ROPES & GRAY

CORONAVIRUS
INFORMATION & UPDATES

June 29, 2020

Analysis: FDA Response to COVID-19: A Shifting Landscape

Attorneys
Beth P. Weinman
Gregory H. Levine
Michael Purcell

In the months since the novel coronavirus (SARS-CoV-2) first appeared in the United States in late 2019, private industry and governmental authorities have recognized and responded to the need to develop and scale up manufacturing of COVID-19 vaccines, diagnostics, therapeutic treatments, and even basic medical supplies. The sense of urgency has increased since mid-December, as over 2.3 million U.S. cases have been confirmed, the disease has claimed the lives of more than 120,000 U.S. residents, and the total number of infections and deaths worldwide has continued to grow.[1]

The U.S. Food and Drug Administration ("FDA") is one of several federal agencies with key roles to play in the nation's response efforts. Attempting to mitigate acute medical product shortages and spur the development of new products and treatments for COVID-19, FDA has issued enforcement discretion guidelines for various product types, waived numerous regulatory requirements, and granted dozens of emergency use authorizations for drugs and devices.[2] However, balancing the need to support rapid access to critical medical products while ensuring their quality, effectiveness, and safety has, in some instances, proven difficult.

In the six months since the HHS Secretary declared COVID-19 to be a public health emergency, FDA has several times chosen to change course by walking back enforcement discretion or revoking emergency use authorizations in light of evidence that increased flexibility was exposing patients and health care providers to more harm than benefit. The emergence of significant fraud in connection with representations about certain products has also led the agency to step up enforcement and tighten its regulatory reins.

Overview of FDA Efforts

In response to the outbreak of the COVID-19 pandemic, on January 31, 2020, Secretary of Health and Human Services ("HHS") Alex Azar issued a determination that a public health emergency existed related to the virus causing COVID-19 under the Public Health Service Act (the "PHE Declaration").[3] The issuance of the PHE Declaration granted the Secretary a variety of emergency powers and set the stage for the far-reaching regulatory response that followed.

Emergency Use Authorizations: Following the PHE Declaration, Secretary Azar also issued a number of determinations under section 564 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") that the existing public health emergency had created circumstances justifying the issuance of expedited regulatory authorization, referred to as emergency use authorization ("EUA"), for certain categories of drugs, biologics and devices.[3] Specifically, EUAs can be granted for unapproved medical products or unapproved uses of approved medical products to diagnose, treat, or prevent serious or life-threatening diseases or conditions where there are no adequate, approved, and available alternatives, though FDA must review periodically the circumstances and appropriateness of any EUA it has issued.[5] As of June 23, FDA has issued 189 active EUAs under these EUA Declarations.[6]

EUAs have not ameliorated supply shortages fully, especially in the case of diagnostics and PPE. However, they have incentivized wider development of needed products and enabled a significantly streamlined FDA review and

authorization process for products coming to market though this pathway. For in vitro diagnostic tests alone, FDA has issued more than 100 unique EUAs, with the number continually growing, and has permitted other in vitro diagnostics to reach the market prior to or without EUA authorization. FDA has also issued 17 EUAs related to PPE for health care providers like filtering facepiece respirators, decontamination systems that enable reuse of compatible respirators in short supply, face shields, gowns and protective barrier enclosures.

FDA Guidance Documents and Enforcement Policies: The agency has also used enforcement policies to permit the marketing of certain products under specified conditions during the public health emergency, despite the fact that such products may lack FDA approval or clearance or may fail to comply with other statutory and regulatory requirements.[7] These policies generally lay out the conditions under which the agency will exercise enforcement discretion to ensure use of products within their scope will not create an undue risk to users. FDA has issued more than 55 COVID-19 related enforcement policies and other guidances related to a variety of products, including COVID-19 diagnostic tests, PPE, hand sanitizers, remote-monitoring devices, ventilators, and therapeutics.

Several EUAs and enforcement policies issued by FDA, especially in the device context, have also included waivers of current good manufacturing practice, registration and listing, and correction and removal reporting requirements, for products within their scope.

A Shifting Landscape

Given the urgent need posed by COVID-19, the speed with which FDA has issued EUAs and enforcement policies, and the regular emergence of new information about the consequences of FDA actions, some agency decisions have required revisiting. FDA's activities relating to non-NIOSH-approved[8] filtering facepiece respirators ("FFRs), its shifting enforcement policies for serology tests, and its recent revocation of the EUA for hydroxychloroquine sulfate and chloroquine phosphate serve as telling illustrations of the challenges facing FDA during this crisis and its occasional need to correct course.

Non-NOISH-Approved FFRs: Throughout the COVID-19 emergency, the shortage of face masks and other FFRs for health care providers has been a persistent source of concern. In response, FDA has promoted the extended use or recycling of previously approved respirators, and permitted the use of otherwise unapproved respirators, surgical masks, and improvised or other non-medical types of masks, though for limited intended uses.[9]

FDA issued an EUA on March 24 permitting the importation of non-NIOSH-approved N95 respirators.[10] N95s provide the highest level of protection against airborne droplets potentially containing the virus causing COVID-19. Under this EUA, the FDA authorized, subject to certain criteria, the distribution of FFRs manufactured in a list of accepted countries with standards similar to NIOSH – namely, Australia, Brazil, Europe, Japan, Korea, and Mexico.[11] However, FDA expressly excluded KN95[12] respirators from China "because of concerns about fraudulent products listed as KN95s."[13] Nevertheless, significant pressure was exerted on FDA to permit the importation of KN95 respirators in response to the persistent shortage of FFRs among providers treating COVID-19 patients.[14]

As the shortage of respirators persisted, and public pressure increased, FDA issued a new EUA on April 3 for non-NIOSH-approved N95 respirators made in China, including KN95s.[15] Under this EUA, one of the means by which

respirators could be authorized was upon a demonstration of acceptable performance to applicable testing standards by independent testing laboratories.[16] The EUA also included an appendix listing the respirators that were so authorized.[17]

Only a month later, on May 7, FDA revised and reissued the EUA. Since its issuance, data had emerged demonstrating that some authorized KN95s did not actually meet the expected filtration performance despite independent lab certifications submitted to FDA claiming otherwise.[18] Consequently, FDA removed respirator models from 74 manufacturers from the EUA.[19] FDA also issued new criteria for EUA requests for Chinese-made KN95s requiring that their effectiveness be confirmed by NIOSH. The scope of the authorization was again narrowed in an additional amendment on June 6.[20]

Finally, as FDA authorized more devices to decontaminate facemasks and respirators, and supply shortages eased somewhat, the agency pulled back on enforcement discretion for non-NIOSH-approved respirators, citing the same performance data that led to the EUA amendment described above. FDA's revised enforcement policy for face masks and respirators noted that the data "indicates that greater FDA oversight of respirators that are not FDA-cleared or authorized under an EUA is important to protect the public health . . . [and a]s a result of these changed circumstances, FDA is discontinuing its previous policy" of non-enforcement for distribution and use of non-NIOSH-approved or FDA-cleared respirators.[21] The policy now recommends using FDA-cleared or NIOSH-approved N95 respirators when available, and prioritizing other FDA-authorized respirators before any other alternatives when they are not.[22]

Supplementing FDA efforts to prevent the further distribution of poor quality or fraudulent respirators, the Department of Justice ("DOJ") has filed criminal charges against two Chinese companies for distributing Chinese-made FFRs that were either falsely labeled as NIOSH-approved N95s or falsely claimed the requisite level of effectiveness.[23] According to the DOJ, testing has demonstrated that these respirators did not meet the minimum standard for N95s.[24] Both criminal complaints charged the companies with the introduction of misbranded respirators into interstate commerce, and one complaint also charged a felony false statements count related to the filing of misleading registration documents with the FDA.[25]

Serology Tests: It is widely recognized by public health experts that "[t]o respond effectively to the COVID-19 outbreak, rapid detection of cases and contacts, appropriate clinical management and infection control, and implementation of community mitigation efforts are critical."[26] However, from the onset of the pandemic, the U.S. has lacked necessary tests and test supplies.[27] On February 4, FDA issued its first EUA for a diagnostic test to the CDC, and in late February issued an enforcement policy permitting the use of validated molecular diagnostic tests prior to receiving EUA authorization. In its policy, FDA limited enforcement discretion to laboratories certified for high-complexity testing under the Clinical Laboratory Amendments Act of 1988 ("CLIA").[28] The policy was subsequently expanded to include commercial manufacturers of molecular diagnostics and to permit the distribution and use of certain serology tests in an amendment to the policy issued on March 16.[29]

Serology tests are used to detect antibodies and can be used to collect information on disease prevalence and the frequency of asymptomatic infection, and to identify individuals who may have developed an adaptive immune response to the virus causing COVID-19. Under its revised policy, FDA exercised enforcement discretion in connection with the distribution and use of serology tests "where the test has been validated, notification is provided to the FDA, and warning statements are included with the tests."[30] FDA emphasized the importance of the requirement that these tests be validated

in some form to ensure test performance,[31] but did not require that serology tests obtain EUA post-validation unless they involved at-home specimen collection.[32]

In a press release announcing that the agency would not require EUAs for serology tests, FDA explained that "serology tests are less complex than molecular tests and are solely used to identify antibodies, which limits their effectiveness for diagnosis."[33] However, on May 4, FDA rescinded and replaced this policy, permitting commercial serology test manufacturers to market their tests after validation and notification to FDA, *but only for up to ten business days before submitting an EUA request*. This policy change applied both to new tests and to tests distributed under FDA's previous policy.[34] In a blog post that same day, FDA officials explained:

Flexibility never meant we would allow fraud. We unfortunately see unscrupulous actors marketing fraudulent test kits and using the pandemic as an opportunity to take advantage of Americans' anxiety. Some test developers have falsely claimed their serological tests are FDA approved or authorized. Others have falsely claimed that their tests can diagnose COVID-19 or that they are for at-home testing, which would fall outside of the policies outlined in our March 16 guidance, as well as the updated guidance. Also, since that time, the FDA has become aware that a concerning number of commercial serology tests are being promoted inappropriately, including for diagnostic use, or are performing poorly based on an independent evaluation by the NIH.[35]

Ever since requiring EUAs for serology tests, FDA has proactively monitored the authorized tests for safety and effectiveness, and has made changes to authorizations as necessary. On June 16, FDA revoked the EUA for a serology test manufactured by Chembio Diagnostic Systems after information from multiple evaluations performed since the test's authorization found that the test was not as accurate as claimed in the original EUA submission.

Chloroquine Phosphate and Hydroxychloroquine Sulfate: While shortages of products like PPE and diagnostic tests have been closely followed throughout the COVID-19 crisis, perhaps no issue has received more attention than the search for vaccines and therapeutics. With few options for treatment, on March 28, FDA issued an EUA for an unapproved use of an approved anti-malarial medication called chloroquine phosphate ("CQ") and an arthritis drug also used for malaria prevention called hydroxychloroquine sulfate ("HCQ") to treat COVID-19 in patients for whom a clinical trial is not available or participation is not feasible.[37] The EUA was limited to drug product supplied from the Strategic National Stockpile to public health authorities. Touted by some political leaders, including U.S. President Donald Trump, as effective for the prevention and treatment of COVID-19, the debate surrounding HCQ and CQ quickly became a political lightning rod. Concern about the drugs was aggravated by reports that the EUA was issued under significant White House pressure, and a whistleblower from the Biomedical Advanced Research and Development Authority (BARDA) alleged that he was removed from his post as director as a result of his opposition to expanding access to these drugs for COVID-19 treatment.[38] In the EUA, FDA expressly noted that its decision to make these drugs more widely available to individuals with COVID-19 who could not participate in a clinical trial was "[b]ased upon limited in-vitro and anecdotal data in case series," but encouraged further clinical research "that may produce evidence concerning the effectiveness of these products in treating COVID-19" before authorizing use in the general population.

FDA soon took pains to reemphasize the limitations of this EUA, warning of serious heart rhythm problems in patients with COVID-19 treated with the drugs.[39] A recent study published in *The Lancet*, which found that CQ and HCQ were associated with higher mortality and did not improve outcomes, was subsequently retracted after questions arose about the reliability of the data used in its analysis.[40] This revocation prompted the World Health Organization (WHO) to

reinitiate a hydroxychloroquine investigation that had been suspended following the *Lancet* study's initial publication. However, results from other subsequently published studies indicated that the drugs are not effective at preventing COVID-19 or at decreasing mortality among infected populations.[41]

In response to these studies, and at the request of BARDA, FDA revoked this EUA on June 15.[42] This decision was ultimately based on both an analysis of new data and a reanalysis of the data and literature relied upon in the initial EUA demonstrating that (1) the suggested dosing regimens in the EUA authorizing labeling were unlikely to produce an antiviral effect; (2) reports of decreased viral shedding with CQ and HCQ treatment were not consistently replicated and recent data assessing probability of negative conversion showed no difference between HCQ and standard of care alone; (3) current U.S. treatment guidelines do not recommend the use of CQ and HCQ in hospitalized patients outside of a clinical trial, and NIH guidelines recommend against such use outside of a clinical trial; and (4) recent data from a large randomized controlled trial shows no evidence of benefit for mortality or other meaningful outcomes in hospitalized COVID-19 patients.[43] FDA nevertheless reminded the public in its press release announcing the EUA revocation that FDA-approved versions of these drugs can still be prescribed off-label for COVID-19 treatment if physicians determine such use is appropriate for their specific patients.[44]

Looking Forward

FDA's issuance of EUAs, enforcement discretion policies and waivers of regulatory requirements has led to greater availability of critical medical products during a dangerous and uncertain time. However, FDA has already had to make a number of course corrections to address the availability of potentially ineffective or harmful products, and its ultimate response to some of these situations is not yet clear. For example, to date, FDA has not sought the return or destruction of non-NIOSH-approved respirators manufactured in China removed from an initial EUA authorization list, or other non-NIOSH-approved respirators marketed under enforcement discretion. Nor has it sought the removal of serology tests marketed by manufacturers that failed to submit timely EUAs under the agency's revised COVID-19 testing policy.

In addition, FDA has not indicated what action it will take in connection with EUAs issued during the COVID-19 public health emergency when the pandemic subsides. EUAs and the declarations that enable them will not automatically terminate at the expiration of the public health emergency.[45] HHS can, however, terminate such declarations and by doing so rescind all of the EUAs issued under them. FDA proactively terminated the declaration issued during the H1N1 emergency, but the declarations for Ebola, Enterovirus, the H7N9 flu, MERS-CoV, and Zika virus, for example, all remain in effect.

Given that significantly more EUAs have been issued in the context of COVID-19 than ever before, and for a broader range of medical products, the agency may determine that it should limit further distribution of products that have not undergone sufficient FDA review or are non-compliant with other regulatory requirements. If FDA were to do so, the agency might consider including recommendations for manufacturers relating to the disposition of products for which EUAs have lapsed, as it did in the case of H1N1. In that context, for example, FDA recommended that states that received PPE authorized under a revoked EUA hold the remaining units for potential use in future emergencies, or hold and distribute them for other uses for which they had been appropriately cleared or approved.[46] In addition, FDA could implement programs to incentivize the return of products for which EUAs have been terminated from hospitals, pharmacies, laboratories or other end-users when manufacturer-driven collection is not feasible or likely. This would be

especially useful in the context of foreign manufactured products that reached the market through brokers or other intermediaries.

Continued distribution of products for which no clearance, approval, EUA, or enforcement discretion applies could lead to warning letters, civil money penalties, injunction actions, or criminal enforcement. Such enforcement actions are likely to be commensurate with risk and more likely in cases where fraudulent conduct can be shown.

FDA's loosening of the regulatory reins during the current pandemic has been largely effective in expanding access to products necessary to respond to the COVID-19 crisis. On the other hand, its need to make mid-course corrections to policies that resulted in distribution of inferior quality or ineffective products illustrates the difficult regulatory challenges wrought by the current pandemic. Only time will tell what role manufacturers, distributors and lawyers may be asked to play to help address the long-term fate of products permitted to reach the market on an emergency basis, once the COVID-19 pandemic eventually subsides or market forces render EUAs no longer necessary.

---

1. Centers for Disease Control and Prevention, COVID-19 Cases, Data, & Surveillance, Cases in the U.S., *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last accessed June 23, 2020); *see also* Coronavirus in the U.S.: Latest Map and Case Count, N.Y. Times, *available at* https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html (last accessed June 23, 2020).
2. FDA has also issued guidance documents and enforcement policies on other COVID-19-related issues, including relating to conducting clinical trials during the COVID-19 emergency, expectations regarding postmarketing adverse event reporting, and other activities impacted by the virus.
3. Secretary of Health and Human Services Alex Azar, Determination that a Public Health Emergency Exists, (Jan. 31, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx. The declaration was renewed on April 21, 2020, effective April 26, 2020.
4. *See e.g.*, Secretary of Health and Human Services Alex Azar, FD&C Act Determination of Public Health Emergency (Feb. 7, 2020), *available at* https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency; Secretary of Health and Human Services Alex Azar, Emergency Use Authorization Declaration, *available at* https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration.
5. FD&C Act Section 564(g)(1).
6. For a complete list of COVID-19 EUAs, including authorizations and fact sheets, *see* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last accessed June 23, 2020).
7. For a complete list of FDA's COVID-19-related enforcement policies and other guidance documents, *see* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders (last accessed June 23, 2020).
8. The National Institute for Occupational Safety and Health ("NIOSH") is an agency within the Centers for Disease Control and Prevention ("CDC"). Among other things, the agency assigns ratings to classifications of filtering respirators to reflect the respirator's effectiveness at filtering particles out of the air the user is breathing, and other safety and effectiveness criteria. NIOSH will not approve a respirator whose level of filtration falls below 95%. *See* Centers for Disease Control; NIOSH-

Approved Particulate Filtering Facepiece Respirators, *available at* https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html.

9. FDA has issued several EUAs for decontamination systems enabling reuse of respirators and a policy of enforcement discretion relating to the distribution and use of certain PPE. *See* Food and Drug Administration, Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency, *available at* https://www.fda.gov/media/136449/download. FAQ resources related to PPE are available on the agency's website. *See* Food and Drug Administration, FAQs on Shortages of Surgical Masks and Gowns During the COVID-19 Pandemic, *available at* https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns-during-covid-19-pandemic (last accessed June 23, 2020); Food and Drug Administration, Use of Respirators, Facemasks, and Cloth Face Coverings in the Food and Agriculture Sector During Coronavirus Disease (COVID-19) Pandemic, *available at* https://www.fda.gov/food/food-safety-during-emergencies/use-respirators-facemasks-and-cloth-face-coverings-food-and-agriculture-sector-during-coronavirus (last accessed June 23, 2020).
10. Food and Drug Administration, EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, *available at* https://www.fda.gov/media/136403/download.
11. EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, at 4.
12. KN95 is the regulatory reference standard in China for FFRs.
13. *See* FAQs on Shortages of Surgical Masks and Gowns During the COVID-19 Pandemic.
14. *See, e.g.*, Ken Bensinger, *Coronavirus Cases Have Surged, But The US Is Refusing To Take The World's Most Available Masks*, BuzzfeedNews (Mar. 29, 2020) *available at* https://www.buzzfeednews.com/article/kenbensinger/coronavirus-kn95-masks-us-wont-import-china.
15. Food and Drug Administration, EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China, *available at* https://www.fda.gov/media/136664/download.
16. EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China, at 3.
17. EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China, Appendix A, *available at* https://www.fda.gov/media/136663/download.
18. National Institute for Occupational Safety and Health, International Assessment Results – Not NIOSH-approved, *available at* https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html (last accessed June 23, 2020). *See also* FAQs on Shortages of Surgical Masks and Gowns During the COVID-19 Pandemic; Food and Drug Administration, FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic, *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic (last accessed June 23, 2020).
19. Food and Drug Administration, Respirator Models Removed from Appendix A, *available at* https://www.fda.gov/media/137928/download.
20. EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China; *see also* FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic.
21. Food and Drug Administration, Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised), at 9, *available at* https://www.fda.gov/media/136449/download.
22. Enforcement Policy for Face Masks and Respirators, at 9.

23. Both companies, along with more than 1,300 other Chinese companies, registered with the FDA using a non-existent company as their legally mandated U.S. representative to sell medical products in the U.S. during the pandemic. *See* Mark Maremont, *U.S. Files Charges Against Chinese N95 Mask Maker*, Wall Street Journal (June 5, 2020), *available at* https://www.wsj.com/articles/u-s-files-charges-against-chinese-n95-mask-maker-11591395929; Austen Hufford, *U.S. Files Charges Against Chinese Mask Manufacturer*, Wall Street Journal (June 17, 2020), *available at* https://www.wsj.com/articles/u-s-files-charges-against-chinese-mask-manufacturer-11592446407.
24. Complaint and Affidavit in Support of Application for Summons, United States of America v. King Year Printing and Packaging Co., Ltd., at 1, *available at* https://www.justice.gov/usao-nj/press-release/file/1283346/download.
25. *Id.*, Criminal Complaint, United States of America v. Crawford Technology (HK) Co., Ltd., Attachment A, *available at* https://www.justice.gov/usao-nj/press-release/file/1286516/download.
26. Food and Drug Administration, Immediately in Effect Guidance Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, at 5, *available at* https://www.fda.gov/media/135659/download.
27. *See, e.g.*, Kelsey Ketchum and Leo O'Connor, *COVID-19 testing problems started early, U.S. still playing from behind*, Modern Healthcare (May 11, 2020), *available at* https://www.modernhealthcare.com/technology/covid-19-testing-problems-started-early-us-still-playing-behind; Abby Goodnough, Katie Thomas, and Sheila Kaplan, Testing Falls Woefully Short as Trump Seeks an End to Stay-at-Home Orders, N.Y. Times (April 15, 2020), *available at* https://www.nytimes.com/2020/04/15/us/coronavirus-testing-trump.html; Kirk Siegler, *Many Who Need Testing For COVID-19 Fail to Get Access*, NPR (April 3, 2020), *available at* https://www.npr.org/2020/04/03/826044608/many-who-need-testing-for-covid-19-fail-to-get-access.
28. FDA News Release, Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics (Feb. 29, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics.
29. FDA Statement, Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics (Mar. 16, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help.
30. Food and Drug Administration, Immediately in Effect Guidance Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency, at 15; *see also* FDA Statement, FDA Provides More Regulatory Relief During Outbreak.
31. *See also* FDA Statement, Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts, *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts.
32. Immediately in Effect Guidance Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, at 14.
33. FDA Statement, Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics.
34. Immediately in Effect Guidance Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, at 15.
35. Dr. Anand Shah and Dr. Jeff Shuren, Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy, *available at* https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy.
36. Food and Drug Administration, Revocation of Emergency Use Authorization for Chembio Diagnostic Systems, Inc. DPP COVID-19 IgM/IgG System, *available at* https://www.fda.gov/media/139109/download.
37. Food and Drug Administration, EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate, *available at* https://www.fda.gov/media/136534/download.

38. *See* Addendum to the Complaint of Prohibited Personnel Practice and Other Prohibited Activity by the Department of Health and Human Services Submitted by Dr. Rick Bright, at 2, *available at* https://www.cnn.com/2020/05/05/politics/rick-bright-full-complaint/index.html.

39. *See* FDA Cautions Against Use of Hydroxychloroquine or Chloroquine, *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or.

40. Mandeep R. Mehra et al, RETRACTED: Hydroxychloroquine or Chloroquine With or Without A Macrolide for Treatment of COVID-19: A Multinational Registry Analysis, The Lancet, *available at* https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext; *see also* Chris Dall, Controversy Over Data in Hydroxychloroquine COVID-19 Study Grows, CIDRAP, *available at* https://www.cidrap.umn.edu/news-perspective/2020/06/controversy-over-data-hydroxychloroquine-covid-19-study-grows.

41. *See, e.g.*, Press Release, No Clinical Benefit from Use of Hydroxychloroquine in Hospitalised Patients with COVID-19, RECOVERY Trial, *available at* https://www.recoverytrial.net/news/statement-from-the-chief-investigators-of-the-randomised-evaluation-of-covid-19-therapy-recovery-trial-on-hydroxychloroquine-5-june-2020-no-clinical-benefit-from-use-of-hydroxychloroquine-in-hospitalised-patients-with-covid-19; David R. Boulware et al, A Randomized Trial of Hydroxychloroquine as Postexposure Prophylaxis for COVID-19, New Eng. J. Med., *available at* https://www.nejm.org/doi/full/10.1056/NEJMoa2016638?query=featured_home#.XtgSPYeCao0.twitter.

42. Food and Drug Administration, Memorandum Explaining Basis for Revocation of Emergency Use Authorization for Chloroquine Phosphate and Hydroxychloroquine Sulfate, at 11, *available at* https://www.fda.gov/media/138945/download.

43. *Id.* at 1.

44. FDA New Release: Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine, *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and.

45. EUAs will either terminate where the criteria for issuance of an EUA are no longer met or where the EUA Declaration is terminated. The former can be satisfied in situations including, but not limited to, a change in the approval status of the product, approval of another product determined to be substantially equivalent, a lack of inventory of the product, and a request from the manufacturer to withdraw the product. For EUA Declarations, termination only occurs upon the earlier of either (1) a determination by the Secretary (in consultation, as appropriate, with the Secretary of Homeland Security or the Secretary of Defense), that the circumstances justifying the emergency use no longer exist; or (2) a change in the approval status of the product such that it is no longer an unapproved product or has an unapproved use. 21 USC § 360bbb-3(b)(3).

46. FDA Commissioner Margaret Hamburg, Letter Re: Disposition of Certain Personal Respiratory Protection Devices Authorized for Emergency Use (June 22, 2010), *available at* https://www.cdc.gov/H1N1flu/EUA/pdf/PPE_Dispostion_Letter_clean.pdf.