ARTICLES

PANDEMIC POLITICS, PUBLIC HEALTH, AND THE FDA

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"It is critical that the American public has complete confidence in this decision-making process. I want to assure them, and you, that the FDA will not authorize or approve any COVID-19 vaccine before it has met the Agency's rigorous expectations for safety and effectiveness. In this effort, science will guide our decisions. FDA will not permit any pressure, from anybody, to change that. We can emerge from this pandemic only if we work together, learn from each other, and are driven by the facts and data."[1] *FDA Commissioner Stephen Hahn, M.D., October 6, 2020.*

"New FDA rules make it more difficult for them to speed up vaccines for approval before Election Day. Just another political hit job!"[2] *President Donald J. Trump, October 6, 2020.*

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1. *Speech: Commissioner Hahn's Remarks to the 2020 FDLI Annual Conference*, U.S. FOOD & DRUG ADMIN. (Oct. 6, 2020), https://www.fda.gov/news-events/speeches-fda-officials/commissioner-hahns-remarks-2020-fdli-annual-conference-10062020 **[**https://perma.cc/Q6K2-XHCE].

2. Donald J. Trump (@realDonaldTrump), TWITTER (Oct. 6, 2020); *see also*, Thomas M. Burton & Rebecca Ballhaus, *White House Agrees to FDA's Guidelines for Vetting Covid-19 Vaccines*, WALL ST. J. (Oct. 6, 2020), https://www.wsj.com/articles/white-house-agrees-to-fdas-guidelines-for-vetting-covid-19-vaccines-11602011953 [https://perma.cc/L9BK-MW8V].

INTRODUCTION

The U.S. Food and Drug Administration (FDA) is on the front lines of the COVID-19 pandemic. The agency is responsible for oversight of the vast spectrum of medical products necessary to protect health care workers and the general public, as well as fostering the rapid development and approval of life-saving detection methods and therapeutic products. The FDA is a long-embattled agency, tasked by Congress with the dual roles of both protecting the public health and facilitating innovation through rapid assessment of medical products. Recent legislation, such as the 21st Century Cures Act, intensifies these aspects of the FDA's innovation mission by mandating the agency consider patient experience data, real-world evidence, and the increased use of biomarkers to demonstrate safety and efficacy, among other things. The FDA has been incrementally accelerating long-standing regulatory processes and expanding the sources of information consulted in product assessment in response to advisory committees, congressional directives, industry perspectives, and stakeholder input.[3]

The FDA has historically operated independently and apolitically as a scientific agency guided by its public health mission.[4] Organizationally, the FDA is an executive branch agency housed within the broader Department of Health and Human Services (HHS), formerly led by Secretary Alex Azar from January 2018 to January 2021. Former FDA Commissioner Hahn, a radiation oncologist appointed by President Trump and who began in his official capacity in December 2019, had a tumultuous tenure as Commissioner given the coronavirus pandemic.[5] Following

3. *See* Jordan Paradise, *Three Framings of "Faster" at the FDA and the Federal Right to Try*, 11 WAKE FOREST J. L. & POL'Y 53 (2020).

4. There have been notable instances of politically motivated agency and executive branch clashes, such as that of Plan B levonorgestrel-based emergency contraceptives. *See* Susan F. Wood, *Inappropriate Obstructions to Access: The FDA's Handling of Plan B*, 16 AMA J. ETHICS 295 (2014).

5. In late 2019, a novel coronavirus was discovered that was ultimately named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This virus causes the coronavirus disease, COVID-19. *See Naming the Coronavirus Disease (COVID-19) and the Virus That Causes It*, WORLD HEALTH ORG.,

Secretary Azar's January 31, 2020 declaration of a public health emergency, triggering FDA's emergency authorities, the agency has been thrust into overdrive to carry out its responsibilities. In recent months, Secretary Azar and President Trump were pitted against Commissioner Hahn in various high-profile scenarios. Commissioner Hahn struggled against the President and HHS secretary for control over the timing and rigor of review and approval of vaccines and treatments for COVID-19. Commissioner Hahn has repeatedly assured the American public that the FDA will not cut corners on assessing the scientific data or jeopardize the public health and trust in the agency.[6] Alternatively, President Trump has regularly commented on the "deep state" at the FDA and criticized the Commissioner for slowing down the approval process. Likewise, the media reported that "Angry Azar" had sights set on ousting Commissioner Hahn.[7] The pandemic politics are charged in an alarmingly unprecedented way among the White House, the HHS, and the FDA.

Despite criticisms of his slowing down the regulatory process and defying the White House,[8] Commissioner Hahn has openly commented on the need for the FDA to have more agility and flexibility in applying standards of product review in the face of the pandemic.[9] Urging that the agency continue a sharp focus on the science and data, Commissioner Hahn had an interest in the discovery of new ways to structure clinical trial endpoints and expedite approval processes while maintaining statistical rigor and validation.[10] Four demonstrative ways the FDA has responded to

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https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it (last visited Feb. 4, 2021). The COVID-19 outbreak was formally declared a pandemic on March 11, 2020. *See* WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 (Mar. 11, 2020), https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

6. Michael Mezher, *Hahn Says COVID-19 Vaccines Will Be Reviewed in 'Real Time'*, RAPS (July 28, 2020), https://www.raps.org/news-and-articles/news-articles/2020/7/hahn-says-covid-19-vaccines-will-be-reviewed-in-re [https://perma.cc/M56X-JL8C] [hereinafter Mezher, *COVID-19 Vaccines*].

7. Adam Cancryn & Dan Diamond, *Angry Azar Floats Plans to Oust FDA's Hahn*, POLITICO (Oct. 22, 2020), https://www.politico.com/news/2020/10/22/azar-plans-oust-hahn-fda-431139 [https://perma.cc/M7G4-GJ5D].

8. *Id.*

9. *Press Release, Coronavirus (COVID-19) Update: FDA Takes New Actions to Accelerate Development of Novel Prevention, Treatment Options for COVID-19*, U.S. FOOD & DRUG ADMIN. (May 11, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-new-actions-accelerate-development-novel-prevention-treatment [https://perma.cc/6P5M-GBP7].

10. *See* Jaimy Lee, *Five Things You Should Know About Stephen Hahn, the New FDA Commissioner*, MARKET WATCH (Dec. 13, 2019), https://www.market

COVID-19 by adapting and expanding existing policy include (1) support of decentralized clinical trials and increased use of telemedicine technology in clinical trials, (2) allowances for use of laboratory-developed tests in disease detection, (3) use of real-world evidence in drug and vaccine development, and (4) enhanced procedures for rapid assessment of expanded use requests for investigational drugs.[11] The means by which the agency has achieved these policy adaptations is significant from an administrative law perspective; actions necessarily need to happen quickly and on the basis of accumulating information about the novel coronavirus.

This article will explore the mechanisms by which the FDA achieved its policy adjustments in these four important areas and trace the history of the agency's statutory and regulatory authority to do so. The article will also examine the scope of Trump Administration Executive Orders impacting administrative agency rulemaking and policy implementation,[12] HHS directives regarding rulemaking procedures,[13] and COVID-specific FDA guidance documents. The article will proceed in four parts. Part I introduces the statutory and regulatory basis of the FDA's longstanding authority to issue policy through guidance documents directed to industry and agency personnel. This part is brief, yet foundational, and is included to frame later parts assessing recent FDA and executive branch activity. Part II explains the FDA's traditional authority in product review and approval, as well as the agency's role in pandemic preparedness and response. Part III analyzes FDA-issued guidance documents from January 1, 2020, to October 6, 2020, keying in on topics and the impact of these guidance documents in order to survey the innovative nature of the guidance documents and their breadth and depth during the pandemic. A guidance published October 6, 2020, by the FDA entitled *Emergency Use Authorizations for Vaccines to Prevent COVID-19* is illustrative of the rapid policymaking undertaken by the FDA to provide direction to industry about how products will be assessed and the measures employed to assure safety and efficacy as informed by statutory requirements. The guidance document is also the source of a contentious standoff between the White House and the agency that played out in October 2020. Part IV explores actions by the current White House and executive branch officials to impact the manner in which agencies develop and disseminate guidance documents, beginning

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watch.com/story/five-things-you-should-know-about-stephen-hahn-trumps-nominee-to-head-fda-2019-11-21 [https://perma.cc/5GXN-6J9B] **(**discussing Commissioner Hahn's Senate committee nomination hearing).

11. Mezher, *COVID-19 Vaccines*, *supra* note 6.

12. Exec. Order No. 13,924, 85 Fed. Reg. 31,353 (May 19, 2020); Exec. Order No. 13,891, 85 Fed. Reg. 55,235 (Oct. 19, 2019).

13. *Statement on Regulatory Process*, U.S. DEPT. HEALTH & HUM. SERVS. (Sept. 20, 2020), https://www.hhs.gov/about/news/2020/09/20/hhs-statement-on-regulatory-process.html [https://perma.cc/6X9M-QU2G].

with an October 9, 2019 Executive Order and ending with an October 21, 2020 Executive Order. These two Executive Orders serve as veritable bookends to the current administrative law tensions during the pandemic. Part V concludes.

I. CONGRESSIONAL AUTHORITY AND AGENCY POLICY ON GUIDANCE DOCUMENTS

The FDA has long operated to communicate to industry utilizing guidance documents, which are policy interpretations that are not legally binding like congressionally enacted legislation or regulations promulgated through notice and comment rulemaking. Guidance documents are issued through less formal means by publication with notice in the Federal Register and publicly accessible document files on the agency website. The term guidance "refers to any written communication that explains an Agency or Center policy or procedure" and "generally refers to guidance for regulated entities (e.g., the pharmaceutical industry)."[14] Guidance documents include, though are not limited to, "documents that relate to: [t]he design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies."[15] In 1997, the FDA expressly provided that guidance documents are nonbinding on the agency.[16] This position was codified by Congress that same year and required FDA to develop good guidance practices, which the FDA subsequently did through notice and comment rulemaking.[17] Among other things contained in the good guidance practices, the guidance document must state that the guidance "does not legally bind the public or FDA."[18]

Thus, the FDA has express congressional authority to issue guidance documents. The legislative language provides several key features for guidance documents issued by the agency through delegation of authority from the Secretary of HHS:

> (1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic

14. *Manual of Policies and Procedures 4000.2*, U.S. FOOD & DRUG ADMIN. (2005), https://www.fda.gov/media/71702/download [https://perma.cc/KSB8-6DJJ].

15. Food and Drugs, 21 C.F.R. § 10.115(b)(2) (2019).

16. The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8,961 (1997).

17. 21 C.F.R § 10.115.

18. *Id.*

> means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.
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> (B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.
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> (C)(i) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.[19]

As a general matter, the FDA typically facilitates public participation through public meetings and notices in the Federal Register calling for stakeholder input on the development of guidance documents where appropriate, such as with matters that are "changes in interpretation or policy that are more than minor in nature" or relating to "highly controversial issues" or "complex scientific issues."[20] Guidance documents that fall into this category are designated by the FDA as "Level 1" guidance documents;[21] those involving the explanation of existing practices or minor changes are designated "Level 2" guidance documents.[22] The procedures for issuance of guidance documents are set forth in the regulations[23] and each Center within the FDA has documented practices for the approval and issuance of guidance documents.[24] Notices of draft and finalized guidance document are published in the Federal Register, and the FDA publishes the

19. 21 U.S.C. § 371(h).
20. *Id.* § 371(h)(C)(i).
21. 21 C.F.R § 10.115(c)(1).
22. *Id.* § 10.115(c)(2).
23. *Id.* § 10.115(g).
24. *Id.* § 10.115(j).

documents to the agency website.[25] Guidance documents may be revised by the agency in response to industry and stakeholder input, or as the result of changing information and developments.[26] Despite both the statute and FDA regulations noting that guidance documents are not legally binding, regulated industry routinely adheres to them as if they impart legal requirements, because courts oftentimes defer to the agency's expertise as a function of inquiries into whether the FDA acted reasonably in light of scientific and technical matters.

II. THE FDA AND ITS ROLE IN PANDEMIC PREPAREDNESS AND RESPONSE

The FDA is a specialized agency within the HHS, tasked with oversight of one quarter of consumer products, including food, cosmetics, drugs, biologics, medical devices, tobacco products, and products that emit radiation.[27] Two federal statutes—the Food Drug and Cosmetic Act (FDCA)[28] and the Public Health Safety Act (PHSA)[29]—set forth legal requirements across this range of products. Drugs, biologics, and medical devices are subject to the most rigorous requirements for development and manufacturing, clinical trials, product review, and clearance and approval. The highest risk products (new drugs, biologics, and life-saving and life-sustaining medical devices) require well-controlled clinical trials demonstrating substantial evidence of safety and efficacy prior to market approval.[30]

Each of these three product areas also have abbreviated routes to market based on comparativeness to other products already on the market.[31] Generic drugs are a useful example: where an applicant demonstrates bioequivalence to an innovator new drug product on the market, the threshold approval requirements are focused on the comparative aspects of those products, manufacturing processes, and labeling. There are also various expedited routes to market that speed innovations for promising products that address an unmet medical need, including breakthrough

25. *Id.* § 10.115(n).

26. *Id.* § 10.115(k).

27. U.S. FOOD & DRUG ADMIN., GLOBAL ENGAGEMENT 2, 4, 10 (2013), https://www.ipqpubs.com/wp-content/uploads/2013/05/FDA_Global-Engagement.pdf [https://perma.cc/87AN-JFN5].

28. 21 U.S.C. § 301 et seq.

29. 42 U.S.C. § 262.

30. 21 U.S.C. § 355(b)(1) (new drugs); 21 U.S.C. §§ 360d, 360e (premarket approval medical devices); 42 U.S.C. § 262(j) (biologics).

31. 21 U.S.C. § 355(j) (generic drugs); 21 U.S.C. §§ 360, 360c ("510(k)" medical devices); 42 U.S.C. § 262(k) (biosimilar and interchangeable biologics).

therapy status, Fast Track, and priority review.[32] Expanded access mechanisms for investigational drugs and devices may also be utilized by the FDA for use in emergency situations.[33]

Where there arises an emerging infectious disease; natural disaster; or chemical, biological, radiological, or nuclear (CBRN) emergency that threatens health and safety, the FDA has a substantial role in rapid response, including advancing measures to incentivize and support development of products, securing the product supply, and ensuring that safe and appropriate medical countermeasures (MCMs) are available.[34] Several foundational laws were enacted by Congress following the terrorist attacks of September 11, 2001, to establish mechanisms for coordination across federal agencies: the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act) of 2002,[35] the Project BioShield Act of 2004,[36] the Pandemic Readiness and Emergency Preparedness (PREP) Act of 2006,[37] the Pandemic and All-Hazards Preparations Act (PAHPA) of 2006,[38] and the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013.[39] The FDA's emergency authorities are triggered when one of the Secretaries of Defense, Health and Human Services, or Homeland Security make a determination of emergency or significant potential for emergency or identification of a material threat.

One of the most significant of the FDA's emergency authorities is the emergency use authorization (EUA) procedure, first introduced in the Project Bioshield Act of 2004, and subsequently amended through legislation.[40] In coordination with the HHS, the FDA may issue an EUA for an unapproved medical product where there is a serious or life-threatening illness or condition caused by CBRN agent as set forth in HHS declaration;

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32. Jordan Paradise, *Three Framings of "Faster" at the FDA and the Federal Right to Try*, 11 WAKE FOREST J. L. & POL'Y 74 (2020).

33. *Id*.

34. These consist of drugs, biologics, medical devices, and respiratory protective devices. U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS & RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY & OTHER STAKEHOLDERS 2 (2017) [hereinafter EUA MEDICAL PRODUCTS GUIDANCE].

35. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

36. Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835.

37. Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, 119 Stat. 2818 (2006).

38. Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831 (2006).

39. Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, 127 Stat. 161.

40. Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004); 21 U.S.C. § 360bbb-3.

reasonable belief that the product may be effective in diagnosing, treating, or preventing the illness or condition caused by the agent (based on totality of scientific data); the product's known and potential benefits outweigh known and potential risks when used for disease or condition; and there is no adequate approved, available alternative.[41] Where the FDA has already approved or cleared a medical product for a specific intended use, section 564A of the FDCA grants the FDA the authority to allow for emergency use for a different intended use without EUA declaration and issuance.[42]

The legislation extends beyond mere EUA issuance. Section 564A also provides for expiration date extensions, where safe and appropriate, to allow longer use of approved medicines and products. This also requires the development of emergency use instructions (EUIs) through coordination between HHS, FDA, and the Centers for Disease Control and Prevention (CDC). It also gives authority for emergency dispensing in the absence of a prescription and provides waivers for deviation from manufacturing standards and FDA-imposed risk evaluation and mitigation strategies.[43] Recipients of an EUA must develop detailed information about the product for health care professionals, authorized dispensers, and patients; must actively monitor and report adverse events; maintain records; and comply with all FDA-imposed requirements and limitations.[44] Under section 564(g)(2), an EUA may be revised or revoked if "the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety."[45]

Following the declaration of emergency from HHS Secretary Azar, the FDA has issued over one hundred medical device EUAs[46] and several for drugs, including one for use of Remdesivir[47] and one for the use of

41. 21 U.S.C. § 360bbb-3(c); *see also* EUA MEDICAL PRODUCTS GUIDANCE, *supra* note 34, at 7–8.

42. 21 U.S.C. § 360bbb-3(a).

43. 21 U.S.C. § 360bbb-3(e); *see also* EUA MEDICAL PRODUCTS GUIDANCE, *supra* note 34, at 7–8.

44. EUA MEDICAL PRODUCTS GUIDANCE, *supra* note 34, at 22–27.

45. 21 U.S.C. § 360bbb-3(g)(2).

46. U.S. FOOD & DRUG ADMIN., CORONAVIRUS DISEASE 2019 (COVID-19) EMERGENCY USE AUTHORIZATIONS FOR MEDICAL DEVICES (2020), https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices [https://perma.cc/T2ED-5YYJ]. These EUAs span blood purification devices, renal replacement therapy devices, in vitro diagnostics, decontamination systems for personal protective equipment (PPE), infusion pumps, PPE, remote and wearable patient monitoring devices, respiratory assist devices, and ventilators and accessories. *Id.*

47. *Fact Sheet for Patients and Caregivers: Emergency Use Authorization of Veklury*, GILEAD (Oct. 2020), https://www.gilead.com/-/media/files/pdfs/remdesivir%20/eua-fact-sheet-for-patients-and-caregivers.pdf [https://perma.cc/926U-9KW

hydroxychloroquine, which was later revoked.[48] The agency is still involved in clinic trial assessment and expedited evaluation processes for treatments and vaccines, including the issuances of EUAs for the Pfizer-BioNTech vaccine on December 11, 2020, and the Moderna vaccine on December 18, 2020.[49] The FDA has also focused acutely on enforcement activities against fraudulent and dangerous products promoted for use in fighting COVID-19 through utilization of warning letters, enforcement actions, and adverse publicity.[50] However, much of the FDA's work has been through guidance documents, as detailed in Part III.

III. SURVEYING FDA COVID-19 GUIDANCE DOCUMENTS

In the wake of the COVID-19 pandemic, the FDA has acted through guidance documents to implement policy change across a broad range of topics. As a means to explore the breadth and depth of these guidance documents, we conducted a search of FDA-issued guidance documents and associated public notice of those documents in both the Federal Register and the FDA's website. A search of the Federal Register for notices, rules, and proposed rules from the FDA from the time period of January 1, 2020, to October 8, 2020, that contained the search term "covid"

2]; U.S. FOOD & DRUG ADMIN., FDA'S APPROVAL OF VEKLURY (REMDESIVIR) FOR THE TREATMENT OF COVID-19—THE SCIENCE OF SAFETY AND EFFECTIVENESS (2020); *see also* Jordan Paradise, *COVID-IP: Staring Down the Bayh-Dole Act with 2020 Vision*, 7 J. L & BIOSCIENCES 10 (2020).

48. U.S. Food & Drug Admin., Letter Revoking EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate, (June 15, 2020), https://www.fda.gov/media/138945/download [https://perma.cc/YC24-6S5H].

49. *See* Letter from Denise M. Hinton, Chief Scientist, Food & Drug Admin., to Elisa Harkins, Pfizer, Inc. (Dec. 23, 2020), https://www.fda.gov/media/144412/download (informing Pfizer of the EUA grant for its vaccine); Letter from Denise M. Hinton, Chief Scientist, Food & Drug Admin., to Carlota Vinals, ModernaTX, Inc. (Dec. 18, 2020), https://www.fda.gov/media/144636/download (informing Moderna of the EUA grant for its vaccine); *see also* Press Release, Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid ("Through the FDA's open and transparent scientific review process, two COVID-19 vaccines have been authorized in an expedited timeframe while adhering to the rigorous standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization that the American people have come to expect from the FDA." (quoting Comm'r Hahn)).

50. Jordan Paradise & Elise Fester, *FDA Publicity and Enforcement in the COVID* Era, 60 WASHBURN L. REV. 77 (2020).

identified sixty-four results.[51] The majority of the results from the Federal Register are merely notices of FDA activities, with only six rules[52] and two proposed rules[53] during the time frame. Of the remaining fifty-six results, thirty-three of the notices do not relate directly to the FDA's response to the pandemic but rather appear in the search results because of a passing mention to the disease in relation to the decision to postpone a meeting or change to a virtual format.[54] Of the twenty-three remaining results, twelve

51. *See* FED. REG., federalregister.gov (search for "covid," then select "advanced search," then filter "Publication Date" for "01/01/2020 to 10/8/2020," "Document Category" for "Rule" or "Proposed Rule" or "Notice," and "Agency" for "Food and Drug Administration").

52. *See* Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency: Guidance for Industry; Availability, 85 Fed. Reg. 23,919 (Apr. 30, 2020) (to be codified at 21 C.F.R. pt. 1); Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency: Guidance for Industry; Availability, 85 Fed. Reg. 17,008 (Mar. 26, 2020) (to be codified at 21 C.F.R. pt. 1, 117, 507); Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry; Availability, 85 Fed. Reg. 34,508 (June 5, 2020) (to be codified at 21 C.F.R. pt. 112); Petition for an Administrative Stay of Action: Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 85 Fed. Reg. 50,950 (Aug. 19, 2020) (to be codified at 21 C.F.R. pt. 882, 895); Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Delayed Effective Date, 85 Fed. Reg. 32,293 (May 29, 2020) (to be codified at 21 C.F.R. pt. 1141); Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use: Guidance for Industry and Food and Drug Administration Staff; Availability, 85 Fed. Reg. 43,989 (July 21, 2020) (to be codified at 21 C.F.R. pt. 1271).

53. *See* Requirements for Additional Traceability Records for Certain Foods; Proposed Rule; Public Meetings; Request for Comments, 85 Fed. Reg. 62,632 (proposed Oct. 5, 2020); Laboratory Accreditation for Analyses of Foods; Extension of Comment Period, 85 Fed. Reg. 19,114 (proposed Apr. 6, 2020).

54. *See, e.g.*, Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments, 85 Fed. Reg. 63,284 (Oct. 7, 2020); Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs, 85 Fed. Reg. 62,306, 62,308 (Oct. 2, 2020) (appearing because of a single mention of COVID-19 related to the decision to accept orphan drug-related submissions and documents via email); Patient-Focused Drug Development for Stimulant Use Disorder; Public Meeting; Request for Comments, 85 Fed. Reg. 61,756 (Sept. 30, 2020); Prescription Drug User Fee Rates for Fiscal Year 2021, 85 Fed. Reg. 46,651, 46,654–55 (Aug. 3, 2020) (appearing in the search results because of two mentions that COVID-19 may affect the PDUFA workload); Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments, 85

of them are notice of either the issuance or withdrawal of specific individual guidance documents,[55] and three are notices of specific EUA revocations and authorizations.[56]

Fed. Reg. 44,541 (July 23, 2020); Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments, 85 Fed. Reg. 41,053 (July 8, 2020); Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Health Care Providers' Understanding of Opioid Analgesic Abuse Deterrent Formulations, 85 Fed. Reg. 40,663 (July 7, 2020); Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments, 85 Fed. Reg. 37,458 (June 22, 2020); Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised); Guidance for Industry; Availability, 85 Fed. Reg. 32,401, 32,402 (May 29, 2020) (mentioning COVID-19 only one time in reference to a postponement of an effective date); Ophthalmic Devices Panel of the Medical Devices Advisory Committee: Notice of Meeting; Postponement, 85 Fed. Reg. 23,970 (Apr. 30, 2020); Fiscal Year 2020 Generic Drug Regulatory Science Initiatives; Public Workshop; Remote Only, 85 Fed. Reg. 23,968 (Apr. 30, 2020); Pulmonary-Allergy Drugs Advisory Committee; Postponed, 85 Fed. Reg. 19,491 (Apr. 7, 2020); Blood Products Advisory Committee; Postponed, 85 Fed. Reg. 16,368 (Mar. 23, 2020).

55. *See* Investigational COVID-19 Convalescent Plasma; Guidance for Industry; Withdrawal of Guidance; Correction, 85 Fed. Reg. 63,277 (Oct. 7, 2020); Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment; Guidance for Industry; Availability, 85 Fed. Reg. 61,008 (Sept. 29, 2020); Investigational COVID-19 Convalescent Plasma; Guidance for Industry; Availability, 85 Fed. Reg. 59,319 (Sept. 21, 2020) (superseding the earlier guidance document by the same name); Investigational COVID-19 Convalescent Plasma; Guidance for Industry; Withdrawal of Guidance, 85 Fed. Reg. 59,320 (Sept. 21, 2020); Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry; Availability, 85 Fed. Reg. 36,595 (June 17, 2020); Revised Recommendations To Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry; Availability, 85 Fed. Reg. 36,598 (June 17, 2020). Institutional Review Board Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency; Guidance for Institutional Review Boards and Clinical Investigators; Availability, 85 Fed. Reg. 35,311 (June 9, 2020); COVID-19: Developing Drugs and Biological Products for Treatment or Prevention; Guidance for Industry; Availability, 85 Fed. Reg. 29,949 (May 19, 2020); Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency; Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff; Availability, 85 Fed. Reg. 29,461 (May 15, 2020); Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability, 85 Fed. Reg. 18,247 (Apr. 1, 2020); Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency;

The remaining results include two notices establishing a new process for bulk publishing of guidance documents[57] and EUAs[58] rather than publishing each one individually as is the regular procedure for publication of notice to the public. These two bulk-publishing process notices detail the FDA's modified guidance and EUA notice procedure in light of the pandemic.[59] Citing efficiency concerns, the FDA announced that it would publish guidance documents and EUAs without prior notice and comment, but it would still solicit and review comments and then revise the guidance documents as necessary.[60] Thus, rather than issuance of

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Immediately in Effect Guidance for Industry; Availability, 85 Fed. Reg. 16,370 (Mar. 23, 2020); Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing Under the Clinical Laboratory Improvement Amendments Prior to Emergency Use Authorization for Coronavirus Disease-2019 During the Public Health Emergency; Immediately in Effect Guidance for Clinical Laboratories and Food and Drug Administration Staff; Availability, 85 Fed. Reg. 13,169 (Mar. 6, 2020).

56. *See* Revocation of Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Antibodies Against SARS-CoV-2, 85 Fed. Reg. 62,739 (Oct. 5, 2020) (reprinting the FDA's rationale for revoking Autobio's EUA for a diagnostic test); Authorizations and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic; Availability, 85 Fed. Reg. 56,231 (Sept. 11, 2020) (reprinting the conditions for the new drug EUAs and rationale for revoking BARDA's drug EUA); Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Antibodies Against SARS-CoV-2, 85 Fed. Reg. 42,414 (July 14, 2020) (reprinting the explanation for the revocation of Chembio's diagnostic medical device EUA).

57. *See* Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, 85 Fed. Reg. 16,949 (Mar. 25, 2020).

58. *See* Process for Publishing Emergency Use Authorizations for Medical Devices During Coronavirus Disease 2019, 85 Fed. Reg. 33,685 (June 2, 2020).

59. *See* Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, 85 Fed. Reg. at 16,949 (announcing the FDA's intent to periodically publish a consolidated Notice of Availability in the Federal Register rather than a separate Notice of Availability for each COVID-19-related guidance document); Process for Publishing Emergency Use Authorizations for Medical Devices During Coronavirus Disease 2019, 85 Fed. Reg. at 33,685 (announcing the FDA's intent to periodically publish a consolidated Notice of Availability containing all the COVID-19-related EUAs during the relevant period rather than an individual Notice of Availability for each EUA issued).

60. Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, 85 Fed. Reg. at 16,949 ("In light of the need to act quickly and efficiently to respond to the COVID-19 public health emergency, FDA anticipates that prior public participation will not be feasible or appropriate before FDA implements COVID-19-related guidance documents. FDA anticipates it will issue COVID-19-related guidance documents for immediate implementation without prior public comment . . . . Although FDA expects that COVID-19-related guidances will be implemented without prior comment, FDA will solicit comment, review all comments received, and revise the guidance documents as appropriate

an individual notice for every individual guidance and EUA issued, the search reveals six bulk notices for the guidance document summaries[61] and two notices for the EUA summaries.[62] These results are summarized in the Table 1 below.

Table 1: Federal Register Search Results for FDA COVID-19 Activity (Janary 1, 2020 – October 8, 2020)

Type of Activity	Number of results
Notices	56
Notice of procedural change for publication of COVID actions	*2*
Notice of compiled EAU authorization/revocations	*2*
Notice of compiled guidance documents	*6*

. . . . Rather than publishing a separate Notice of Availability (NOA) for each COVID-19-related guidance document, FDA intends to publish periodically a consolidated NOA. This periodic NOA will announce the availability of all the COVID-19-related guidance documents that issued during the relevant period. The consolidated NOA will provide instructions to the public on submitting comments on COVID-19-related guidance documents, including the docket number(s) associated with each guidance document, information on how to view the dockets, and instructions for persons interested in obtaining a copy of a COVID-19-related guidance document."); Process for Publishing Emergency Use Authorizations for Medical Devices During Coronavirus Disease 2019, 85 Fed. Reg. 33,686 ("Rather than publishing a separate Notice of Availability (NOA) for each COVID-19 related EUA for a medical device, FDA intends to publish periodically a consolidated NOA. This periodic NOA will announce the availability of all the COVID-19 related EUAs for medical devices that issued during the relevant period.").

61. *See* Guidance Documents Related to Coronavirus Disease 2019; Availability, 85 Fed. Reg. 55,678 (Sept. 9, 2020); Guidance Documents Related to Coronavirus Disease 2019; Availability, 85 Fed. Reg. 46,641 (Aug. 3, 2020); Guidance Documents Related to Coronavirus Disease 2019 (COVID-19); Availability, 85 Fed. Reg. 38,372 (June 26, 2020); Guidance Documents Related to Coronavirus Disease 2019 (COVID-19); Availability, 85 Fed. Reg. 31,513 (May 26, 2020); Guidance Documents Related to Coronavirus Disease 2019 (COVID-19); Availability, 85 Fed. Reg. 28,010 (May 12, 2020); Product-Specific Guidances; Guidance for Industry; Availability, 85 Fed. Reg. 20,694 (Apr. 14, 2020).

62. *See* Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability, 85 Fed. Reg. 42,407 (July 14, 2020); Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability, 85 Fed. Reg. 34,638 (June 5, 2020).

Notice of individual guidance documents	*12*
Notice of individual EAU authorizations/revocations	*3*
Notices related to committee meetings and information collection	*33*
Rules	6
Guidance documents	*4*
Petition for an Administrative Stay of Action	*1*
Delayed effective date	*1*
Proposed Rules	2
TOTAL	**64**

While the Federal Register search revealed only twelve specific guidance documents in response to the pandemic, the FDA has actually issued sixty-three COVID-19-related guidance documents as of October 8, 2020.[63] The FDA has compiled all of its COVID-related information on its website, easily accessible from the FDA.gov homepage.[64] On its COVID resource page, it links to its compilation of all the COVID-19-related guidance documents, organized in a searchable table, categorized by title, type, product area, and date posted.[65] Of those sixty-three guidance documents, sixty-one were final guidance documents and only two were

63. *See COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders [https://perma.cc/X3UJ-RAUU] (last updated Dec. 23, 2020).

64. *See Coronavirus Disease 2019 (COVID-19)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19 [https://perma.cc/2EFU-R9GC] (last visited Oct. 8, 2020) (compiling the FDA's latest COVID-19 news, safety warnings, EUAs, personal protective equipment updates, frequently asked questions, and contact information); *see also* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ [https://perma.cc/Z39K-TJ2H] (last visited Aug. 12, 2020) (featuring in the top center of its homepage in large, bolded print a single clickable link to the FDA's COVID-19 page reading "FDA Takes Action to Address Coronavirus Disease 2019 (COVID-19)" with smaller, text underneath "FDA is working with U.S. Government partners, including CDC, and international partners to address the pandemic.").

65. *See COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders*, *supra* note 63 (accessible by clicking on the second list item on the left-hand menu of the FDA's COVID-19 main resource page).

immediately in effect guidance documents.[66] The following tables, Table 2 and Table 3, show the breakdown of guidance documents by product area and guidance type, as categorized by the FDA.[67] The categorizations often overlap, meaning that multiple product areas or multiple audiences are involved in a given guidance document.

Table 2: Guidance Documents by Product Area

Product Area	Number of Guidance documents
Medical Devices	23
Drugs	24
Biologics	22
Food & Beverages	11
Animal & Veterinary	8

Table 3: Guidance Documents by Audience

Guidance Audience	Number of Guidance documents
Industry	54
FDA Staff	20
Clinical Laboratories	3
Investigators	3
Commercial Manufacturers	2
Institutional Review Boards (IRBs)	2
Health Care Professionals	2
Generic Drug Development	1

66. The two immediately in effect guidances were U.S. FOOD & DRUG ADMIN., POLICY FOR TEMPORARY COMPOUNDING OF CERTAIN ALCOHOL-BASED HAND SANITIZER PRODUCTS DURING THE PUBLIC HEALTH EMERGENCY (Aug. 7, 2020) and U.S. FOOD & DRUG ADMIN., POLICY FOR CORONAVIRUS DISEASE-2019 TESTS DURING THE PUBLIC HEALTH EMERGENCY (REVISED) (May 11, 2020) [hereinafter COVID-19 TESTS GUIDANCE].

67. Several of the guidances have multiple product areas and audiences listed. This table counts each label for each guidance, resulting in double-counting of several guidances which is why the total would be higher than sixty-three.

Egg Producers	1

The Appendix to this article identifies all of these guidance documents by title, type, product area, audience, and date. Of these sixty-three guidance documents identified by the FDA on the website, they can further be categorized as "innovative" and "non-innovative" in substance and form. Many of the guidance documents simply eased reporting requirements temporarily;[68] loosened enforcement guidelines on low-risk medical devices like disinfectants,[69] masks,[70] hospital gowns,[71] and electronic thermometers;[72] or modified enforcement for high-risk medical

68. U.S. FOOD & DRUG ADMIN., 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 (June 19, 2020); U.S. FOOD & DRUG ADMIN., POSTMARKETING ADVERSE EVENT REPORTING FOR MEDICAL PRODUCTS AND DIETARY SUPPLEMENTS DURING A PANDEMIC (May 8, 2020); U.S. FOOD & DRUG ADMIN., REPORTING AND MITIGATING ANIMAL DRUG SHORTAGES DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (May 7, 2020); *see also* U.S. FOOD & DRUG ADMIN., POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY GUIDANCE FOR INDUSTRY AND HEALTH CARE PROFESSIONALS (Mar. 22, 2020) (temporarily suspending enforcement of REMS that would require in-person imaging or laboratory testing if there is no compelling reason to complete the test).

69. U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY FOR MANUFACTURE OF ALCOHOL FOR INCORPORATION INTO ALCOHOL-BASED HAND SANITIZER PRODUCTS DURING THE PUBLIC HEALTH EMERGENCY (COVID-19) (June 1, 2020); U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY FOR PREPARATION OF CERTAIN ALCOHOL-BASED HAND SANITIZER PRODUCTS DURING THE PUBLIC HEALTH EMERGENCY (COVID-19) (June 1, 2020); U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR STERILIZERS, DISINFECTANT DEVICES, AND AIR PURIFIERS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Mar. 29, 2020); U.S. FOOD & DRUG ADMIN., POLICY FOR TEMPORARY COMPOUNDING OF CERTAIN ALCOHOL-BASED HAND SANITIZER PRODUCTS DURING THE PUBLIC HEALTH EMERGENCY (Mar. 29, 2020) [hereinafter COMPOUNDING HAND SANITIZER GUIDANCE].

70. U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR FACE MASKS AND RESPIRATORS DURING THE CORONAVIRUS DISEASE (COVID-19) PUBLIC HEALTH EMERGENCY (REVISED) (May 2020).

71. U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR GOWNS, OTHER APPAREL, AND GLOVES DURING THE CORONAVIRUS DISEASE (COVID-19) PUBLIC HEALTH EMERGENCY (Mar. 30, 2020).

72. U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR CLINICAL ELECTRONIC THERMOMETERS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Apr. 4, 2020).

devices directly related to treatment.[73] A few guidance documents were aimed at addressing complications in transportation and the supply chain for food and drugs,[74] while others temporarily amended food labeling policies.[75] Several guidance documents focus directly on COVID-19

73. U.S. FOOD & DRUG ADMIN., POLICY FOR THE TEMPORARY USE OF PORTABLE CRYOGENIC CONTAINERS NOT IN COMPLIANCE WITH 21 CFR 211.94(E)(1) FOR OXYGEN AND NITROGEN DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 20, 2020); U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR EXTRACORPOREAL MEMBRANE OXYGENATION AND CARDIOPULMONARY BYPASS DEVICES DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Apr. 6, 2020); U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR INFUSION PUMPS AND ACCESSORIES DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Apr. 5, 2020); U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR VENTILATORS AND ACCESSORIES AND OTHER RESPIRATORY DEVICES DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Mar. 22, 2020).

74. U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR VIRAL TRANSPORT MEDIA DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (July 20, 2020); U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY DURING THE COVID-19 PUBLIC HEALTH EMERGENCY REGARDING THE QUALIFIED EXEMPTION FROM THE STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION (May 22, 2020); U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY FOR COMPOUNDING OF CERTAIN DRUGS FOR HOSPITALIZED PATIENTS BY OUTSOURCING FACILITIES DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (REVISED) (May 21, 2020); U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY FOR COMPOUNDING OF CERTAIN DRUGS FOR HOSPITALIZED PATIENTS BY PHARMACY COMPOUNDERS NOT REGISTERED AS OUTSOURCING FACILITIES DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (REVISED) (May 21, 2020); U.S. FOOD & DRUG ADMIN., EXEMPTION AND EXCLUSION FROM CERTAIN REQUIREMENTS OF THE DRUG SUPPLY CHAIN SECURITY ACT DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 30, 2020); U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY REGARDING ENFORCEMENT OF 21 CFR PART 118 (THE EGG SAFETY RULE) DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 6, 2020) [hereinafter EGG SAFETY RULE GUIDANCE] (permitting vendors who normally would only sell eggs for further processing to sell to the table egg market if needed and certain conditions are met to address the market imbalance in demand for table eggs versus eggs from restaurants and other similar establishments).

75. U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY REGARDING PACKAGING AND LABELING OF SHELL EGGS SOLD BY RETAIL FOOD ESTABLISHMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 3, 2020); U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY REGARDING NUTRITION LABELING OF STANDARD MENU ITEMS IN CHAIN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 1, 2020); U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY REGARDING NUTRITION

diagnostic testing,[76] treatment,[77] and vaccine development.[78] And some guidance documents were promulgated to fill gaps for issues the FDA had never encountered before, such as returning refrigerated transport vehicles to food use after using them to preserve human remains[79] and adjusting statistical analyses to account for COVID-19 complications in clinical trials.[80]

Many of the guidance documents promulgated by the FDA in response to COVID-19 simply addressed issues that had never arisen before. For example, in May 2020 the FDA had to issue a guidance detailing proper procedure for returning refrigerated transport vehicles to food uses after using them to preserve human remains.[81] The guidance notes that the COVID-19 pandemic has necessitated additional refrigerated storage and recognized that vehicles usually used for food may be instead used to store human remains.[82] The FDA stated that it had received questions about if and how these vehicles and storage units could be returned to their intended use, so they responded by issuing a guidance intended to supplement existing regulations on cleaning and disinfecting these vehicles.[83] Similarly, the COVID-19 pandemic led to increased

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LABELING OF CERTAIN PACKAGED FOOD DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Mar. 26, 2020).

76. COVID-19 TESTS GUIDANCE, *supra* note 66.

77. U.S. FOOD & DRUG ADMIN., PRODUCT-SPECIFIC GUIDANCES FOR CHLOROQUINE PHOSPHATE AND HYDROXYCHLOROQUINE SULFATE (Apr. 13, 2020).

78. *See* U.S. FOOD & DRUG ADMIN., DEVELOPMENT AND LICENSURE OF VACCINES TO PREVENT COVID-19 (June 30, 2020) [hereinafter DEVELOPMENT AND LICENSURE OF VACCINES GUIDANCE].

79. U.S. FOOD & DRUG ADMIN., RETURNING REFRIGERATED TRANSPORT VEHICLES AND REFRIGERATED STORAGE UNITS TO FOOD USES AFTER USING THEM TO PRESERVE HUMAN REMAINS DURING THE COVID-19 PANDEMIC (May 12, 2020) [hereinafter REFRIGERATED STORAGE RETURN GUIDANCE].

80. U.S. FOOD & DRUG ADMIN., STATISTICAL CONSIDERATIONS FOR CLINICAL TRIALS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY GUIDANCE FOR INDUSTRY (June 16, 2020).

81. *See* REFRIGERATED STORAGE RETURN GUIDANCE, *supra* note 79; *see also* Rachel Premack, *The FDA Just Released a Ghoulish Handbook for How to Convert Trucks from Storing Coronavirus Victims' Bodies to Hauling Food*, BUS. INSIDER (May 13, 2020, 4:40 PM), https://www.businessinsider.com/coronavirus-federal-memo-reveals-trucks-used-for-dead-2020-5 [https://perma.cc/7TAT-SYJY] (highlighting the role food cold storage vehicles have played in storing COVID-19 victims' remains); Jeremy Rose, *As an ER Doctor, I Fear Our Era's Defining Symbol Will Be the Refrigerator Truck*, WASH. POST (Apr. 11, 2020, 5:05 PM), https://www.washingtonpost.com/outlook/2020/04/11/refrigerated-truck-morgue-coronavirus/ [https://perma.cc/9E8F-89GZ].

82. REFRIGERATED STORAGE RETURN GUIDANCE, *supra* note 79.

83. REFRIGERATED STORAGE RETURN GUIDANCE, *supra* note 79, at 4.

demand for essential sanitizers and disinfectants.[84] In order to alleviate the demand while still promoting effective sanitizers, the FDA eased enforcement to allow state-licensed pharmacies, federal facilities, and registered outsourcing facilities to make their own sanitizers, provided they follow the FDA's recipe precisely.[85] Likewise, as a prophylactic measure against an anticipated egg shortage[86] due to COVID-19 supply chain disruptions, the FDA implemented a temporary policy permitting egg producers who currently only sell eggs to facilities for further processing to sell directly to consumers in retail establishments.[87] All of the aforementioned guidance documents arose out of the novel circumstances created by the COVID-19 pandemic, but the policies enacted are not likely to continue beyond the emergency.

However, other guidance documents significantly expanded FDA policy in certain areas, including telemedicine,[88] clinical trials,[89] and remote

84. *See, e.g.*, Chloe Taylor, *Sales of Hand Sanitizer Are Skyrocketing Due to the Coronavirus, Leading to Rationing and Price Hikes*, CNBC (Mar. 3, 2020, 9:22 AM), https://www.cnbc.com/2020/03/03/coronavirus-hand-sanitizer-sales-surge-leading-to-price-hikes.html [https://perma.cc/Z8VD-QRVC] (citing a 255% year-on-year increase in hand sanitizer sales in February 2020); Ganda Suthivarakom, *Coronavirus Has Caused a Hand Sanitizer Shortage. What Should You Do?*, N.Y. TIMES (Mar 11, 2020), https://www.nytimes.com/2020/03/11/smarter-living/wire cutter/coronavirus-hand-sanitizer.html [https://perma.cc/K622-8YGZ] (documenting the shortage of hand sanitizers and providing do-it-yourself recipes and other recommendations for alternative sanitizing methods).

85. *See* COMPOUNDING HAND SANITIZER GUIDANCE, *supra* note 69; *see also* Jacquie Lee, *Hand Sanitizer Shortages Push FDA to Let Pharmacists Make It*, BLOOMBERG (Mar. 14, 2020, 12:54 PM), https://www.bloomberg.com/news/articles/2020-03-14/hand-sanitizer-shortages-push-fda-to-let-pharmacists-make-it [https://perma.cc/G5K7-WVWC].

86. *See* Lauren Reiley, *Stress-Baking and Hoarding Have Led to a Retail Egg Shortage. There Are Eggs in the Pipeline, but Maybe Not Enough*, WASH. POST (Mar. 26, 2020, 6:33 PM), https://www.washingtonpost.com/business/2020/03/26/shortages-eggs-stress-baking/ [https://perma.cc/HK4Y-4AG6].

87. *See* EGG SAFETY RULE GUIDANCE, *supra* note 74.

88. *See* U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR REMOTE DIGITAL PATHOLOGY DEVICES DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Apr. 24, 2020) [hereinafter REMOTE DIGITAL PATHOLOGY GUIDANCE]; U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR DIGITAL HEALTH DEVICES FOR TREATING PSYCHIATRIC DISORDERS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Apr. 14, 2020).

89. *See* U.S. FOOD & DRUG ADMIN., FDA GUIDANCE ON CONDUCT OF CLINICAL TRIALS OF MEDICAL PRODUCTS DURING COVID-19 PUBLIC HEALTH EMERGENCY (updated Dec. 4, 2020) [hereinafter CLINICAL TRIALS OF MEDICAL PRODUCTS GUIDANCE].

monitoring devices.[90] These guidance documents appear to have the potential to have impacts beyond the pandemic and indicate a shift in FDA action. These far-reaching guidance documents can be categorized as "innovative," as opposed to the non-innovative guidance documents temporarily in effect to manage immediate extenuating circumstances. For example, the *Guidance on Conduct of Clinical Trials of Medical Products During COVID-19* originally published on March 18, 2020, allowed for modifications to protocols without prior Institutional Review Board (IRB) approval.[91] Additionally, it permitted remote monitoring so that participants would not have to submit to in-person testing.[92] Furthermore, it allowed for medications to be sent directly to participants in certain studies, where appropriate.[93] The FDA also issued several guidance documents that permitted remote monitoring of patients[94] as well as remote ophthalmic assessments,[95] remote maternal and fetal monitoring,[96] and remote digital pathology devices.[97] Likewise, the FDA expanded the authority for investigators to modify clinical trial protocols without preclearance from the IRB or notification to the FDA.[98] As part of these protocol modifications, the FDA allowed investigators to shift to remote monitoring, testing, and imaging where possible to reduce the chance of person-to-person transmission of the virus.[99] While the FDA has stated that each of these guidance documents are only in effect for the duration of the public

90. *See* U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR NON-INVASIVE REMOTE MONITORING DEVICES USED TO SUPPORT PATIENT MONITORING DURING THE CORONAVIRUS DISEASE-2019 (COVID-19) PUBLIC HEALTH EMERGENCY (REVISED) (June 5, 2020) [hereinafter REMOTE PATIENT MONITORING GUIDANCE]; U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR NON-INVASIVE FETAL AND MATERNAL MONITORING DEVICES USED TO SUPPORT PATIENT MONITORING DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Apr. 23, 2020) [hereinafter FETAL AND MATERNAL MONITORING DEVICES GUIDANCE]; U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR REMOTE OPHTHALMIC ASSESSMENT AND MONITORING DEVICES DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (Apr. 6, 2020) [hereinafter REMOTE OPHTHALMIC ASSESSMENT AND MONITORING GUIDANCE].

91. *See* CLINICAL TRIALS OF MEDICAL PRODUCTS GUIDANCE, *supra* note 89.

92. CLINICAL TRIALS OF MEDICAL PRODUCTS GUIDANCE, *supra* note 89.

93. CLINICAL TRIALS OF MEDICAL PRODUCTS GUIDANCE, *supra* note 89.

94. *See* REMOTE PATIENT MONITORING GUIDANCE, *supra* note 90.

95. *See* REMOTE OPHTHALMIC ASSESSMENT AND MONITORING GUIDANCE, *supra* note 90.

96. *See* FETAL AND MATERNAL MONITORING DEVICES GUIDANCE, *supra* note 90.

97. *See* REMOTE DIGITAL PATHOLOGY GUIDANCE, *supra* note 88.

98. *See* CLINICAL TRIALS OF MEDICAL PRODUCTS GUIDANCE, *supra* note 89.

99. CLINICAL TRIALS OF MEDICAL PRODUCTS GUIDANCE, *supra* note 89.

health emergency,[100] it is not difficult to imagine the convenience to patients, providers, participants, and investigators coupled with improved and more accurate technologies could outweigh the need to return to completely in-person trials and treatments.

The FDA itself considers its response to COVID-19 innovative, specifying five areas and which are reflected in the guidance documents discussed above. These include (1) using real-world data to identify potential treatments for further study; (2) establishing a 3D printing partnership; (3) collaborating with diverse sources across government, academia, and industry to promote using real-world data to inform their response; (4) creating a treatment acceleration program; and (5) accelerating guidance document development to support researchers and innovators.[101]

The FDA has also been working in collaboration with other organizations to accelerate research and improve its COVID response. For example, the FDA is a member of the COVID-19 Evidence Accelerator, an organization designed to aggregate data and analytics related to the epidemic, organized by the Reagan-Udall Foundation for the FDA in collaboration with Friends of Cancer Research.[102] The Accelerator, which includes both a diagnostics and therapeutics branch, is intended to complement data and research efforts already underway at the FDA by harnessing more real-world data.[103] Similarly, in May of 2020, the FDA

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100. In fact, the FDA includes the boilerplate statement "This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2))," on all the guidances classified as relating to COVID-19.

101. *See Innovation to Respond to COVID-19*, U.S. FOOD & DRUG ADMIN. (July 16, 2020), https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/innovation-respond-covid-19 [https://perma.cc/V288-PEAQ].

102. *See* Statement from Amy Abernethy, Principal Deputy Commissioner, Office of the Commissioner, *Coronavirus (COVID-19) Update: FDA Collaborations Promote Rigorous Analyses of Real-World Data to Inform Pandemic Response*, U.S. FOOD & DRUG ADMIN. (May 19, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-collaborations-promote-rigorous-analyses-real-world-data-inform [https://perma.cc/NMV9-J2YB]; *COVID-10 Evidence Accelerator*, FRIENDS CANCER RES., https://www.focr.org/covid19 [https://perma.cc/M89D-2V95] (last visited Aug. 24, 2020).

103. *See Coronavirus (COVID-19) Update: FDA Takes Additional Action to Harness Real-World Data to Inform COVID-19 Response Efforts*, U.S. FOOD & DRUG ADMIN. (June 18, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-action-harness-real-world-data-inform-covid-19 [https://perma.cc/9666-R4C3]; *see also* Reagan-

partnered with a data company, Aetion, to examine COVID patient medication treatments and related complications.[104] Aetion's software uses electronic medical records to generate real-world evidence which the FDA can then use to analyze diagnostics, medications, and risk factors for COVID-19 in diverse patient populations.[105] As part of the collaboration, Aetion will review pharmacy claims, electronic medical records, hospitals, and labs related to COVID-19 patients.[106]

One of the areas where one would expect to see increased innovation would be in the development of a COVID-19 vaccine. For example, the Evidence Accelerator is incorporating significant real-world data in its research. However, the FDA's vaccine development guidance makes no mention of real-world data.[107] Rather, it emphasizes that a vaccine must be at least 50% more effective than a placebo and that showing immune response data alone will not be enough. Arguably, the vaccine guidance is novel in that it encourages (but does not require) investigators to use a diverse subject pool, including racial and ethnic diversity as well as pregnant, elderly, and individuals with other serious medical conditions, contrary to historical FDA preference for strict subject criteria to avoid confounding variables.[108]

IV. AN EXECUTIVE YEAR IN REVIEW: ACTIVITY WITH POTENTIAL TO INFLUENCE FDA OPERATIONS

Alongside the FDA's guidance document activity to effectuate rapid policy innovation, the White House and Executive Branch officials, like former Secretary of HHS Alex Azar, have issued a number of actions and orders that implicate the FDA, from an administrative law perspective, as they address the regulatory process and guidance documents. Table 4 details these recent activities.

Udall Found. & Friends of Cancer Rsch., COVID-19 EVIDENCE ACCELERATOR (Aug. 24, 2020), https://www.evidenceaccelerator.org/ [https://perma.cc/R3T3-7AFV] .

104. *See* Jacquie Lee, *FDA Teams Up With Data Company Aetion to Study Virus Progression*, FRIENDS CANCER RES. (May 19, 2020), https://www.focr.org/news/bloomberg-law-fda-teams-data-company-aetion-study-virus-progression-1 [https://perma.cc/A7TX-U9CN]; *see also* Statement from Amy Abernethy, *supra* note 102.

105. *See* Statement from Amy Abernethy, *supra* note 102; *see generally* AETION (Aug. 24, 2020), https://www.aetion.com/ [https://perma.cc/AM9S-3T9W].

106. *See* Lee, *supra* note 104.

107. DEVELOPMENT AND LICENSURE OF VACCINES GUIDANCE, *supra* note 78.

108. Jeannie Baumann, *FDA Presses Industry to Better Diversify Covid-19 Testing Pool*, BLOOMBERG L. (July 1, 2020), https://bnanews.bna.com/pharma-and-life-sciences/look-beyond-healthy-volunteers-in-virus-vaccine-tests-fda-says [https://perma.cc/U4G3-82NW].

Table 4: Executive Branch Actions 2019–2020

Date	**Document**	**Source**	**Title/Action**
Oct. 9, 2019	Ex. Order 13891	President Trump	*Improving the Rule of Law through Improved Agency Guidance Documents*[109]
May 19, 2020	Ex. Order 13924	President Trump	*Regulatory Relief to Support Economic Recovery*[110]
Aug. 20, 2020	85 Fed. Reg. 51396	U.S. Dept. HHS	*Department of Health and Human Services Good Guidance Practices*[111]
Sept. 15, 2020	Memo & Press Release	HHS Secretary Azar	*Statement on Regulatory Process*[112]
Sept./Oct. 2020	Press Reports	Media	White House initially refuses FDA COVID-19 EUA Guidance Document[113]
Oct. 21, 2020	Ex. Order 13957	President Trump	*Creating Schedule F in the Excepted Service*[114]

109. Exec. Order No. 13,891, 84 Fed. Reg. 55,235 (Oct. 9, 2019).

110. Exec. Order No. 13,924, 84 Fed. Reg. 31,353 (May 19, 2020). Fox News reported that at a Cabinet meeting prior to signing, the President noted "We've done far more regulation cutting than any president in history." *See* Morgan Phillips & Blake Burman, *Trump Announces Executive Order to Make Hundreds of Deregulations Amid Coronavirus Permanent*, FOX NEWS (May 19, 2020), https://www.foxnews.com/politics/trump-executive-order-to-identify-regulations-that-can-be-suspended-for-coronavirus-recovery [https://perma.cc/THY2-UM5S].

111. Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 51,396 (Aug. 20, 2020).

112. *HHS Statement on Regulatory Process*, U.S. DEP'T. HEALTH & HUM. SERVS. (Sept. 20, 2020), https://www.hhs.gov/about/news/2020/09/20/hhs-statement-on-regulatory-process.html [https://perma.cc/TV5F-W38W].

113. Cecelia Smith-Schoedenwalder, *Report: White House Blocks New FDA Guidelines on Coronavirus Vaccine Approval*, U.S. NEWS & WORLD REP. (Oct. 6, 2020), https://www.usnews.com/news/national-news/articles/2020-10-06/report-white-house-blocks-new-fda-guidelines-on-coronavirus-vaccine-approval [https://perma.cc/46H9-V48L].

114. Exec. Order No. 13,957, 85 Fed. Reg. 67,631 (Oct. 21, 2020).

Executive Order 13891, *Improving the Rule of Law through Improved Agency Guidance Documents*, specifically addresses the procedures for issuing guidance documents and instructs agencies to perform a number of tasks with respect to their own guidance documents. The order emphasizes the nonbinding nature of guidance documents and the requirements that public input be taken into account and the documents be readily available to the public.[115] The order directs that within 120 days after the Office of Management and Budget (OMB) issues an implementing memo, each agency "shall establish or maintain on its website a single, searchable, indexed database" of guidance documents.[116] Agencies are further directed to review all guidance documents and rescind those "that should no longer be in effect."[117] For guidance documents that are identified by the Director of OMB, each agency is required to issue a report to the Director giving reasons for maintaining those guidance documents; the report is also to be given to the President.[118] Agencies are also required, within 300 days of the OMB implementing memo, to finalize regulations or amend existing regulations setting forth procedures and processes for issuing guidance documents, including enumerated requirements identified in the order.[119] Guidance documents deemed "significant"[120] require additional aspects under the order, including a 30 day period of public notice and comment, as well as a public response from the agency as to "major concerns raised in comments, except when the agency for good cause finds (and incorporates such finding and a brief statement of reasons therefor into the guidance document) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public

115. Exec. Order No. 13,891, 84 Fed. Reg. 55,235 (Oct. 9, 2020).

116. *Id.* at 55,236.

117. However, the order does allow the agency to reinstate guidance documents within 240 days without regular procedures. *See id.* at 55,236.

118. *Id.* at 55,236–37.

119. *Id.* at 55,237.

120. The order provides:

> "Significant guidance document'' means a guidance document that may reasonably be anticipated to: (i) lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (ii) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (iii) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles of Executive Order 12866.

Id. at 55,236.

interest."[121] Significant guidance documents also require the approval "on a non-delegable basis by the agency head or by an agency component head appointed by the President, before issuance" and review by the Office of Information and Regulatory Affairs (OIRA) prior to issuance.[122]

Executive Order 13924, *Regulatory Relief to Support Economic Recovery*, introduces directives to all agencies given the national health emergency of the coronavirus.[123] The order urges agencies to examine whether regulations are inhibiting recovery and use existing legal authority to rescind, modify, or implement exemptions to regulations and other requirements.[124] It also directs agencies to utilize fairness in administrative enforcement and adjudications, including the use of enforcement discretion, against businesses, and small businesses in particular, in the face of "often-complex regulations in complicated and swiftly changing circumstances."[125] Agencies are instructed to use emergency authorities and are encouraged to proceed through non-regulatory action when appropriate.[126] As part of agency operations, the order expressly directs heads of agencies to:

> identify regulatory standards that may inhibit economic recovery and shall consider taking appropriate action, consistent with applicable law, including by issuing proposed rules as necessary, to temporarily or permanently rescind, modify, waive, or exempt persons or entities from those requirements, and to consider exercising appropriate temporary enforcement discretion or appropriate temporary extensions of time as provided for in enforceable agreements with respect to those requirements, for the purpose of promoting job creation and economic growth, insofar as doing so is consistent with the law and with the policy considerations.[127]

The HHS released a proposed rule in conformance with Executive Order 13891 on August 20, 2020. Notably, the proposed rule impacts all divisions of HHS except the FDA because the FDA has its own good guidance documents, statutory provisions, regulations, and policies and procedures.[128] The rule creates a distinction between guidelines in

121. *Id.* at 55,237.
122. *Id.*
123. Exec. Order No. 13,924, 85 Fed. Reg. 31,353 (May 19, 2020).
124. *Id.* at 31,353–54.
125. *Id.*
126. *Id.* at 31,354.
127. *Id.*
128. Erin Atkins & Stephanie Trunk, *HHS Proposes New Practices for Issuance of Guidance Documents*, JD SUPRA (Sept. 2, 2020), https://www.jdsupra.

"guidance documents" and "significant guidance documents."[129] As a reflection of the language in the Executive Order, key features of the proposed rule include the role of guidance documents to state policies on statutory, regulatory, technical, and scientific issues, or to interpret a preexisting regulation.[130] HHS notes in the proposed rule that guidance documents can be issued in a variety of formats, including letters, memoranda, circulars, bulletins, advisories, and preambles, and thus the content of the document, rather than the format, would determine whether it is a guidance document.[131] The proposed rule also exempts categories of documents from being under the umbrella of guidance documents.[132] Pursuant to this proposed rule, guidance documents will undergo a thirty-day notice and comment requirement and will need to be fully supported by duly enacted statutes and regulations in order to be compliant with the Supreme Court's ruling in *Azar v. Allina Health Services* (2019).[133] The proposed rule also introduces a modified disclaimer, which provides that a guidance document does not have the force and effect of law and does not bind the public, "unless specifically incorporated into a contract." Furthermore, the disclaimer must state: "This document is intended only to provide clarity to the public regarding existing requirements under the law."[134][135] In all, the proposed rule recites the requirements and directives set forth in the Executive Order, and, most importantly, does not apply to the FDA.

On September 15, 2020, Secretary Azar issued a memorandum to all federal administrative agencies under the auspices of HHS mandating that no regulation should issue unless and until it was approved by the Secretary and the White House and the Secretary formally signed that regulation.[136] The Department in its *Statement on Regulatory Process* provides that this involves "simply the ministerial, administrative act of attaching a signature to a document" and was not motivated by policy

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com/legalnews/hhs-proposes-new-practices-for-issuance-71156/ [https://perma.cc/MQY6-B5JB]; Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 51,396 (Aug. 20, 2020).

129. Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. at 51,396 (Aug. 20, 2020).

130. *Id.*

131. *Id.*

132. *Id.* at 51,397.

133. *Id.*

134. *Id.*

135. *Id.*

136. *Statement in Regulatory Process*, U.S. DEP'T HEALTH & HUM. SERVS. (Sept. 15, 2020), https://www.hhs.gov/about/news/2020/09/20/hhs-statement-on-regulatory-process.html [https://perma.cc/A6UX-FNHD].

considerations.[137] Within the statement the HHS includes the following in response to allegations that the action was undertaken to restrict the FDA:

> **Was the memo targeted at the Food and Drug Administration or any particular divisions of HHS?** No, the memo covers all Operating and Staff Divisions of HHS. Large agencies that release a significant amount of rules, such as the Food and Drug Administration, already have robust processes for sending any rules through departmental and White House clearance. Those processes will remain unchanged, except that they will now conclude with the Secretary's signing the rule in all cases.[138]

Subsequently, in late September through early October, multiple news outlets were reporting that the White House was refusing to accept the FDA's guidance document entitled *Emergency Use Authorizations for Vaccines to Prevent COVID-19*, which was presented to the President as required by Executive Order.[139] On Face the Nation on September 27, White House Chief of Staff Mark Meadows openly questioned the FDA's guidance document: "We're trying to make sure that the guidance we give is not a[n] inhibitor to getting things out fast, but it also doesn't detract from it."[140] There was widespread speculation that the move was politically motivated because the measures contained within the guidance document regarding demonstrating efficacy and tracing adverse events would have the effect of making approval of a vaccine prior to the election impossible.

On October 6, 2020, the FDA issued *Emergency Use Authorizations for Vaccines to Prevent COVID-19* by publishing the guidance document on its website.[141] It is unclear what communications were had among the White House, the HHS, and the FDA, but the guidance document is currently in effect. Ten days later, on October 16, 2020, the Government Accountability Office (GAO) announced that it would investigate alleged White House interference with the CDC and the FDA.[142]

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137. *Id.*

138. *Id.*

139. *See, e.g.*, Smith-Schoedenwalder, *supra* note 113.

140. Sydney Lupkin, *FDA Releases Long-Awaited COVID-19 Guidance*, NPR (Oct. 6, 2020), https://www.npr.org/sections/health-shots/2020/10/06/920942575/fda-releases-long-awaited-covid-19-vaccine-guidance [https://perma.cc/4J2C-BYVG].

141. *Emergency Use Authorization for Vaccines to Prevent COVID-19*, U.S. FOOD & DRUG ADMIN. (Oct. 2020), https://www.fda.gov/media/142749/download [https://perma.cc/2RFG-5KUG].

142. Letter from Orice Williams Brown, Managing Dir., U.S. Gov't Accountability Office: Cong. Relations, to Elizabeth Warren, Sen., U.S. Senate (Oct. 16, 2020), https://www.warren.senate.gov/imo/media/doc/21-0015%20

The investigation is responsive to a letter penned by Senator Elizabeth Warren and jointly signed by Gary Peters, Committee on Homeland Security & Governmental Affairs and Patty Murray, Committee on Health, Education, Labor & Pensions.[143] The letter requested the GAO "review whether the CDC and FDA's scientific integrity and communications policies have been violated and whether those policies are being implemented as intended to assure scientific integrity throughout the agency."[144]

On October 21, 2020, President Trump issued the Executive Order, *Creating Schedule F in the Excepted Service*.[145] This order creates Schedule F within the excepted service of the government made up of "employees in confidential, policy-determining, policy-making, or policy-advocating positions." Agency heads are directed to identify employees within such roles and relocate them to the new Schedule F classification.[146] The order notes "[f]aithful execution of the law requires that the President have appropriate management oversight regarding this select cadre of professionals."[147] Once moved, such employees will essentially be at-will employees, without the current personnel protections afforded to other federal workers.[148] The response to the order has been swift, with some lawmakers moving quickly to introduce legislative bills that would reverse the order, which has been dubbed an attack on the public service system, while others applaud the new order as a justified executive action.[149] Unquestionably, the order will make it easier for the President to say

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Warren.pdf [https://perma.cc/SP6R-ZQKQ] [hereinafter GAO Letter]; *see also* Dan Diamond, *Government Watchdog Will Probe Trump Officials Interference at CDC, FDA*, POLITICO (Oct. 19, 2020), https://www.politico.com/news/2020/10/19/government-watchdog-trump-cdc-fda-430175 [https://perma.cc/W6NB-6M8M].

143. GAO Letter, *supra* note 142; *see also* Letter from Gary C. Peters et al., Sens., U.S. Senate, to Christi A. Grimm, Principal Deputy Inspector Gen., U.S. Dep't of Health & Human Servs. (Oct. 1, 2020), https://www.hsgac.senate.gov/imo/media/doc/201001_Letter_%20PetersMuarryWarrenSchumerHHS%20Political%20Interference%20Letter.pdf [https://perma.cc/BJ9Q-SWT9] [hereinafter Senate Letter].

144. GAO Letter, s*upra* note 142; *see also* Senate Letter, *supra* note 143.

145. Exec. Order No. 67,631, 84 Fed. Reg. 67,631 (Oct. 21, 2020).

146. *Id.*

147. *Id.*

148. *Id.*

149. *Lawmakers Respond to Executive Order on Schedule F in Excepted Service*, FED MANAGER (Oct. 27, 2020), https://fedmanager.com/news/lawmakers-respond-to-executive-order-on-schedule-f-in-excepted-service [https://perma.cc/2SM3-PXNM].

"You're Fired" to a historically insulated class of federal employees operating at the highest levels of the government.[150]

CONCLUSION

> As this pandemic has evolved, it was clear to all of us that some FDA processes needed to be adjusted to accommodate the urgency of the pandemic and I think the entire FDA team has now seen first-hand that we need to take a critical look at some of our processes and policies.[151]
> *FDA Commissioner Stephen Hahn, M.D., May 29, 2020*

The administrative tension was palpable during the Trump administration. Some view the pandemic-induced changes to the regulatory process as a positive development, providing flexibility to agencies through deregulation.[152] Others question whether the deregulation activity is compromising public health and safety, and destabilizing public confidence in the FDA. Throughout it all, Commissioner Hahn assured the public that "good science and sound data" would guide the FDA's decisions on vaccines and other products to treat, diagnose, and mitigate the impact of COVID-19.[153] It remains to be seen what the future holds for the pandemic and for administrative functioning of the FDA.

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150. Natalie Alms, *Trump Order Creates Schedule F, to Speed Hiring and Firing in Key Positions*, FCW (Oct. 21, 2020), https://fcw.com/articles/2020/10/21/trump-schedule-f-civil-service.aspx [https://perma.cc/8YMK-F5EP].

151. Michael Mezher, *Hahn: FDA Will Make Some Changes Amid COVID-19 Permanent*, RAPS (June 1, 2020), https://www.raps.org/news-and-articles/news-articles/2020/6/hahn-fda-will-make-some-changes-amid-covid-19-perm [https://perma.cc/FTU3-PFEZ] (quoting Commissioner Stephen Hahn).

152. Phillips & Burman, *supra* note 110. "The Trump administration has used the pandemic to spur a deregulation campaign, notably removing regulations to telemedicine and removing barriers to accelerate coronavirus vaccine or cure development." *Id.*

153. Kari Oakes, *Hahn: COVID-19 Vaccine Decision Will Be "Deliberative,"* RAPS (Aug. 11, 2020), https://www.raps.org/news-and-articles/news-articles/2020/8/hahn-covid-19-vaccine-decision-will-be-deliberativ [https://perma.cc/2FGJ-XQG4].

Appendix: FDA Guidance Documents,
January 1, 2020 – October 6, 2020

Title	Audience									Product Area					Date
	Industry	FDA Staff	Clinical Laboratories	Investigators	Commercial Manufacturers	IRBs	Health Care Professionals	Generic Drug Development	Egg Producers	Medical Devices	Drugs	Biologics	Food & Beverages	Animal & Veterinary	
Emergency Use Authorization for Vaccines to Prevent COVID-19	•											•			Oct. 6
FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (Updated September 21, 2020)	•			•		•				•	•	•			Sept. 21
Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment	•										•	•			Sept. 14
Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency	•										•	•		•	Sept. 10
Investigational COVID-19 Convalescent Plasma; Guidance for Industry (Updated: September 2, 2020)	•											•			Sept. 2

Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products	•											•			Aug. 27
Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers	•										•	•			Aug. 19
Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency	•										•				Aug. 7
Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)	•										•				Aug. 7
Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)	•										•				Aug. 7
Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency		•	•		•					•					July 20
Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers	•	•								•		•			July 22

Development and Licensure of Vaccines to Prevent COVID-19	•											•		June 30
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	•	•								•				June 19
Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry	•									•	•	•		•	June 16
Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency	•										•				June 8
Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency (Revised)	•	•								•					June 5
Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency	•												•	•	June 4

Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency				•		•					•	•			June 2
Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID-19 Public Health Emergency	•												•		May 27
Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers	•										•	•			May 26
Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)	•	•								•					May 26
Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					May 26

Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	•												•		May 22
Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines	•												•		May 22
Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•		•			May 21
Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised)	•										•				May 21
Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised)	•										•				May 21

Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency	•										•				May 14
Returning Refrigerated Transport Vehicles and Refrigerated Storage Units to Food Uses After Using Them to Preserve Human Remains During the COVID-19 Pandemic	•												•	•	May 12
COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products	•			•							•	•			May 11
COVID-19: Developing Drugs and Biological Products for Treatment or Prevention	•										•	•			May 11
Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (Revised)		•	•		•					•					May 11
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic	•									•	•	•	•		May 8
CVM GFI #271 Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency	•													•	May 7

Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency	•										•	•			Apr. 30
Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•	•				•			•					Apr. 24
Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Apr. 23
Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Apr. 23
Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency	•										•				Apr. 22
Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency	•												•		Apr. 22

Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94(e)(1) For Oxygen and Nitrogen During the COVID-19 Public Health Emergency	•										•				Apr. 20
Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Apr. 16
Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Apr. 14
Product-Specific Guidances for Chloroquine Phosphate and Hydroxychloroquine Sulfate								•			•				Apr. 13
Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Apr. 6
Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Apr. 6

Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID-19 Public Health Emergency									•				•		Apr. 6
Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Apr. 5
Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Apr. 4
CVM GFI #270 - Guidance on the Conduct and Review of Studies to Support New Animal Drug Development during the COVID-19 Public Health Emergency	•													•	Apr. 3
Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID-19 Public Health Emergency	•												•		Apr. 3
Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency	•											•			Apr. 2
Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria	•											•			Apr. 2

Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency	•												•		Apr. 1
Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency	•	•								•					Mar. 30
Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•					Mar. 29
Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry	•										•	•			Mar. 27
Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency	•												•		Mar. 26
CVM GFI #269 - Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak	•													•	Mar. 24

Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	•	•								•						Mar. 22
Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals	•						•					•	•			Mar. 22