particular product types, FDA issued a number of COVID-19 PHE-related policies that will terminate immediately upon the expiration of the PHE. These include but are not limited to policies that offer flexibility in the context of clinical trials,[17] and that alter procedures for FDA inspections and audits[18] and requirements for drug and biologic manufacturing.[19] FDA also issued policies related to PHE-dependent authorities to alter reporting requirements on certain issues, including requiring reporting on potential or current medical device supply disruptions during the PHE.[20] All of these policies will terminate at the end of the PHE.

PREP Act Immunity

On March 10, 2020 then-HHS Secretary Azar also issued a declaration under the PREP Act providing immunity from tort liability to certain individuals and entities involved in the manufacture, distribution, administration, or use of certain covered countermeasures related to COVID-19 that includes, but is not necessarily limited to, the use of approved or cleared products, products being researched pursuant to investigational new drug ("IND") applications or investigational device exemptions ("IDEs"), and EUA products.[21] The PREP Act Declaration was subsequently amended 10 times to

clarify and expand the scope of covered countermeasures and qualified individuals covered by PREP Act immunity. PREP Act immunity extends to, among other covered individuals and countermeasures:

- Manufacturers and distributors of covered countermeasures;
- Health care providers using telehealth to provide or administer covered countermeasures, including drugs, devices, or biologics aimed at treating, diagnosing, curing, preventing, or mitigating COVID-19 for patients in any other state;
- Health care providers licensed in one state providing vaccinations against COVID-19 to patients in any state; and
- Pharmacists ordering and administering, and pharmacy interns administering, COVID-19 and other vaccines to children ages 3-18 in accordance with the Advisory Committee on Immunization Practices ("ACIP") recommendations.

  Because PREP Act immunity is tied to the PREP Act Declaration, rather than the PHE Declaration, the White House's announcement does not impact the protections offered under the PREP Act. The PREP Act Declaration and its attendant protections are effective until either (1) the PREP Act Declaration is formally revoked; or (2) October 1, 2024, whichever comes first.

Ultimately, the expiration of the PHE is likely to be felt most directly by entities whose operations have changed pursuant to FDA's COVID-19 operational guidances, and manufacturers of medical devices being distributed under FDA's device-related enforcement discretion policies, as the end of the PHE automatically triggers the termination of these policies. FDA has stated that it plans to offer additional insight in the form of a *Federal Register* notice for manufacturers of other products and for other FDA-regulated entities to clarify which policies may remain intact even after the PHE. Holders of EUAs and professionals operating under the protection of PREP Act immunity will not be directly affected by the end of the PHE and may continue to act under these policies even after the PHE expires unless FDA states otherwise. However, manufacturers and distributors of all medical device products impacted by PHE-related policies or authorities – including EUAs – should familiarize themselves with FDA's transition plans and begin planning for a return to more standard FDA regulation.

Ropes & Gray will continue to monitor developments in this area. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.

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1. Secretary of Health and Human Services Alex Azar, Determination that a Public Health Emergency Exists, (Jan. 31, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.
2. Secretary of Health and Human Services Xavier Becerra, Renewal of Determination that a Public Health Emergency Exists (Jan. 11, 2023), *available at* https://aspr.hhs.gov/legal/PHE/Pages/covid19-11Jan23.aspx. The declaration had previously been renewed on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, and October 13, 2022.
3. *See e.g.*, Secretary of Health and Human Services Alex Azar, FD&C Act Determination of Public Health Emergency (Feb. 7, 2020), *available at* https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency.
4. 85 FR 7316 (Feb. 7, 2020). For a complete overview of FDA's COVID-19 EUA efforts related to IVDs, *see* https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

5. 85 FR 18250 (Apr. 1, 2020). For a complete overview of FDA's COVID-19 EUA efforts related to vaccines, *see* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.
6. *Id.* For a complete overview of FDA's COVID-19 EUA efforts related to drugs and non-vaccine biological products, *see* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.
7. 85 FR 13907 (Mar. 10, 2020); 85 FR 17335 (Mar. 27, 2020).
8. 21 U.S.C. § 360bbb-3(b)(3).
9. *See, e.g.*, U.S. Food and Drug Administration, Revocation of Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability, 86 FR 48712 (Aug. 31, 2021); U.S. Food and Drug Administration, Revocation of Authorization of Emergency Use of a Medical Device During COVID-19, 86 FR 17162 (Apr. 1, 2021); *see* also U.S. Food and Drug Administration, Revocation of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus, 82 FR 29883 (Jun. 30, 2017); U.S. Food and Drug Administration, Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Ebola Virus, 83 FR 37813 (Aug. 2, 2018).
10. *See, e.g.*, U.S. Food and Drug Administration, Revocation of Four Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19, 88 FR 6751 (Feb. 1, 2023); *see* also U.S. Food and Drug Administration, Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus, 84 FR 49314 (Sep. 19, 2019).
11. *See, e.g.*, U.S. Food and Drug Administration, Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus, 84 FR 38636 (Aug. 7, 2019); U.S. Food and Drug Administration, Revocation of Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of and/or Diagnosis of Zika or Ebola Virus, 85 FR 910 (Jan. 8, 2020).
12. U.S. Food and Drug Administration, Draft Guidance: Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, *available at* https://www.fda.gov/media/155039/download.
13. 21 U.S.C. § 360bbb-3(b)(3).
14. U.S. Food and Drug Administration, COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders, *available at* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders. (last accessed Feb. 7, 2023).
15. *See, e.g.*, U.S. Food and Drug Administration, Final Guidance: Policy for Coronavirus Disease-2019 Tests (Revised), at 2, *available at* https://www.fda.gov/media/135659/download.
16. U.S. Food and Drug Administration, Draft Guidance: Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, *available at* https://www.fda.gov/media/155038/download.
17. *See, e.g.*, U.S. Food and Drug Administration, Final Guidance: FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 PHE, *available at* https://www.fda.gov/media/136238/download.
18. *See, e.g.*, U.S. Food and Drug Administration, Final Guidance: Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 PHE Questions and Answers, *available at* https://www.fda.gov/media/141312/download.
19. *See, e.g.*, U.S. Food and Drug Administration, Final Guidance: Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 PHE, *available at* https://www.fda.gov/media/142051/download.
20. U.S. Food and Drug Administration, Final Guidance: Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised), *available at* https://www.fda.gov/media/137712/download.
21. 85 FR 15198 (Mar. 17, 2020).