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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

HEALTH FREEDOM DEFENSE FUND, INC.; RUSSELL AND LISA ADAMS, husband and wife, on their own behalf and as natural guardian for and on behalf of their minor children, C.A.A., W.N.A., and T.R.A.; HUGH and RENATA PARIS PEDDY, husband and wife, on their own behalf and as natural guardians for and on behalf of their minor child, A.P.;

Plaintiffs,

vs.

KEITH ROARK, LARA STONE, AMBER LARNA, DAN TURNER, and GRETCHEN GORHAM, all in their official capacities as members of the BOARD OF TRUSTEES OF BLAINE COUNTY SCHOOL DISTRICT NO. 61, as well as in their personal capacities for the Section 1983 claims asserted herein,

Defendants.

Case No. 1:21-cv-406

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

DEMAND FOR JURY TRIAL

Plaintiffs HEALTH FREEDOM DEFENSE FUND, INC. ("HFDF"); RUSSELL and LISA ADAMS and their minor children, C.A.A., W.N.A., and T.R.A.; and HUGH and RENATA PARIS PEDDY, and their minor child A.P. by and through their undersigned counsel, sue Defendants

KEITH ROARK, LARA STONE, AMBER LARNA, DAN TURNER, and GRETCHEN GORHAM, all in their official capacities as members of the BOARD OF TRUSTEES OF BLAINE COUNTY SCHOOL DISTRICT NO. 61, as well as in their personal capacities for the Section 1983 claims asserted herein, and allege as follows:

PRELIMINARY STATEMENT

1. Plaintiffs challenge Blaine County School District Board of Trustees' "Guidelines for Face Coverings at School," adopted by Defendants Keith Roark, Lara Stone, Amber Larna, Dan Turner, and Gretchen Gorham as the Board of Trustees of Blaine County School District No. 61 on August 19, 2021 (the "Mask Mandate"), a true and correct copy of which is attached hereto as Exhibit A. The Mask Mandate requires that all staff and students wear a face covering at school indoors while Blaine County is identified at yellow, orange, or red levels of transmission as defined by the CDC data tracker.

2. The wearing of 'face coverings"[1] is purportedly required for a medical purpose, i.e., to prevent transmission of the virus known as SARS-CoV-2, which has been determined to cause the ailment known as COVID-19. The Mask Mandate must be struck down because:

a. The Mask Mandate is preempted under the Supremacy Clause by the federal law under which the Food and Drug Administration ("FDA") issued the Emergency Use Authorization ("EUA") for mask use, which requires that use of masks must

[1] The FDA defines face masks as a device and includes face coverings as a subset. See Exhibit B, FDA April 24, 2020 letter to Manufacturers of Face Masks; Health Care Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders. ("A face mask is a device, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth face coverings as a subset. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as "*face masks*" that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a "device" under section 201(h) of the Act. Generally, *face masks fall within this definition when they are intended for a medical purpose*. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks.") emphasis added.

be optional to the user because the normal testing, evaluation, and approval process for use of such masks has been bypassed by the FDA due to an emergency;

b. The Mask Mandate implements a mandatory human experiment under which the staff and students of Blaine County School District No. 61 are forced to use a medical device when the medical impact on adults and children (including physical and psychological short and long-term side-effects) of such use has not been tested, evaluated, and approved by the FDA under normal procedures and is therefore unknown (experimental), and thus violates international law, federal law, and Idaho law;

c. The Mask Mandate violates Plaintiffs' fundamental human rights deeply rooted in American history and traditions, is not narrowly tailored to achieve a compelling state interest, and therefore violates the due process clause of the Fourteenth Amendment to the Constitution; and

d. The Mask Mandate has been placed in force and enforced by the Defendants herein operating under color of law who have deprived Plaintiffs of rights, privileges and immunities secured by the Constitution and laws of the United States, as noted above.

INTRODUCTION

3. None of the currently available face coverings for COVID-19 has received final approval from the FDA. Rather, such face coverings are *unapproved products* that have been authorized for emergency use under an Emergency Use Authorization ("EUA"). A true and correct copy of the EUA authorizing the use of masks during the current emergency (the "Mask EUA") is attached hereto as Exhibit B.

4. The statute granting the FDA the power to authorize a medical product for emergency use requires, *inter alia*, that the person being administered the unapproved product be advised of his or her right to refuse administration of the product. *See* 21 U.S.C. §360bbb-3(e)(1)(A) ("Section 360bbb-3").

5. The FDA has taken the position that the terms and conditions of the Mask EUA preempt state and local laws that would impose obligations that are inconsistent with those terms and conditions. *See* Exhibit C, Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders at 39-40.[2]

6. The Mask EUA specifies that "emergency use of face masks must be consistent with, and may not exceed, the terms of this letter…". See Exhibit B.

7. It is by now well-settled that medical experiments, better known in modern parlance as clinical research, may not be performed on human subjects without the express consent of the individual. This human right against human experimentation has its roots in the Nuremberg Code of 1947, has been ratified by the 1964 Declaration of Helsinki, the United States Code of Federal Regulations, the law of Idaho, and indeed is so universally recognized across the globe that it constitutes a *jus cogens* norm under international law. In short, forced human experiments are universally recognized as against the law. Such globally recognized international standards are binding upon the United States and, when violated, create a cause of action enforceable by citizens of the United States damaged thereby.

[2] "FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564… To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular medical product within the scope of the declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," and "conflicts with the exercise of Federal authority under [§ 564]."""

8. Masks are traditionally worn by healthcare workers, who are trained in their use, and only for short periods of time.

9. The short and long-term medical impact and psychological side-effects to children and adults from being forced to consistently wear masks, especially for hours on end while at school or work, have not been studied. Indeed, the evidence is that wearing masks for extended periods of time is harmful, and that this harm is in no way counterbalanced by any benefit.

10. The Mask Mandate thus constitutes a grand medical experiment, and forcing every person in a public place in Blaine County School District No. 61 to wear a face covering constitutes a violation of international law, federal law, and Idaho law, all of which prohibit human experiments absent informed consent.

11. Even if the Mask Mandate does not constitute a mandatory human experiment, the Mask Mandate (a) violates Plaintiffs' fundamental human rights deeply rooted in American history and traditions (such as the right to bodily integrity and personal autonomy, the right of self-determination in health care, and the right of parents to determine the health care of their children), (b) is not narrowly tailored to achieve a compelling state interest, and (c) therefore violates the due process clause of the Fourteenth Amendment to the Constitution. Indeed, the Mask Mandate serves no state interest at all (let alone a compelling one) in that it cannot, even according to the FDA, be said to reduce or prevent the spread of COVID-19.

12. There is no "pandemic exception" to the Constitution or any of the law relied upon by Plaintiffs. Plaintiffs therefore ask that the Court intervene to protect their rights.

PARTIES

13. Plaintiff HFDF, is a not-for-profit public benefit Wyoming corporation with its headquarters in Sandpoint, Idaho. HFDF is a member organization that seeks to advocate and educate the public on the topics of medical choice, bodily autonomy, and self-determination, and

that opposes laws and regulations that force individuals to submit to the administration of medical products, procedures, and devices against their will.

14. Several of Plaintiff HFDF's members reside in Blaine County, Idaho, and within Blaine County's School District No. 61, and are directly affected by the Mask Mandate, as more fully set out in Declarations 1 through 3 attached hereto and made a part hereof as Composite Exhibit D. Plaintiff HFDF's members therefore would have standing in their own right to bring the causes of action asserted by Plaintiff HFDF. As well, the interests at stake in this case are germane to Plaintiff HFDF's purpose, and neither the claims asserted nor the relief requested by Plaintiff HFDF require the individual participation of Plaintiff HFDF's members. Plaintiff HFDF therefore has standing to bring this case, which presents a justiciable issue for the Court.

15. Plaintiffs Russell and Lisa Adams are residents of the age of majority of the State of Idaho, domiciled in Blaine County, Idaho. Mr. and Mrs. Adams are of sound mind and have the capacity to bring this lawsuit. Mr. and Mrs. Adams are the father and mother, respectively, and natural guardians of C.A.A., W.N.A., and T.R.A., three minor children who attend schools subject to the jurisdiction of Blaine County School District No. 61. C.A.A., W.N.A., and T.R.A. are subject to the Mask Mandate, and, although Mr. and Mrs. Adams object to the Mask Mandate, all three minors routinely wear masks as required by the Mask Mandate, but Mr. and Mrs. Adams do not consent to the same and assert their parental rights to determine whether or not C.A.A., W.N.A., and T.R.A. should wear a face covering. Mr. and Mrs. Adams therefore have standing to bring this case, on their own behalf and on behalf of C.A.A., W.N.A., and T.R.A., which presents a justiciable issue for the Court.

16. Plaintiffs Hugh and Renata Paris Peddy are residents of the age of majority of the State of Idaho who are domiciled in Blaine County, Idaho. Mr. and Mrs. Peddy are of sound mind and have the capacity to bring this lawsuit. Mr. and Mrs. Peddy are the father and mother,

respectively, and natural guardians of A.P., a minor child who attends a school subject to the jurisdiction of Blaine County School District No. 61. A.P. is subject to the Mask Mandate, and, although Mr. and Mrs. Peddy object to the Mask Mandate, A.P. routinely wears a face covering as required by the Mask Mandate, but Mr. and Mrs. Peddy do not consent to the same and assert their parental rights to determine whether or not A.P. should wear a face covering. Mr. and Mrs. Peddy therefore have standing to bring this case, on their own behalf and on behalf of A.P., which presents a justiciable issue for the Court.

17. Plaintiffs Mr. and Mrs. Adams and C.A.A., W.N.A., and T.R.A.; and Mr. and Mrs. Peddy and A.P.; are referred to herein as the "Individual Plaintiffs".

18. Allegations regarding "Plaintiffs" herein below shall be deemed to include the Individual Plaintiffs and Plaintiff HFDF.

19. Defendants Keith Roark, Lara Stone, Amber Larna, Dan Turner, and Gretchen Gorham are each of them trustees of the Board of Trustees of Blaine County School District No. 61 (collectively "the Board of Trustees"). The Board of Trustees is the governing body of Blaine County School District No. 61 pursuant to Idaho Code § 33-501, a school district established by the Idaho Legislature, that has enacted laws that deprive and infringe, or threaten to deprive and infringe, Plaintiffs of certain rights, privileges, and immunities under the laws and Constitution of the United States, under the laws and Constitution of the State of Idaho, and under international law so widely adopted and accepted as to establish *jus cogens*. The Board of Trustees, each of them and collectively, constitute a person under 42 U.S.C. § 1983. *See* Monell v. Dep't of Soc. Servs., 436 U.S. 658 (1978). Keith Roark, Lara Stone, Amber Larna, Dan Turner, and Gretchen Gorham are being sued in their official capacity as trustees of the Board of Trustees, as well as in their personal capacities.

JURISDICTION AND VENUE

20. This Court has jurisdiction to hear all federal claims asserted in this case under 28 U.S.C. § 1331, which confers original jurisdiction on federal district courts to hear suits arising under the laws and Constitution of the United States; the Supremacy Clause of the Constitution of the United States, which allows federal district courts to hear suits alleging preemption of state and local laws by the Constitution and federal laws made in pursuance thereof; and 42 U.S.C. § 1983 and 28 U.S.C. § 1343 in relation to Defendants' deprivation and infringement under color of law of the Individual Plaintiffs' rights, privileges, and immunities secured by the United States Constitution and laws, as detailed further herein.

21. This Court has jurisdiction over the claims asserting violations of the laws and Constitution of the State of Idaho through its supplemental jurisdiction under 28 U.S.C. § 1367(a), as those claims are so closely related to the Plaintiffs' federal question and Section 1983 claims that they form part of the same case or controversy under Article III of the United States Constitution.

22. This Court has the authority to award the requested declaratory relief under 28 U.S.C. § 2201; the requested injunctive relief under 28 U.S.C. § 1343(a); and attorneys' fees and costs under 42 U.S.C. § 1988.

23. The United States District Court for the District of Idaho is the appropriate venue for this action pursuant to 28 U.S.C. § 1391(b)(1) and (2) because it is the District in which Defendants reside, and/or have deprived the Individual Plaintiffs of the rights and liberties under the laws and Constitution of the United States, and have violated the laws and Constitution of the State of Idaho, all as is further alleged herein. It is also the District in which a substantial part of the events giving rise to Plaintiffs' claims have occurred and continue to occur.

FACTUAL BACKGROUND

The Genesis of the Universal Prohibition of Human Experimentation Without Consent.

24. Among the horrors that emerged from the rubble of World War II were stories of

barbaric medical experiments performed on unwilling victims of Nazi Germany's concentration camps.

25. On August 8, 1945, the victorious Allies established an International Military Tribunal (the "IMT"). Under the aegis of the IMT, the law authorized the creation of U.S. military tribunals for the trial of "lower-level" war criminals, such as doctors accused of conducting medical experiments without the subjects' consent.[3]

26. A U.S. military tribunal subsequently found 15 doctors guilty of conducting nonconsensual experiments, which included the testing of drugs for immunization against malaria, epidemic jaundice, smallpox, and cholera. "In every single instance appearing in the record," the tribunal concluded, "subjects were used who did not consent to the experiments. . . ." The tribunal sentenced seven of the doctors to death, and the remaining eight to life in prison.

27. As part of its final judgment, the tribunal promulgated the Nuremberg Code on Permissible Medical Experiments. Point One of the Nuremberg Code states: "The voluntary consent of the human subject is absolutely essential."

28. This standard has since been repeatedly ratified and adopted around the globe, in laws, treaties, regulations, and ethical guidelines for medical research. For example, in 1964, the World Medical Association adopted the Declaration of Helsinki, which provides that human subjects "must be volunteers and informed participants in the research project." Declaration of Helsinki at Art. 20.

29. Although themselves non-binding, the principles underlying the Declaration of Helsinki and the Nuremberg Code have been incorporated into international conventions, as well as the laws and regulations of countries around the world, including the United States of America.

[3] Sources for the historical facts set forth herein can be found in *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009), which explains in detail the history and reasons why the prohibition against nonconsensual human experimentation should be regarded as a *jus cogens* norm.

30. The International Covenant on Civil and Political Rights of the United Nations, which went into effect in 1976, provides in Article I that "[a]ll peoples have the right of self determination" and in Article 7 that "no one shall be subjected without his free consent to medical or scientific experimentation."

31. The informed consent principles of the Declaration of Helsinki were also incorporated by a 2001 Directive passed by the European Parliament and the Council of the European Union.

32. In addition, 35 members of the Council of Europe have signed the Convention on Human Rights and Biomedicine, which provides that informed consent is required for a subject's involvement in medical research.

33. In 2005, the General Conference of UNESCO adopted the Universal Declaration on Bioethics and Human Rights, requiring free and informed consent for participation in medical research-oriented treatments.

34. On December 1, 2020, the High Court of Justice, Queen's Bench Division, Administrative Court in the United Kingdom concluded that minors lack the ability to give informed consent to the administration of puberty blockers to treat gender dysphoria because the procedure remains experimental.[4]

35. These principles have been adopted by statutes and regulations in the United States.

36. In 1979, the Department of Health, Education and Welfare issued the Belmont Report, which addressed the issue of informed consent in the human experimentation setting. The Report identified respect for self-determination by "autonomous persons" as the first of three "basic ethical principles" which "demands that subjects enter into the research voluntarily and with

[4] *See Bell v. The Tavistock and Portman NHS Foundation Trust*, Case No. CO/60/2020, [2020] EWHC 3274 (Admin) (Engl. & Wales) https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf.

adequate information."

37. Ultimately, the principles of the Belmont Report, which itself was guided by the Nuremberg Code and the Declaration of Helsinki, were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research. *See* 21 C.F.R. § 50.20.[5]

38. The Department of Health and Human Services has similarly adopted this standard in its regulations governing grants for medical research. *See* 45 C.F.R. § 46.116. The United States clearly regards itself as bound by the provisions of the Nuremberg Code and the Declaration of Helsinki.

39. The State of Idaho has adopted the principle of informed consent for all medical treatment. *See* I.C. § 39-4501 *et seq*, the Medical Consent and Natural Death Act (requiring informed consent for medical treatment).

40. For these and other reasons, the prohibition against nonconsensual human experimentation must be regarded not only as established by U.S. law and regulations, but also as so broadly recognized by all nations as to constitute a *jus cogens* norm under international law.

The Use of Face Coverings by the General Population is Experimental, and the Mask Mandate is a Forced Human Experiment.

41. Prior to the COVID-19 pandemic, the only time masks were prescribed for use in public spaces in the United States was during the 1918 flu pandemic. Even then, they were only mandated in a handful of cities for a matter of a few weeks—certainly not for months on end.[6]

[5] The exceptions to this standard are extremely narrow, and require certification by a researcher and an independent physician that, for example, "[t]he human subject is confronted with a life-threatening situation necessitating the use of the test article"; informed consent cannot be obtained from the subject; time does not permit obtaining informed consent from the subject's legal representative; and "there is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject." 21 C.F.R. § 50.23. *See also* 21 C.F.R. § 50.24 (providing a similarly narrow exception to informed consent requirements for emergency research).

[6] For instance, San Francisco, one of only a handful of municipalities to implement a mask mandate, instituted their mandate on October 22, 1918, which expired on November 21; then reimplemented it on December 17, 1918, and the mayor repealed it on February 1, 1919. *See* "The Mask Slackers of 1918," New York Times, https://www.nytimes.com/2020/08/03/us/mask-protests-1918.html, last viewed October 15, 2021.

42. Accordingly, the scientific literature regarding the short-term and long-term medical and psychological impact of wearing face masks as a general practice throughout the day by children and adults is sparse. However, forty-four mostly experimental studies, and sixty-five publications, have demonstrated consistent, recurrent, and uniform presentation of physiological and psychological adverse effects of mask wearing such that "long-term disease-relevant consequences of masks are to be expected,"[7] and are especially concerning for children.

43. According to the National Institute of Health, "clinical research is medical research involving people." "Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device (for example, a pacemaker) is safe and effective in people."[8] According to Merriam Webster, an experiment is to "try out a new procedure, idea, or activity."[9]

44. Plaintiffs allege, and will show at the trial of this matter, that the Mask Mandate is in fact a medical experiment being forced on unwilling participants. The Mask Mandate meets the definition of an experiment in that it is a new procedure, idea, or activity. It also meets the definition of a clinical trial in that the result of the Mask Mandate will be to determine whether a medical device, the face covering, is safe for people for extended use, because at this time that issue is unknown.

45. As a factual matter, the Mask Mandate is a human experiment forced on the citizens, students, teachers and visitors of Blaine County School District No. 61, including

[7] Kisielinski, K.; Giboni, P.; Prescher, A.; Klosterhalfen, B.; Graessel, D.; Funken, S.; Kempski, O.; Hirsch, O. Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards? Int. J. Environ. Res. Public Health 2021, 18, 4344. https://doi.org/10.3390/ijerph18084344
[8] U.S. Department of Human Services, National Institute on Aging, What Are Clinical Trials and Studies?, https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies, Last viewed on September 14, 2021.
[9] "Experiment", Merriam-Webster.com Dictionary, Merriam-Webster, https://www.merriam-webster.com/dictionary/experiment. Last viewed on September 14, 2021.

Plaintiffs.

Masks Have No Benefit in Reducing or Preventing Infection From SARS-CoV-2.

46. In the EUA authorizing general emergency use of face masks, the FDA stated that it would "would misrepresent the product's intended use" to state that it "is for use such as infection prevention or reduction". *See* Exhibit B, 4.

47. Similarly, in its Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised),[10] the FDA stated in three instances that face masks are not intended to reduce or prevent infection:

> The product is not intended for any use that would create an undue risk in light of the public health emergency, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses ***or uses for infection prevention or reduction or related uses*** and does not include particulate filtration claims. *Id.* at 8-9.

48. The first randomized controlled trial of the use of masks to prevent SARS-CoV-2 infection found that the effect of masks on reducing or preventing infection was inconclusive.[11]

49. A study published in the Emerging Infectious Disease Journal in May 2020 found that ten randomized control trial studies of the use of face masks to control the influenza virus, an RNA-based virus with similar dispersion patterns and particle sizes to SARS-CoV-2, showed no significant reduction in influenza transmission with the use of face masks, and in fact found "no evidence to support a protective effect of personal protective measures or environmental measures in reducing influenza transmission."[12]

50. Similarly, a study of nearly two thousand United States Marine Corp recruits

[10] Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised May 2020), https://www.fda.gov/media/136449/download Last viewed on October 15, 2021.
[11] Henning Bundgaard et, al, Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial: Annals of Internal Medicine: Vol 174, No 3, https://www.acpjournals.org/doi/pdf/10.7326/M20-6817 Last viewed on October 15, 2021.
[12] Xiao J, Shiu E, Gao H, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. Emerging Infectious Diseases. 2020;26(5):967-975. doi:10.3201/eid2605.190994, https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article, Last viewed on September 14, 2021.

published in the New England Journal of Medicine on November 11, 2020, indicated, among other preventative measures, that masks did not reduce or prevent the spread of SARS-CoV-2.[13]

51. The WHO announced in 2020 that "at present, there is no direct evidence (from studies on COVID-19) on the effectiveness of face masking of healthy people in the community to prevent infection of respiratory viruses, including COVID-19."[14]

52. Cloth masks, such as those generally used by the public, are particularly problematic, according to a randomized control trial conducted on cloth masks intending to protect against the influenza virus in 2015. The study concluded that due to moisture retention, reuse of cloth masks, and poor filtration, cloth masks may actually result in an increased risk of infection.[15]

53. Even studies advocating for mask usage acknowledge that masks, once they have been worn for hours or even minutes, are likely to lose any effectiveness they might have due to the increase in moisture and pressure of breathing or coughing, and that using homemade masks or any mask without proper training can render them completely ineffective.[16]

54. Accordingly, diligent and unbiased scientific inquiry does not support the proposition that the Mask Mandate can or will reduce or prevent the spread of SARS-CoV-2.

Asymptomatic Spread of SARS-CoV-2 is a Myth

55. The idea that SARS-CoV-2 can be spread by individuals who are showing no symptoms of COVID-19, and who never become symptomatic of the disease, has been a

[13] Andrew G. Letizia, M.D et al, SARS-CoV-2 Transmission among Marine Recruits during Quarantine, https://www.nejm.org/doi/full/10.1056/NEJMoa2029717, last viewed on October 15, 2021.
[14] World Health Organization. (2020). Advice on the use of masks in the context of COVID-19: interim guidance, 5 June 2020. World Health Organization. https://apps.who.int/iris/handle/10665/332293. Last viewed on October 15, 2021.
[15] C Raina MacIntyre et al, A cluster randomised trial of cloth masks compared with medical masks in healthcare workers, https://pubmed.ncbi.nlm.nih.gov/25903751/, Last viewed on October 15, 2021.
[16] Davies, A., Thompson, K., Giri, K., Kafatos, G., Walker, J., & Bennett, A. (2013). Testing the Efficacy of Homemade Masks: Would They Protect in an Influenza Pandemic? Disaster Medicine and Public Health Preparedness, 7(4), 413-418. https://doi.org/10.1017/dmp.2013.43

justification to require masking.

56. In a cluster of cases in southern Germany, careful follow-up and rigorous documentation showed that "little to no transmission occurred from asymptomatic case-patients."[17] The authors even cautioned against studies that conflated pre-symptomatic individuals—those in the short interval before symptoms appear—in with truly asymptomatic individuals, which clouds the reality of the pandemic—exactly what articles like those published in the University of Chicago School of Medicine website, among others, do.[18]

57. At a September 4, 2020 official press conference, Dr. Anthony Fauci stated that "[E]ven if there is some asymptomatic transmission, in all the history of respiratory borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person, even if there is a rare asymptomatic person that might transmit, an epidemic is not driven by asymptomatic carriers."[19]

58. Even more unambiguously, in a large-scale study of nearly ten million Chinese residents, out of more than 1,100 close contacts of 300 asymptomatic cases that tested positive by PCR, none showed a positive test and no new infections could be traced to asymptomatic infected persons.[20]

59. Transmission comes from and is driven almost entirely by symptomatic individuals. Requiring all students and staff of Blaine County School District No. 61 to wear masks everywhere they go is pointless when the primary individuals transmitting SARS-CoV-2 are symptomatic and therefore can be addressed in a narrowly constrained manner.

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[17] Bender JK, et al. Analysis of asymptomatic and presymptomatic transmission in SARS-CoV-2 outbreak, Germany, 2020. Emerg Infect Dis. 2021 Apr. https://doi.org/10.3201/eid2704.204576.
[18] Anderson, Mitch. "Asymptomatic coronavirus infections contribute to over 50% of spread, according to UChicago study", UChicagoMedicine, https://www.uchicagomedicine.org/forefront/coronavirus-disease-covid-19/asymptomatic-coronavirus-infections-contribute-to-over-50-percent-of-spread, Last viewed September 15, 2021.
[19] https://www.youtube.com/watch?v=vrAvjU2LBkg. Last viewed September 15, 2021.
[20] Cao, S. et al. (2020) Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China. Nat. Commun. 11:5917. https://doi.org/10.1038/s41467-020-19802-w

The Physical Properties of Masks Establish that they Cannot Prevent Virus Spread.

60. The physical properties of mask construction demonstrate that masks simply cannot prevent the virus from exiting the nose and mouth of infected individuals into the air around them to be breathed in by others. According to current knowledge, the SARS-CoV-2 virus has a diameter of 60 nm to 140 nm [nanometers (a billionth of a meter)]. It is expelled from the respiratory system in miniscule droplets of moisture emitted during coughing, talking, or breathing, the smallest of which are barely 10 micrometers in diameter.[21] The thread diameter of medical and non-medical facemasks, on the other hand, range from 55 µm to 440 µm [micrometers (one millionth of a meter)], which is more than 1000 times larger than the diameter of the virus. Even if the mask initially blocked some of the expelled respiratory droplets or aerosol particles, once masks become damp with moisture from breath, the viruses are freed from their droplets and are pushed to the outside of the mask by the pressure of exhalation and ultimately are expelled into the air regardless.

61. The physical impossibility of filtering the SARS-CoV-2 virus with masks is exacerbated by the lack of any seal between the wearer's face and the mask, which allows breath to exit wholesale without any filtering whatsoever into the air around the wearer to be breathed in by others.

62. The Occupational Safety and Health Agency has set standards for the use of masks to prevent infection by viruses. These masks seal effectively around the nose and mouth and prevent the inhalation or exhalation of viruses into the air by those wearing them but can only be used with an external source of oxygen being pumped into the mask, much like a diver wearing

[21] Mittal, R., Ni, R., & Seo, J. (2020). The flow physics of COVID-19. Journal of Fluid Mechanics, 894, F2. https://doi.org/10.1017/jfm.2020.330

an oxygen tank. The face coverings being used by the public at large are not such masks, and are therefore not designed to, nor do they, prevent or reduce infection by the SARS-CoV-2 virus.

63. The Mask Mandate therefore serves no compelling state interest.

Prolonged Use of Masks May Cause Physiological and Psychological Harm

64. Not only does the Mask Mandate not reduce or prevent the spread of SARS-CoV-2, the prolonged use of masks by children and adults is detrimental in the following specifics which will be shown by Plaintiffs in the trial of this matter:

a. Breathing is one of the most important and necessary physiological functions to sustain life and health. Humans are welcomed into the world with their first breath, and ushered from it with their last. The human body requires a continuous and adequate oxygen supply to all organs and cells for normal function and survival. Breathing is also an essential process for removing metabolic byproducts, like carbon dioxide, occurring during cell respiration. Masks are significantly detrimental to human breathing function because they force users to rebreathe their own expelled air over extended periods of time, increasing levels of carbon dioxide and other detrimental elements in the body;

b. Wearing a mask mechanically restricts breathing by increasing the resistance of air movement during both the inhalation and exhalation process, as well as dramatically increasing the dead space volume during breathing. Masks therefore deprive users of oxygen and raise carbon dioxide levels in the body, which causes the following non-exhaustive list of physical symptoms and damage:

i. Fatigue;

ii. Loss of concentration;

iii. Headaches;

iv. Loss of reaction time;

v. Damage to brain cells and brain function;

vi. Long-term neurodegenerative diseases;

vii. Impaired cognitive development in children;

viii. Increased disposition to viral and bacterial illnesses;

ix. Hypertension;

x. Cardiovascular disease;

xi. Exacerbation of existing chronic conditions; and

xii. Premature aging.

c. Masks cause the following non-exhaustive list of detrimental physiological effects:

i. Hypoxia;

ii. Hypercapnia;

iii. Shortness of Breath;

iv. Increased lactate concentration;

v. Acidosis;

vi. Toxicity;

vii. Chronic inflammation;

viii. Self-Contamination;

ix. Increase in stress hormone levels;

x. Increased muscle tension; and, without limitation,

xi. Immunosuppression.

d. Masks cause the following non-exhaustive list of psychological effects:

i. Fear;

ii. Claustrophobia;

iii. Mood disturbances;

iv. Anxiety;

v. Depression and feelings of isolation;

vi. Compromised cognitive performance; and

vii. Acute social anxiety.

65. Masks have been used as a form of torture in prisons, to isolate prisoners from one another and dehumanize them.

66. Masks dehumanize society, by separating members of society from one another. The face is the avatar of the person; the essential tool for inter-human recognition and interaction. Hiding the face isolates people from one another, atomizing the members of society, and breaking down the social structure naturally social humans require.

Masks Disrupt Normal Child Development.

67. The World Health Organization specifically states that children aged 5 years and younger should not be required to wear masks, based on "the safety and overall interest of the child," and that the decision for children aged 6-11 to wear masks should take into account the "potential impact of wearing a mask on learning and psychosocial development."[22]

68. Requiring children to wear masks, especially for extended periods of time, disrupts their development, for reasons that include but are not limited to the following:

a. Nonverbal communication is one of the most important channels for the social

[22] Coronavirus disease (COVID-19): Children and Masks, August 21, 2020. World Health Organization. https://www.who.int/news-room/q-a-detail/q-a-children-and-masks-related-to-covid-19, last viewed October 11, 2021.

development of younger children. Furthermore, facial expression is one of the central signals through which we communicate our own emotional state and infer the emotional state of others, which makes this one of the fundamental building blocks for the development of high emotional and social competence. Children in particular have yet to learn how to reliably interpret these signals in the faces of others, which is critical to the development of empathy. The wearing of masks inhibits the development of this important ability.

b. Mask-wearing can also cause children to experience a negative distortion of emotional experience. Fear and sadness are more likely to be read from the eyes and joy from the mouth region. The wearing of masks could therefore lead to the perception of less positive and more negative emotions in the faces of others.

c. The inability to see faces also interferes with a child's early education. One of the goals of daycare, preschools, and elementary schools is to teach children cooperation and communication skills, but this pedagogical work is jeopardized when the child cannot see the teacher or caregiver's face. As well, a masked face impairs the development of attachment and relationships, which are essential for the education and upbringing of children. It is precisely the personal and familiar contact with between child and staff that is enormously important for early childhood education. That is why it is important that employees in daycare and pre-k facilities do not cover their faces during normal activities.

d. The wearing of masks is also associated with the impairment of verbal skills development. A mask mutes the voice's higher frequencies, while visual signals from mouth and lip movement are completely obstructed. This has a particularly detrimental effect on a child's ability to learn language, which especially impacts

children for whom English is a second language.

Plaintiffs' Injury and Standing to Seek Declaratory and Injunctive Relief

Plaintiffs Russell and Lisa Adams' Minor Children Have Been Injured by the Mask Mandate, and Their Rights Have Been Violated.

69. Plaintiffs Russell and Lisa Adams' minor children C.A.A., four years old; W.N.A., six years old; and T.R.A., nine years old; are subject to the Mask Mandate, to which Russell and Lisa Adams object. C.A.A., W.N.A., and T.R.A. have all been negatively impacted by the Mask Mandate, in that they are being denied the normal social, psychological and developmental experience essential to normal development of children their age. They are under stress and being damaged by the Mask Mandate physically, emotionally, and psychologically. W.N.A. and T.R.A. are stressed and anxious about the masks, and both are injured in their education as they are learning Spanish as a second language in a dual immersion program, and cannot even see the teacher's mouth enunciate the words they are attempting to learn.

Plaintiffs Hugh and Renata Paris Peddys' Minor Child Has Been Injured by the Mask Mandate, and His Rights Have Been Violated.

70. Plaintiffs Hugh and Renata Paris Peddys' minor child, A.P., fourteen years old, has been adversely affected by the Mask Mandate. Concerned for their child's educational and social development, the Peddys moved to Blaine County in an attempt to escape school lockdowns in California. A.P. has sensory issues and has difficulty tolerating masks. He has a narrow nasal passage and suffers from severe sinus congestion from wearing a mask all day at school. This has affected his ability to sleep at night, making him tired and ill-prepared to learn during the day. Because his classmates are also wearing masks, A.P. cannot read their faces and emotions and has been socially isolated, unable to make new friends at his new school and community.

The Right to Breath is a Fundamental Human Right Deeply Rooted in American History and Traditions.

71. Breathing in a free and unobstructed manner sufficient to oxygenate blood and expel

various waste products of cell activity has been a time-honored tradition of each and every citizen of this Nation since well prior to its founding. This essential tradition is thus deeply rooted in our history. Indeed, ancient texts refer to the "breath of life." Poets have written odes to breath itself. The reason water boarding is considered torture is because it makes its victim feel unable to breathe, creating the terrorizing feeling that death is imminent. Research has not revealed any human who did not constantly breathe from the time he or she was born, until the time he or she died. It is a universally accepted practice undertaken by citizens of the United States as well as by citizens of each and every nation across the globe.

72. The current situation in the United States is the first time in our history when members of the public in general have been required to wear face masks for months at a time. The same is asked of children as young as four years old, for whom the concerns as to their health and development are paramount in any rational society. It is massively invasive of a fundamental human right deeply rooted in our history and tradition, an invasion which serves little to no purpose, as the science shows and as Plaintiffs will prove at trial.

73. All conditions precedent to bringing this lawsuit have been performed, excused, or waived.

COUNT I

(All Plaintiffs vs. All Defendants)

FEDERAL PREEMPTION / VIOLATION OF THE SUPREMACY CLAUSE

74. Plaintiffs reallege and incorporate by reference their allegations in Paragraphs 1 – 73, as if fully alleged herein, and further allege:

75. Federal laws and regulations governing the approval and administration of medical products such as masks completely preempt any and all contrary or inconsistent laws of the States and/or local governments.

76. The masks remain an investigational product, despite the FDA's Emergency Use Authorization.

77. Title 21 United States Code, Section 360bbb-3(e)(1)(A)(ii), and regulations and internal protocols of the United States Food and Drug Administration promulgated thereunder, provide in relevant part that all individuals to whom an investigational product is to be administered under an Emergency Use Authorization be informed "of the option to accept or refuse administration of the product. . . ."

78. Because the masks are an investigational product, approved for use under an Emergency Use Authorization, the laws and regulations of the United States prohibit its administration to any person who does not consent to its administration.

79. Plaintiffs do not consent on behalf of themselves or their minor children to the requirement to wear masks.

80. The Mask Mandate is therefore patently contrary to United States law, and thus preempted and invalid.

81. As well, Title 21, Part 50 of the Code of Federal Regulations governs the protection of human subjects in the conduct of all clinical investigations regulated by the U.S. Food and Drug Administration.

82. 21 C.F.R. § 50.20 provides that, "[e]xcept as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."

83. Under the EUA, the masks remain in the clinical investigation stage.

84. None of the exemptions provided in sections 50.23 and 50.24 would apply to Plaintiffs.

85. Accordingly, the Mask Mandate patently violates federal law and regulations governing the administration of experimental medicine, and is thus preempted.

86. Plaintiffs have no adequate remedy at law available against Defendants for the injuries and the irreparable harm they will imminently suffer as a direct result of the Mandate.

WHEREFORE, Plaintiffs respectfully request that the Court enter a declaratory judgment that Defendants' Mask Mandate violates and is preempted by the laws and regulations of the United States governing the administration of investigational medical products, for an injunction prohibiting enforcement of the Mask Mandate, for attorneys' fees, costs pursuant to 42 U.S.C. § 1988, and such further relief as the Court deems just.

COUNT II

(All Plaintiffs vs. All Defendants)

VIOLATION OF SUBSTANTIVE DUE PROCESS

42 U.S.C. § 1983

87. Plaintiffs reallege and incorporate by reference their allegations in Paragraphs 1 – 73, as if fully alleged herein, and further allege:

88. Plaintiffs have a protected liberty interest, secured by the Due Process Clause of the United States Constitution, international protocols and treaties adopted by and entered into by the United States, and by the laws and regulations of the United States, to be free from forced medical experimentation.

89. This right is further recognized as a *jus cogens* norm under the laws of nations.

90. As set forth more fully above, the forced administration of masks is, under the circumstances, experimental medicine.

91. As well, or in the alternative, Plaintiffs have a protected liberty interest, secured by the Due Process Clause of the United States Constitution, to be free from non-consensual

administration of medical procedures and devices, and/or to be free from the forced administration of medical procedures and devices that Plaintiffs reasonably believe will cause them harm.

92. As well, or in the alternative, Plaintiffs have a fundamental right, secured by the Due Process Clause of the United States Constitution:

a. to personal autonomy and bodily integrity;

b. to control and/or consent to the administration of medical products and medical care to their minor children; and, without limitation,

c. to self-determination in matters of medical care and the administration of medical products and devices.

93. Defendants' Mandate is not sufficiently narrowly tailored, or lacks a rational basis, as the FDA itself has stated that Defendants may not represent masks as being effective against viral spread, numerous studies have confirmed that masks are not effective against viral spread, and Plaintiffs will show at trial that masks are damaging in a variety of ways to those who are forced to wear them consistent with the requirements of the Mask Mandate.

94. Plaintiffs have no adequate remedy at law available against Defendants for the injuries and the irreparable harm they will imminently suffer as a direct result of the Mandate.

WHEREFORE, Plaintiffs respectfully request that the Court enter a declaratory judgment that Defendants' Mask Mandate violates Plaintiffs' substantive Due Process rights, for an injunction prohibiting enforcement of the Mask Mandate, for attorneys' fees, costs pursuant to 42 U.S.C. § 1988, and such further relief as the Court deems just.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury for all matters so triable.

DATED this 15th day of October, 2021.

The Davillier Law Group

Allen Shoff, ISB# 9289 – Of the Firm

Counsel for Plaintiff

EXHIBIT A

Blaine County School District No. 61

Guidelines for Face Coverings At School

Blaine County School District #61

Guidelines for Face Coverings at School

In accordance with our district return to learn plan and CDC recommendations to reduce the spread of COVID-19, Blaine County School District is **requiring** that all staff and students wear a face covering at school while our county is identified as in the yellow, orange or red levels of transmission as defined by CDC data tracker, unless one of the following applies:

- Inability to remove their own face-covering, or
- Have a medical condition precluding them from wearing a face-covering, or
- Other exceptions based on case manager and team decision

Face covering options include:

- A securely attached cloth face-covering which covers the nose and mouth,
- A securely attached medical-grade paper covering which covers the nose and mouth, OR
- A clear face-shield which wraps around the face and extends to below the chin.

Blaine County School District #61

GUIDELINES FOR FACE-COVERINGS AT SCHOOL

The CDC recommends that all people 2 years of age and older wear a cloth face covering in public settings and when around people who don't live in your household, especially when other social distancing measures are difficult to maintain.

Blaine School District require one of the following face-coverings for all staff and students during the 2021/2022 school year while our county is identified as in the yellow, orange or red levels of transmission as defined by CDC data tracker:

- Securely attached face-coverings that cover the student's nose and mouth. These may be made of cloth or medical-grade paper. These coverings may be homemade or commercially purchased.

- Clear face shields. According to the CDC, if face shields are used without a mask, they should wrap around the wearer's face, and extend to below the chin. Although, at this time, the CDC does not recommend the use of face shields as a substitute for cloth face-coverings, face shields may be an alternative for those who are listed, (above), as exceptions to wearing cloth face-coverings.

Face coverings exceptions are allowed under the following circumstances:

- When outside such as at recess, outdoor learning times, etc.
- Persons with medical conditions or religious exemption that prevent them from wearing a face covering, with appropriate documentation.
- Anyone who is unconscious, incapacitated, or unable to remove the face covering without assistance.
- Other exceptions, based on case manager and team decision, with appropriate documentation.

If your child's healthcare provider has determined that he/she should not wear either of these face coverings, please call the school to request an exemption form, and have your healthcare provider complete and return it to school.

Face covering exemption

In the event that a face covering exemption is in place for a student, additional mitigation strategies will be implemented for the individual student or other students and staff.
These may include:

- adjusted seating arrangements
- additional physical distancing
- increased sanitation and hand washing

Revised 08/2021

EXHIBIT B

FDA Face Mask Letter of Authorization

April 24, 2020

To: Manufacturers of Face Masks;
Health Care Personnel;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders.

On April 18, 2020, in response to concerns relating to insufficient supply and availability of face masks,[1,2] the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) authorizing the use of face masks for use by members of the general public, including health care personnel (HCP)[3] in healthcare settings as personal protective equipment (PPE), to cover their noses and mouths, in accordance with Centers for Disease Control and Prevention (CDC) recommendations, to prevent the spread of the virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States

[1] A face mask is a device, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth face coverings as a subset. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a "device" under section 201(h) of the Act. Generally, face masks fall within this definition when they are intended for a medical purpose. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks).

[2] Surgical masks are not covered within the scope of this authorization. Surgical masks are masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are regulated under 21 CFR 878.4040 as class II devices requiring premarket notification. Additionally, these masks meet certain fluid barrier protection standards and Class I or Class II flammability tests. More information on the distinction is provided in FDA guidance, titled "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.

[3] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

citizens living abroad, and that involves the virus that causes COVID-19.[4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[5]

On April 24, 2020 in response to questions and concerns that have been received by FDA since issuance of the April 18, 2020 letter of authorization and having concluded that revising the April 18, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the April 18, 2020 letter in its entirety with amendments[6] incorporated. Specifically, FDA is clarifying through this re-issued letter that facemasks, including cloth face coverings, are authorized to be used by HCP only as source control[7,8] in accordance with CDC recommendations under this EUA.[9] As stated in the April 18 letter, face masks are authorized for use by the general public to cover their noses and mouths, in accordance with CDC recommendations.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of face masks for use in accordance with CDC recommendations, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

For the most current CDC recommendations on the use of face masks by the general public during COVID-19, please visit CDC's webpage: Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission For the most recent recommendations on use of face masks by HCPs in a healthcare setting, see: Strategies to Optimize the Supply of PPE and Equipment.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of face masks in accordance with CDC recommendations as source control as described in the Scope of Authorization (Section II) to

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[4] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020)

[5] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

[6] The amendments to the April 18, 2020 letter clarify that the eligible facemasks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for filtering face piece respirators or for surgical face masks. This reissued EUA does not change any aspects of the April 18, 2020 letter with respect to the use of face masks by the general public.

[7] Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19.

[8] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

[9] In addition, health care employers should refer to standards of the Occupational Safety and Health Administration (OSHA) that apply to PPE to protect workers and infectious disease hazards. *See* 29 CFR 1910 subpart I.

help prevent spread of the virus during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face masks may be effective as source control to help prevent the spread of SARS-CoV-2 by infected individuals who may or may not have symptoms of COVID-19 during the COVID-19 pandemic, and that the known and potential benefits of face masks, when used in accordance with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of face masks for source control by the general public and for HCPs to help prevent the spread of the virus due to face mask shortages during the COVID-19 pandemic.[10,11]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of face masks, including cloth face coverings, as source control for use by members of the general public, as well as HCP in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of the SARS-CoV-2 during the COVID-19 pandemic. The facemasks are not intended to be used by HCPs as PPE, meaning they are neither substitutable for respiratory protective devices such as filtering face piece respirators, nor for surgical face masks. This use is consistent with face masks regulated as Class I 510(k)-exempt face masks under 21 CFR 878.4040.

Authorized Face Masks

Face masks are authorized under this EUA when they are intended for use as source control, by members of the general public as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic. Authorized face masks must meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);

[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[11] Providing authorization for the introduction into interstate commerce of face masks by manufacturers that do not customarily engage in the manufacture of medical devices helps meet the needs of the healthcare system. In addition, increased availability of face masks helps meet the needs for source control for the general population, reserving FDA-cleared surgical masks and FDA-cleared or -authorized N95 and N95 equivalent Face Filtering Respirators for use by HCP. Providing HCP who are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to help prevent HCP exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
4. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction;
5. The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration; and
6. The product is not labeled for use in high risk aerosol generating procedures.[12]

Manufacturers of face masks that are used as described above and meet the above requirements (i.e., are within this section (the Scope of Authorization, Section II)) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA's posting and public announcement of this EUA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization, serves as face mask manufacturers' notification of authorization.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of face masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that face masks may be effective as described within this section (the Scope of Authorization, Section II) of this letter, pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I of this letter, and concludes that face masks (as described in this section, the Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of face masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), face masks, as source control, are authorized for use by members of the general public, as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.

[12] Examples of aerosol generating procedures in healthcare settings may be found at https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html

III. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under sections 520(f)(1). FDA grants that waiver, including the quality system requirements under 21 CFR Part 820 and labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements in 21 CFR Part 830 and 21 CFR 801.20, except that face masks must include the labeling elements specified in the Conditions of Authorization (Section IV).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers and Distributors of Authorized Products[13]

A. Manufacturers and Distributors will make face masks available with labeling that includes a description of the product as a face mask, including a list of the body contacting materials (which does not include any drugs or biologics).

B. Manufacturers and Distributors of authorized products shall not label the product: 1) as a surgical mask, to provide liquid barrier protection; 2) for use in a clinical setting where the infection risk level through inhalation exposure is high; 3) for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses; 4) as a respiratory protective device; or 5) for high risk aerosol-generating procedures.

C. Manufacturers must make the required labeling available to each end user or end user facility (each hospital) in hard copy or in an alternative format (e.g., electronic labeling on the manufacturer's website). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

D. Manufacturers and Distributors will include instructions for recommended cleaning and/or disinfection materials and processes, if applicable, for their authorized product(s). Manufacturers must provide these instructions, if applicable, to each end user or end user facility (e.g., each hospital) in hard copy or in an alternative format (e.g., electronic instructions). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

[13] The requirements under 21 CFR Part 806 (Reports of Corrections and Removals) and 21 CFR Part 807 (Registration and Listing) do not apply to products authorized under an EUA. As such, compliance with these regulations are not required under this EUA.

E. Manufacturers will have a process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA. See FDA's webpage "Medical Device Reporting (MDR): How to Report Medical Device Problems"[14] for reporting requirements and procedures.[15]

F. Manufacturers and distributors will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

G. Through a process of inventory control, manufacturers and distributors will maintain records of the entities to which they distribute the face masks and the numbers of each such product they distribute.

H. Manufacturers and distributors are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Conditions Related to Advertising and Promotion

I. All printed matter, including advertising and promotional materials, relating to the use of the authorized face mask shall be consistent with the labeling elements listed in Section II of this EUA, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

J. No printed matter, including advertising or promotional materials, relating to the use of the authorized face mask may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.

K. All advertising and promotional descriptive printed matter relating to the use of the product shall clearly and conspicuously state that

- The product has not been FDA cleared or approved
- The product has been authorized by FDA under an EUA for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices,

[14] FDA guidance, titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

[15] Also refer to FDA guidance, titled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic" available at https://www.fda.gov/media/72498/download.

during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

EXHIBIT C

Emergency Use Authorization of Medical Products and Related Authorities" Guidance for Industry and Other Stakeholders

Emergency Use Authorization of Medical Products and Related Authorities

Guidance for Industry and Other Stakeholders

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of the Chief Scientist
Office of Counterterrorism and Emerging Threats

January 2017

Procedural
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Emergency Use Authorization of Medical Products and Related Authorities

Guidance for Industry and Other Stakeholders

Additional copies are available from:

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U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of the Chief Scientist
Office of Counterterrorism and Emerging Threats

Procedural

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Contains Nonbinding Recommendations

Emergency Use Authorization of Medical Products and Related Authorities[1]

Guidance for Industry and Other Stakeholders

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance explains FDA's general recommendations and procedures applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[2] as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)[3]. The provisions in PAHPRA, described in section II of this guidance, include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, including emerging infectious disease threats such as pandemic influenza. PAHPRA clarifies and enhances FDA's authority to support emergency preparedness and response and foster the

[1] This guidance was prepared by the Office of Counterterrorism and Emerging Threats (OCET) in cooperation with the Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), and Center for Drug Evaluation and Research (CDER).

[2] 21 U.S.C. 360bbb-3, 360bbb-3a, and 360bbb-3b. Section 564 was first added to the FD&C Act by the Project BioShield Act of 2004 (Public Law 108-276). Hereafter in this document, statutory references (e.g., "section __") are to the FD&C Act, except where otherwise indicated.

[3] Public Law 113-5. Section 3088 of the 21st Century Cures Act, signed into law by the President on December 13, 2016, amends sections 564, 564A, and 564B of the FD&C Act to add new authorities to: (1) authorize emergency use of unapproved animal drugs, (2) make applicable other emergency use authorities (e.g., to issue emergency dispensing orders, waive compliance with current good manufacturing practices (CGMPs), make available Centers for Disease Control and Prevention (CDC) emergency use instructions, and extend expiration dates) to approved animal drugs, and (3) allow unapproved animal drugs to be held for emergency use. While much of what is described in this guidance will apply to these new authorities, this guidance does not by its terms reference them; FDA asks anyone interested in utilizing these authorities to contact FDA directly to discuss how to proceed. FDA plans to review these new authorities and address any new procedural issues raised as we develop more experience with these new authorities.

development and availability of medical products for use in these emergencies. These medical products, also referred to as "medical countermeasures" or "MCMs," include drugs[4] (e.g., antivirals and antidotes), biological products (e.g., vaccines, blood products, and biological therapeutics), and devices (e.g., *in vitro* diagnostics and personal protective equipment). This guidance finalizes the draft guidance, *Emergency Use Authorization of Medical Products and Related Authorities (April 2016)* and replaces the following two guidance documents, *Emergency Use Authorization of Medical Products* (July 2007) and *Emergency Use Authorization Questions and Answers* (April 2009).

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. SCOPE OF GUIDANCE

This document is intended to inform all stakeholders[5] involved in emergency response activities and FDA staff of FDA's general recommendations and procedures for:

(1) Issuance of Emergency Use Authorizations (EUAs) under section 564;

(2) Implementation of the emergency use authorities set forth in section 564A; and

(3) Reliance on the governmental pre-positioning authority set forth in section 564B."

[4] Throughout this guidance references to "drugs" and "drug products" include both drugs approved under the FD&C Act and biological products licensed under the Public Health Service (PHS) Act, but not biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

[5] For purposes of this guidance, "stakeholders" include industry and government sponsors and other government stakeholders/entities involved in emergency response activities (including Federal, State, local, tribal, or territorial government stakeholders/entities). The term "government stakeholders" refers to the public health and/or emergency response agencies or their agents/delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundaries (e.g., city, county, tribal, territorial, State, or Federal), or functional range or sphere of authority (e.g., law enforcement, public health, military health) to prescribe, administer, deliver, distribute, hold, or dispense a medical product during an emergency situation.

Section 564, as amended by PAHPRA, permits the Commissioner[6] to authorize the emergency use of an unapproved medical product or an unapproved use of an approved[7] medical product for certain emergency circumstances (discussed in section III.A of this guidance) after the HHS Secretary has made a declaration of emergency or threat justifying authorization of emergency use. The Commissioner may issue an EUA to allow an MCM to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a CBRN agent when there are no adequate, approved, and available alternatives. Section III of this guidance addresses EUAs.

Section 564A, as added by PAHPRA, establishes streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved MCMs *without* FDA issuing an EUA, which can be a resource-intensive process. These authorities, and the definition of eligible products to which they apply, are discussed in section IV of this guidance. These authorities, which apply only to eligible FDA-approved medical products intended for use during a CBRN emergency, include provisions that:

- Empower FDA to extend the expiration date of an eligible FDA-approved MCM stockpiled for use in a CBRN emergency and to establish appropriate conditions relating to such extensions, such as appropriate storage, sampling, and labeling;

- Permit FDA to waive otherwise-applicable current good manufacturing practice (CGMP) requirements[8] (e.g., storage or handling) to accommodate emergency response needs;

- Allow emergency dispensing of MCMs during an actual CBRN emergency event without requiring an individual prescription for each recipient[9] of the MCM or all of the information otherwise required or by responders who may not otherwise be

[6] As provided in section 1003 and existing delegations of authority (found in the FDA Staff Manual Guide 1410.10), the Secretary of Health and Human Services (HHS Secretary or Secretary of HHS) has delegated most of the authorities under sections 564, 564A, and 564B to the Commissioner of FDA (Commissioner). Thus, this guidance refers to either FDA or the Commissioner rather than the HHS Secretary, except where the HHS Secretary has traditionally exercised the authority or has delegated it to another official (e.g., the authority to issue emergency use instructions pursuant to section 564A(e) was delegated to the Director of the CDC).

[7] Unless otherwise specified, the terms “approved product” and “FDA-approved product” refer to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the FD&C Act or section 351 of the PHS Act, as applicable. For purposes of this document, an "unapproved" product refers to a product that is not approved, licensed, or cleared for commercial distribution under section 505, 510(k), or 515 of the FD&C Act or section 351 of the PHS Act; an "unapproved use of an approved product" refers to a product that is approved, licensed, or cleared under such a provision but for which the specific use is not an approved, licensed, or cleared use of the product. See section 564(a)(2).

[8] As applied to medical devices, these are referred to as “Quality System Regulation” requirements. See 21 CFR 820.

[9] For purposes of this guidance, the term "recipient(s)" refers to individual(s) to whom an MCM product is administered or on whom the product is used.

licensed to dispense, if permitted by state law in the state where such dispensing occurs or if in accordance with an order issued by FDA; and

- Permit the Centers for Disease Control and Prevention (CDC) to create and issue "emergency use instructions" (EUI) concerning the FDA-approved conditions of use for eligible products.[10]

In addition, PAHPRA amended section 505-1(k) to authorize FDA to waive Risk Evaluation and Mitigation Strategy (REMS) requirements for CBRN emergencies.

Finally, section 564B, also added by PAHPRA, permits government stakeholders to pre-position (e.g., stockpile, forward-deploy) MCMs in anticipation of FDA approval or clearance, authorization of an investigational use, or the issuance of an EUA, to enable these stakeholders to prepare for potential rapid deployment during an actual CBRN emergency. This authority is discussed in section V of this guidance.

III. EMERGENCY USE AUTHORIZATIONS

The EUA authority under section 564 allows FDA to facilitate availability and unapproved uses of MCMs needed to prepare for and respond to CBRN emergencies. The EUA authority is separate and distinct from use of a medical product under an investigational application (i.e., Investigational New Drug Application (IND) or Investigational Device Exemption (IDE)), section 561 expanded access authorities,[11] and section 564A emergency use authorities discussed in section IV of this guidance.

[10] U.S. Department of Health and Human Services, Delegation of Authority of section 564A(e) of the Federal Food, Drug, and Cosmetic Act, December 16, 2013, see http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/UCM510446.pdf.

[11] For general information on expanded access mechanisms, see http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm.

A. EUA DECLARATION JUSTIFYING EMERGENCY USE

1. Determinations to Support an EUA Declaration

Before FDA may issue an EUA, the HHS Secretary must declare that circumstances exist justifying the authorization (section 564(b)(1)). This declaration (referred to in this guidance as an "EUA declaration"),[12] must be based on one of the following actions:

1. A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a CBRN agent(s);[13]

2. A determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a CBRN agent(s);[14]

3. A determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent(s);[15] or

[12] The HHS declaration of emergency or threat of emergency is issued only for purposes of empowering the FDA Commissioner to issue an EUA. It is distinct from, and is not dependent on, an HHS public health emergency declaration under section 319 of the PHS Act, a Public Readiness and Emergency Preparedness (PREP) Act declaration (discussed in section VII of this document), or any other type of emergency declaration.

[13] Section 564(b)(1)(A).

[14] Section 564(b)(1)(B).

[15] Section 564(b)(1)(C). Prior to the PAHPRA amendments, the Secretary would have made the determination that there is a public health emergency under section 319 of the PHS Act. Under amended section 564(b)(1)(C), the Secretary can make the emergency or threat of emergency determination that includes any and all of the elements required by statute (e.g., that the emergency affects national security, U.S. citizens living abroad, etc.) when making the declaration justifying the EUA under section 564(b)(1)(C). If there is an applicable section 319 public health emergency determination in place, the Secretary may conclude that any additional elements required by the statute (e.g., that the emergency affects national security, citizens living abroad, etc.) are met when issuing a declaration under section 564(b)(1).

4. The identification of a material threat, by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act, that is sufficient to affect national security or the health and security of United States citizens living abroad.[16]

After the Secretary of HHS issues an EUA declaration based on one of these four determinations, and after consulting (to the extent feasible and appropriate given the applicable circumstances) with the Assistant Secretary for Preparedness and Response (ASPR), the Director of the National Institutes of Health (NIH), and the Director of CDC,[17] the Commissioner may authorize the emergency use of an unapproved product or an unapproved use of an approved product, provided that other statutory criteria are met.

In appropriate circumstances, an HHS EUA declaration may support issuance of more than one EUA. For example, based on an HHS EUA declaration that circumstances exist to justify the authorization of emergency use of diagnostics for a specified biological agent, FDA may authorize emergency use for multiple diagnostic tests to meet the need, provided that each EUA meets the statutory criteria for issuance.

2. Termination of an EUA Declaration

When an EUA declaration is terminated, then any EUA(s) issued based on that declaration will no longer remain in effect.[18] The HHS Secretary's EUA declaration will terminate on the earlier of: (1) a determination by the HHS Secretary that the circumstances that precipitated the declaration have ceased (after consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense), or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved (section 564(b)(2)). For example, an EUA issued to allow an unapproved use of an approved product may no longer be needed if that product is later approved by FDA for the use permitted by the EUA.

[16] Section 564(b)(1)(D). We note that, while section 564(b)(1)(D) specifically refers to the identification of a material threat "sufficient to affect national security or the health and security of United States citizens living abroad," section 319F-2 of the PHS Act, 42 USC 274d-6b, refers only to a "material threat against the United States population sufficient to affect national security," without specific reference to "the health and security of United States citizens living abroad." Because Congress chose not to amend the latter provision when it added the "material threat" provision to section 564, FDA concludes that a material threat determination necessarily encompasses the health and security of U.S. citizens living abroad. And as such, it would be an appropriate basis for a declaration. Thus, an EUA could be justified by a threat to the health and security of U.S. citizens living abroad whether or not a particular material threat determination issued pursuant to section 319F-2 expressly refers to the health and security of U.S. citizens living abroad.

[17] Section 564(c).

[18] As discussed in section III.G of this guidance, an EUA may also be revoked under certain conditions.

Before an EUA declaration terminates, the Secretary of HHS must provide advance notice that is sufficient to allow for the disposition of an unapproved product, and of any labeling or other information provided related to an unapproved use of an approved product (section 564(b)(3)).[19]

B. EUA MEDICAL PRODUCTS

1. Criteria for Issuance

During the effective period of the HHS Secretary's EUA declaration, FDA may authorize the introduction of a medical product into interstate commerce when the product is intended for use during an actual or potential emergency. EUA candidate products include medical products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the FD&C Act or section 351 of the PHS Act.

After the requisite determination and declaration have been issued, and after feasible and appropriate consultations, FDA may issue an EUA only if FDA concludes that the following four statutory criteria for issuance have been met. If the product does not meet the statutory criteria for issuance or is not otherwise an appropriate candidate, an alternative regulatory mechanism (i.e., access under an IND or IDE, which can include expanded access protocols[20]) may be an appropriate means to provide patients access to an unapproved use of a product in a CBRN emergency.

a. Serious or Life-Threatening Disease or Condition

For FDA to issue an EUA, the CBRN agent(s) referred to in the HHS Secretary's EUA declaration must be capable of causing a serious or life-threatening disease or condition.

b. Evidence of Effectiveness

Medical products that may be considered for an EUA are those that "may be effective" to prevent, diagnose, or treat serious or life-threatening diseases or conditions that can be caused by a CBRN agent(s) identified in the HHS Secretary's declaration of emergency or threat of emergency under section 564(b). Potential EUA products also include those that may be effective to mitigate a disease or condition caused by an FDA-regulated product (including a product authorized for emergency use under section 564 or an approved product) used to diagnose, treat, or prevent a disease or condition caused by a CBRN agent.

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[19] The Secretary of HHS publishes in the Federal Register notice of each EUA declaration justifying issuance of an EUA, with an explanation of the basis of the declaration under section 564(b)(1), as well as any advance notice of termination of such a declaration.

[20] For general information on expanded access mechanisms, see http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm.

The "may be effective" standard for EUAs provides for a lower level of evidence than the "effectiveness" standard that FDA uses for product approvals.[21] FDA intends to assess the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis, as explained below. If, based on the totality of the scientific evidence available, it is reasonable to believe that the product may be effective for the specified use, FDA may authorize its emergency use, provided that other statutory criteria for issuing an EUA also are met.

c. Risk-Benefit Analysis

A product may be considered for an EUA if the Commissioner determines that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product. In making this assessment, FDA must take into consideration the material threat posed by the CBRN agent(s) identified in the HHS Secretary's declaration of emergency or threat of emergency if applicable (section 564(c)).

In determining whether the known and potential benefits of the product outweigh the known and potential risks, FDA intends to look at the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may include (but is not limited to): results of domestic and foreign clinical trials, *in vivo* efficacy data from animal models, and *in vitro* data, available for FDA consideration. FDA will also assess the quality and quantity of the available evidence, given the current state of scientific knowledge. The types of evidence that FDA may consider and that should be submitted to support a request for an EUA are discussed more fully in section III.D.2 of this guidance.

d. No Alternatives

For FDA to issue an EUA, there must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the disease or condition. A potential alternative product may be considered "unavailable" if there are insufficient supplies of the approved alternative to fully meet the emergency need. A potential alternative product may be considered "inadequate" if, for example, there are contraindicating data for special circumstances or populations (e.g., children, immunocompromised individuals, or individuals with a drug allergy), if a dosage form of an approved product is inappropriate for use in a special population (e.g., a tablet for individuals who cannot swallow pills), or if the agent is or may be resistant to approved and available alternative products.

[21] Regulations regarding treatment INDs and IDEs also use the terminology "may be effective." A request for a treatment IND for a drug or biologic intended to treat an immediately life-threatening disease may be granted when, among other things, there is evidence that the drug may be effective for its intended use in its intended population (21 CFR 312.320(a)(3)(ii)). For devices, a treatment IDE may be withdrawn if FDA determines that the available scientific evidence fails to provide a reasonable basis for concluding that the device "may be effective for its intended population" (21 CFR 812. 36(d)(2)(iv)(A)). It should be noted that FDA's decisions on requests for EUAs and treatment INDs and IDEs involve product-specific and circumstance-dependent determinations of risks and benefits. FDA also notes that the amount, type, and quality of evidence available to support an EUA may not always be the same as that required for expanded access, IDEs, or humanitarian device exemptions under the FD&C Act and FDA regulations.

2. Categories of Products

MCMs that may be considered for an EUA include unapproved products as well as approved products intended for unapproved uses.[22] Examples of "unapproved uses of approved products" include:

- Use of an approved antibiotic as prophylaxis based on exposure to, or treatment of, a disease caused by a bacterium (or class of bacteria) that is not included in the indications and usage section of the approved labeling for the antibiotic;
- Substitution of a critical reagent of a cleared *in vitro* diagnostic (IVD) with another reagent that has not been cleared for use with the device.

Submission of an IND or IDE is not required for potential EUA products, although FDA anticipates that many unapproved products for which an EUA is requested will already be under evaluation through such mechanisms. In fact, human data derived in the course of studies conducted under an IND or IDE may help to support an FDA conclusion that the available evidence is adequate to support an EUA consistent with the statutory criteria for issuance.

C. PRE-EUA ACTIVITIES AND SUBMISSIONS

Early engagement between an industry or government sponsor[23] and FDA about potential EUA products will facilitate more complete EUA requests and enhance FDA's ability to review and ultimately grant the EUA as appropriate. FDA also recognizes that circumstances can change rapidly, and planning for a potential emergency may unexpectedly transition to a response effort. Therefore, FDA strongly encourages the sponsor of a product that might be considered for an EUA, particularly one at an advanced stage of development, to contact the appropriate FDA Center before submitting a formal request for an EUA. For purposes of this guidance, these submissions and related interactions are referred to as "pre-EUA" activities.

FDA's review of a pre-EUA submission is not an indication of FDA's views on the product's potential to be used under an EUA, or that the sponsor has obtained or submitted all the information necessary for FDA to review a formal request for consideration of an EUA. Pre-EUA activities are not a substitute for sponsor efforts to develop the product toward approval, including submission and, when appropriate, implementation of proposals for clinical trials

[22] EUAs may be requested and issued to authorize prescribing for unapproved uses of approved products, often referred to as "off-label" uses because, under emergency circumstances, licensed prescribers may not be able to make the case-by-case individual patient prescribing decisions that occur within the practice of medicine. CDC, for example, may act as the nation's doctor in recommending an unapproved use of an approved product. In such cases, CDC may request that FDA issue an EUA to authorize such unapproved use, often with the intended purpose of preserving liability protections afforded under the Public Readiness and Emergency Preparedness (PREP) Act, described in section VI of this guidance.

[23] For purposes of this guidance, the term "sponsor" is used when referring to the applicant, submitter, or person requesting an EUA. If specifically referring to a government or industry sponsor only, then "government" or "industry" is used as an adjective to describe the specific type of sponsor, e.g. government sponsor or industry sponsor.

designed to determine whether the product is safe and effective for its intended use. In addition to design and implementation of clinical trials for development efforts in non-emergency settings, for some MCMs and for some emergency response plans, FDA encourages sponsors to design and propose appropriately controlled clinical trials that could be conducted during the emergency response either to run in parallel with an EUA or instead of an EUA.

Pre-EUA activities may include discussions with FDA about a potential EUA product. Such discussions may occur prior to the submission of a formal request for consideration of an EUA or issuance by the HHS Secretary of an EUA declaration. They may also include discussions about the appropriate vehicle to use (e.g., IND or IDE, Master File, pre-EUA submission) for submitting data on the product prior to submission of a formal request for consideration of an EUA.

Generally, FDA recommends that a sponsor submitting data as part of "pre-EUA" activities follow recommendations for submitting pre-IND, IND, and device pre-submissions to the relevant medical product Center.[24] A "pre-EUA" submission is typically separate from other developmental submissions on file with FDA; its existence does not imply that any specific set of qualifications has been met but represents the initiation of a series of preliminary interactions to discuss potential suitability for EUA consideration. In addition, FDA requests that the sponsor follow the recommendations for the content of the submission outlined in section III.D.2 of this guidance and for the format of the submission contained in section III.D.3 of this guidance.

As with requests for issuance of EUAs, FDA prioritizes its pre-EUA activities based on a variety of factors. Many of these are discussed more fully in section III.D.4.a of this guidance. Examples of additional factors FDA may take into account in prioritizing pre-EUA activities may include: progress on product development targets or milestones; competing FDA obligations or exigent circumstances (e.g., user fee deadlines, other Agency priorities); and whether there is a significant likelihood that the product would be retained in or added to government stockpiles if the product is authorized for use in an emergency. The extent of, and timelines for, review of such submissions will be determined on a case-by-case basis and will depend on the nature of the submission (e.g., whether an IND or IDE for the product already is on file), the circumstances of the emergency, and the workload of the review staff.

[24] For detailed information on meetings about product development with CDER and CBER, see FDA's guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants* (Revision 1). In the *Federal Register* of March 11, 2015 (80 FR 12822), FDA published a notice announcing the availability of a draft guidance *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (Revision 2). The revised draft guidance updates the guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants* (Revision 1) and, when finalized, will represent the Agency's current thinking on the topic. For detailed information on meetings about product development for a device, including those that are regulated by CBER, see *Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff* (February 2014) at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.

D. REQUEST FOR AN EUA

1. Preparedness and Response

FDA can issue an EUA not only during an emergency to support a rapid public health response, but also for significant potential of an emergency (e.g., in advance of an emergency) based on the requisite EUA declaration by the HHS Secretary, to support preparedness planning. The circumstances of a CBRN emergency may afford FDA or other stakeholders little time to consider the statutory criteria and appropriate conditions to ensure safe and effective use of an MCM when an event occurs. For instance, some CBRN events may require dispensing of MCMs within just a few hours of identification or notification of an exposure. It may be necessary to use other MCMs, such as IVDs, to identify the presence of a CBRN agent in an individual. An EUA issued before an emergency could permit use of an MCM during an emergency without the need for further authorization by FDA, assuming no new information about the product or emergency requires amendment and/or reissuance of the EUA. Section 564 thus reflects the fact that some scenarios may support issuance of an EUA before an emergency (including if the emergency is occurring in another country but not yet in the U.S.) to better enable federal, state, local, tribal, and territorial governments to plan for such use during an emergency.

Based on experience, FDA expects that many requests for an EUA will be submitted by government sponsors (e.g., HHS or the Department of Defense (DoD)), although industry sponsors may also submit such a request.

2. Information Recommendations

a. Summary of Recommended Information and/or Data

FDA recommends that a request for an EUA include a well-organized summary of the available scientific evidence regarding the product's safety and effectiveness, risks (including an adverse event profile) and benefits, and any available, approved alternatives to the product. The exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency or threat of emergency and the nature of the candidate product. FDA may seek additional data and information on a case-by-case basis to ensure that the statutory criteria for issuance of an EUA are met.[25]

FDA recommends that the following information be submitted in any request for an EUA:

- A description of the product and its intended use (e.g., identification of the serious or life-threatening disease or condition for which the product may be effective; where, when, and how the product is anticipated to be used; and/or the population(s) for which the product may be used);

[25] FDA recognizes that data and information available in support of a request for an EUA for preparedness purposes and a request for an EUA during an emergency response may differ.

- A description of the product's FDA approval status (e.g., whether the product is unapproved or whether it is approved but the EUA is for an unapproved use); whether the product or intended use is under an investigational application (e.g., if an IND/IDE is in effect or has been submitted; whether the product is approved in a foreign country for either the proposed use or another use; information on the use of the medical product by either a foreign country or an international organization (e.g., the World Health Organization (WHO));

- The need for the product, including identification of any approved alternative product(s) and their availability and adequacy for the proposed use, and the unmet need(s) the EUA would address;

- Available safety and effectiveness information for the product (discussed in more detail below);

- A discussion of risks and benefits, including available information concerning the threats posed by the CBRN agent(s) involved (discussed in more detail below within this section);

- Information on chemistry (as applicable), manufacturing, and controls; a list of each site where the product, if authorized, is or would be manufactured, and the current CGMP status of the manufacturing site(s);

- Information about the quantity of finished product on hand and the surge capabilities of the manufacturing site(s);

- Information comparable to an FDA-approved package insert or instructions for use; drafts of the "Fact Sheets" to be furnished to health care professionals or authorized dispensers[26] and recipients of the product, which typically are part of pre-EUA discussions (see section III.E.1 of this guidance); and a discussion of the feasibility of providing such information in an emergency;

[26] It may be appropriate in certain emergency scenarios for responders (e.g., government personnel, volunteers) to administer or dispense an MCM authorized for use under an EUA. These responders could include individuals who are not licensed health care professionals or who are licensed health care professionals yet would be acting outside of their State's professional scope of practice by administering or dispensing the MCM. Such responders are referred to in this guidance as "authorized dispensers."

- If seeking an extension of a product's labeled expiration date, any available information in support of such an extension[27] (e.g., information on product stability such as test results; prior and anticipated storage and handling conditions; the lots, batches, or other units affected; any prior expiration date extensions; and for medical devices, an explanation of labeled expiration date, such as whether the inclusion of such information was based on a premarket requirement, requirements of another regulatory body, or a business decision); and

- Any right of reference[28], as applicable.

b. Recommended Safety Information

(i) In General

The amount and type(s) of safety information that FDA recommends be submitted as part of a request for an EUA will differ depending upon a number of factors, including whether the product is approved for another indication and, in the case of an unapproved product, the product's stage of development. FDA anticipates that, for some products, data from controlled clinical trials will be available. For others, FDA expects to consider clinical experience from other than a controlled trial if the circumstances warrant. In addition, for some devices (e.g., IVDs), if clinical data are not available, FDA may consider accepting data solely from bench testing, if the circumstances warrant. FDA expects to interpret safety information in light of the seriousness of the clinical condition, alternative diagnostics, prophylaxis, or alternative therapies (if any), and the specific circumstances of the emergency or threat of emergency. FDA encourages any sponsor of a candidate product to have early discussions with FDA (even before a determination of actual or potential emergency) about the nature and type of safety data that might be appropriate to submit to FDA.

(ii) Unapproved Uses of Approved Products

If the new indication uses a similar dose, duration, route of administration, or mechanism of action (as appropriate given the nature of the product), and the intended patient population is

[27] Although FDA generally intends to address extensions of product expiration dates pursuant to section 564A(b) separately (see section IV.B of this guidance), there may be instances when an EUA candidate product may be beyond or nearing its labeled expiration date during an emergency. For example, if FDA issues an EUA for an approved product (i.e., to address unapproved use of that product), then the EUA may include expiration date extension as part of the authorization (section 564(e)(2)(B)(i)). Thus, FDA recommends that a request for an EUA for use, or anticipated use, of an approved product that is approaching or beyond its labeled expiration date include any available information that may support an extension of the product's expiration date (e.g., storage conditions, name of manufacturer, lot number(s), labeled expiration date, etc.).

[28] For purposes of this guidance, a "right of reference" means the authority to rely upon, and otherwise use, data submitted from reports of an investigation or data previously submitted to FDA in support of an application, including the ability to make available the underlying raw data for FDA audit, if necessary. Sponsors who are not the owner of the submitted document(s)/data may need to seek written permission demonstrating their right of reference.

similar, to that for which the product is approved, FDA recommends that the request for an EUA reference the approved application, including right of reference as applicable. If the new use poses a different risk to the patient population (e.g., suggesting the possibility of increased toxicity), FDA recommends that information from relevant *in vitro* studies, animal toxicology studies, and (if available) human clinical data and experience be provided to support such a use.

(iii) Unapproved Products

The range of available data for unapproved products will differ widely. FDA recommends that any request for consideration for an EUA include available preclinical testing data, such as *in vitro* and animal toxicology data. FDA also encourages that human safety information from clinical trials and individual patient experience be provided, if available. Data submitted in the request should attempt to link the likely exposure to the MCM to any relevant, existing preclinical data. Similarly, when animal data are used, sufficient information should be provided to link the results of these data to expected exposures to the MCMs related to the proposed use in humans. Any information on safety associated with use in humans of this or related compounds or devices of a similar design should also be submitted.

c. Recommended Effectiveness Information

FDA recognizes that comprehensive effectiveness data are unlikely to be available for every EUA candidate product, and the information necessary to authorize emergency use of a product will also depend on the circumstances of the CBRN emergency, as well as available knowledge about the product's safety profile. FDA plans to assess the sufficiency of the effectiveness data and the risk-benefit profile of each candidate product on a case-by-case basis.

FDA recommends that requests for consideration for EUAs include[29] any available relevant scientific evidence regarding the following:

- Product's mechanism(s) of action to diagnose, treat, or prevent the disease or condition underlying the request;
- For drugs, preclinical testing data, such as *in vitro* evidence of the effect of the product in preventing or reducing the toxicity of the specified agent;
- Data on activity or effectiveness in animals that would contribute to understanding potential effects in humans, including but not limited to any animal efficacy studies available for products being developed under the Animal Rule;[30]

[29] For products under an IND or IDE, or for which there is a Drug or Device Master File, sponsors may refer to the appropriate document on file containing such information, with appropriate right of reference as applicable.

[30] See 21 CFR 314.600 (drugs) or 21 CFR 601.90 (biological products); see also *Product Development Under the Animal Rule* – Guidance for Industry (October 27, 2015), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM399217.pdf .

- Evidence from human experience relevant to assessing activity, effectiveness, and dosing (e.g., in published case reports, uncontrolled trials, controlled trials, and any other relevant human use experience);

- For drugs, data to support the proposed dosage for the intended use (including pharmacokinetics and pharmacodynamics data, and for vaccines or antibody therapies, immunogenicity and/or achievement of protective levels of relevant parameters of immunity); and

- For IVDs, device performance data to support the intended use such as analytical sensitivity and analytical specificity, and data from testing fresh, contrived, banked or archived specimens.

d. Other Data Considerations

FDA recommends that a request for an EUA include the following types of data, as appropriate and to the extent feasible:

- Well-organized study reports that provide a complete assessment and analysis, including any statistical analyses, of available safety and effectiveness data and an interpretation of the findings. If final study reports are not yet available, any available interim study reports should be provided and clearly identified as such; and

- Source data for clinical studies, nonclinical laboratory studies, and any animal studies that contribute to assessing activity or effectiveness of the product in the treatment of the underlying disease or condition or a closely related disease or condition, such as case report tabulations for key studies; case report forms for all patients who died during the clinical studies and for all persons who did not complete the study due to an adverse event, regardless of causality; relevant reports in the published literature; and translations of source materials that are in a language other than English.

FDA recommends that requests for EUAs include statements on whether the nonclinical laboratory studies were conducted in compliance with applicable Good Laboratory Practice for Nonclinical Laboratory Studies regulations (GLP)[31] and whether the clinical studies were conducted in compliance with applicable Good Clinical Practice standards[32]. FDA also recommends specifying the methods and quality systems used to ensure the quality and integrity of data from any animal studies submitted in support of an EUA request but not performed under GLP.

Data from any ongoing testing (e.g., longer term stability data) or other data or information that may change FDA's evaluation of the product's safety or effectiveness and that become available

[31] See 21 CFR Part 58.

[32]Information available at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.

during the period of review or the term of the EUA. Such data should be submitted to FDA when such data become available, including any appropriately controlled clinical trials conducted in parallel with the EUA during the emergency response. Data that are required to be submitted under the condition(s) established as part of the authorization of an EUA should be submitted as specified in the EUA.

e. Discussion of Risks and Benefits

FDA recommends that a request for an EUA include a discussion of the candidate product's known and potential risks and benefits, which includes a synthesis of the data and information requested above, including:

- Measures taken to mitigate risk or optimize benefit;
- Limitations, uncertainty, and data gaps;
- A description of circumstances, if any, under which the product should not be used (e.g., contraindications); and
- To the extent known, information concerning the threats posed by the CBRN agent(s) (actually or potentially) involved, and anticipated response and operational considerations that may be relevant to an assessment of risks and benefits.

3. Format of Submissions

FDA recommends that each submission begin with a section that describes the contents and organization of the included materials. The sponsor of an investigational or marketing application for the product or anyone with a right of reference may refer to data or other information previously submitted to the FDA in a marketing application, investigational application, or Master File.[33]

FDA expects material to be provided in a reviewable form and sufficiently complete to permit substantive review. Nevertheless, FDA recognizes that, in rapidly developing or unexpected emergency circumstances, or when previously unanticipated or unavailable MCMs are being considered, it may not be possible for a sponsor to provide all of the requested data or to provide it in the format suggested in a timely manner. In such circumstances, FDA will accept and evaluate the request for an EUA based on data in the form the sponsor is able to submit. However, a request that is missing data, poorly documented, or otherwise incomplete will make FDA's determination of whether the product's benefits outweigh its risks more difficult and could result in a request for additional information, the need for a longer time period for review, or a decision not to authorize emergency use of the candidate product.

Prior to submitting any materials to FDA, FDA recommends contacting the relevant medical product Center (e-mails provided below) for any specific directions unique to the

[33] FDA requests that references to previously submitted data or information specify where the data or information can be found (e.g., identify file by submission date, name, reference number, volume, and page number).

submission. Submissions, including a cover letter, may be provided in electronic or paper format. General information, as well as links to Center-specific submission preparation guidelines, is included in the Center contact information below. When a request is submitted in paper, FDA recommends that a minimum of three copies be provided to the relevant medical product Center address below.

In addition, FDA recommends that an email alert, highlighting the urgency if related to an imminent or ongoing emergency and including the cover letter to the submission, be sent to the following email addresses:

- The identified Center email address below;
- EUA.OCET@fda.hhs.gov; and
- Any other previously established contacts within the Center familiar with the submission.

For the Center for Biologics Evaluation and Research:

Emails for EUAs related to biological products regulated by CBER: CBEREUA@fda.hhs.gov

Paper submissions:
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

Electronic submissions:
CBER is prepared to receive electronic EUA submissions in standardized electronic Common Technical Document (eCTD). Contact ESUBPREP@fda.hhs.gov for information or visit http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm

For the Center for Devices and Radiological Health:

Email for EUAs related to IVD medical devices: device@fda.hhs.gov

Email for EUAs related to non-IVD medical devices: cdrhemcm@fda.hhs.gov

Paper submissions for both:
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center
Food and Drug Administration
10903 New Hampshire Avenue
WO66-G609
Silver Spring, MD 20993-0002
ATTN: EUA

For the Center for Drug Evaluation and Research:

Emails for drug and biological products regulated by CDER: CDEREUA@fda.hhs.gov

Paper submissions:
Food and Drug Administration
Center for Drug Evaluation and Research Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Electronic submissions:
CDER is prepared to receive electronic EUA submissions in standardized electronic Common Technical Document (eCTD) format as well as non-eCTD format. Contact ESUB@fda.hhs.gov for information or visit http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

4. FDA Processing of an EUA Request

a. Prioritization of Requests

(i) In General

FDA intends to establish priorities for its review of requests to issue an EUA based on a variety of factors. These include:

- The seriousness and incidence of the clinical disease or condition (e.g., based on federal requirements, federal partner prioritization requests);

- The public health need for the product and, when known, the safety and effectiveness of other potential MCMs;
- The urgency of the treatment need (i.e., the window of opportunity for treatment can vary for different medical conditions);
- Availability and adequacy of the information concerning the likelihood that the product may be safe and effective in preventing, treating, or diagnosing the condition;
- The potential role that use of the product may have in ensuring national security;
- Whether the product is included in government stakeholder stockpiles;
- The extent to which the product would serve a significant unmet medical need, including in:
    - A subpopulation (e.g., pregnant women, infants, and children, and immunocompromised persons)
    - The stage of the emergency response (e.g., evolving understanding of the disease or condition and/or MCMs in the context of an ongoing public health response, availability of previously authorized MCMs);
- Whether the request is from (or supported by) a government stakeholder (e.g., the proposed emergency use will be appropriately coordinated with, augment, and not interfere with official government stakeholder response efforts[34]);
- The availability of the product, (e.g., the quantity and manufacturing capacity); and
- Whether other mechanisms, such as developing a clinical study protocol under an IND or IDE for investigational use, typically in coordination with government stakeholders, or granting access to an investigational product under an IND or IDE expanded access authority, might be more appropriate for allowing emergency access to products under development (e.g., when there are little or no safety or efficacy data available).

(ii) Additional Considerations for Prioritizing Requests for an EUA in Advance of an Emergency

The statutory criteria for issuing an EUA are the same whether the EUA is issued before or during a CBRN emergency. Therefore, in deciding whether to issue an EUA in advance of an emergency for preparedness purposes, FDA will make a case-by-case assessment of product risks and benefits based on the totality of available safety and efficacy data consistent with the

[34] For example, FDA often encourages EUA submissions from commercial developers of diagnostic tests to expand laboratory testing capacity during emergencies, consistent with U.S. government response plans.

criteria for issuance of an EUA in section 564(c), just as it would in considering a request for an EUA to be issued during an emergency response.

It will not be appropriate to issue an EUA for every potential MCM or in anticipation of each emergency scenario. For example, FDA anticipates that, in all but the most catastrophic scenarios, only comparatively mature products (e.g., those with demonstrated safety data and in advanced stages of efficacy testing) are likely to meet the minimum risk-benefit criteria for an EUA for preparedness purposes. In addition, the extent to which the proposed use of an MCM is supported by operational planning, whether the MCM is already held in a government stockpile, and whether timely and comprehensive pre-EUA submissions have been available for FDA review will be relevant to the prioritization of a request for an EUA for preparedness purposes.

Nevertheless, the extent to which the sponsor is actively pursuing FDA approval for the MCM is relevant to FDA's prioritization of requests to issue an EUA in advance of an emergency for preparedness purposes[35], and the duration of such an EUA if issued. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for MCMs; the issuance of an EUA in advance of an emergency (or during an emergency) is not an appropriate endpoint for new product development.

Section 564 expressly states that FDA's authority to allow emergency use of an unapproved product, or unapproved use of an approved product, does not authorize a delay in FDA's review or other consideration of any pending application. If an EUA remains in effect for more than one year, FDA must provide the sponsor written explanation of obstacles to approval and specific actions to be taken by FDA and the sponsor to overcome them.[36] Moreover, FDA is required to review the circumstances and appropriateness of an EUA periodically, including progress made with respect to the approval of the product.[37] FDA generally does not anticipate allowing an EUA issued in advance of an emergency for preparedness purposes to remain in effect indefinitely. If the sponsor is not actively working to advance the MCM's development for an approval, FDA may reconsider the EUA's status and/or consider terminating the EUA.

b. Review of Requests to Issue an EUA

A formal request to issue an EUA generally should not be submitted until the Secretary of HHS has issued an EUA declaration under section 564(b)(1). In particular, although section 564 allows FDA to issue an EUA for preparedness purposes, in such cases the HHS Secretary must first declare that circumstances exist justifying such an authorization in advance of an actual emergency based on a formal determination of a significant potential for emergency or a material

[35] As stated in section III.C with regard to pre-EUA activities, an EUA is not a substitute for sponsor efforts to develop the product toward approval, including conducting clinical trials designed to determine whether the product is safe and effective for its intended use. When appropriate, FDA encourages sponsors to design and propose appropriately controlled clinical trials that could be conducted during the emergency response either to run in parallel with an EUA or instead of an EUA.

[36] Section 564(b)(5).

[37] Section 564(g)(1).

threat determination. FDA typically coordinates closely with HHS and other relevant government sponsors throughout the EUA process, from pre-EUA submissions to final disposition, including the need for issuance of the EUA declaration and any consultations on EUAs with federal partners.[38] Moreover, a formal request for issuance of an EUA typically will have the benefit of FDA feedback based on pre-EUA submission activities.

A sponsor seeking an EUA should submit its formal request in the form of an EUA submission, including reference to relevant pre-EUA submissions previously reviewed by FDA, and request to issue the EUA through the same process outlined in section III.D.3 of this guidance. Typically the data and other information in EUA submissions have already been reviewed by FDA and have had the benefit of FDA Center feedback based on pre-EUA submissions and interactions with FDA prior to submission of the request to issue an EUA.

c. Disposition of Requests

FDA is prepared to issue EUAs expeditiously (e.g., within hours or days) when circumstances warrant and adequate information has been made available for prior review through pre-EUA interactions. Generally, the timelines for FDA review and action on a request to issue an EUA will be determined on a case-by-case basis and will depend on factors such as:

- The product profile;
- The existence, if any, of pending applications for the product;
- The nature of the emergency, potential emergency, or threat of emergency;
- The organization and completeness of the request submission; and
- The workload of the reviewing Center's personnel.

A letter to the sponsor authorizing the emergency use(s) of an MCM will be signed by the Commissioner (or his/her designee) and will include a description of the authorized product and its use(s), any contraindications for the product, the criteria for issuance of the authorization, the scope of the authorization, waiver of certain requirements (if applicable), and any conditions on the authorized use. An authorized EUA will consist of (1) the signed letter of authorization and (2) any accompanying authorized materials (e.g., Fact Sheet for health care professionals, Fact Sheet for recipients, instructions for use, etc.).[39]

FDA may decline to review or issue an EUA based on any number of factors. For example, the candidate product may fail to meet the necessary criteria identified in section 564 and discussed in section III.B.1 of this guidance, or it may fail to meet any one of the factors given the

[38] Section 564(c).

[39] The EUA letter of authorization and accompanying authorized materials will be posted on FDA's website at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current.

circumstances of the emergency or threat of emergency (see section III.D.4.a of this guidance for a discussion of factors FDA will consider in reviewing requests for prioritization of EUA requests). Under such circumstances, the relevant product Center will notify the sponsor that the EUA review cannot be prioritized or FDA declines to issue an EUA for the candidate product.

E. CONDITIONS OF AUTHORIZATION

FDA may establish conditions on an EUA necessary or appropriate to protect the public health. Section 564(e)(1) establishes conditions applicable to unapproved products; section 564(e)(2) sets forth conditions applicable to unapproved use of approved products, which are similar, but not identical, to those applicable to unapproved products. Within these sections, some conditions are required (to the extent practicable given the applicable circumstances of the emergency or threat of emergency), whereas others may be imposed entirely at the discretion of FDA.[40]

1. Information Relating to the EUA Product

a. Information for Health Care Professionals or Authorized Dispensers

For an unapproved product (section 564(e)(1)(A)(i)) and for an unapproved use of an approved product (section 564(e)(2)(A)), FDA must (to the extent practicable given the circumstances of the emergency) establish conditions to ensure that health care professionals who administer the EUA product are informed:

- That FDA has authorized the emergency use of the product (including the product name and an explanation of its intended use);
- Of the significant known and potential benefits and risks of the emergency use of the product, and the extent to which such benefits and risks are unknown; and
- Of available alternatives and their benefits and risks.

Therefore, FDA recommends that a request for an EUA include a “Fact Sheet" for health care professionals or authorized dispensers that includes essential information about the product. In addition to the required information, Fact Sheets should include:

- A description of the disease/condition;
- Any contraindications or warnings;

[40] See Appendix A for a table of required and discretionary conditions. Note that the statute states that FDA shall “establish such conditions on an authorization under this section as [FDA] finds necessary or appropriate to protect the public health” with respect to unapproved products and then provides examples of such conditions by use of the term “including” (section 564(e)(1)(A)). FDA interprets this language as giving FDA the authority and the responsibility to impose other conditions, not specified as examples in the statutory language, that may be necessary or appropriate in the circumstances of a particular emergency.

- Dosing information (if applicable), including any specific instructions for special populations; and

- Contact information for reporting adverse events and additional information about the product.

Health care professionals or authorized dispensers will likely have very limited time to review Fact Sheets during an emergency and, therefore, FDA anticipates that Fact Sheets typically will be brief (i.e., a few pages). FDA makes available on its website Fact Sheets for products for which an EUA is issued.[41]

FDA further recommends that Fact Sheets target the health care professional or authorized dispenser who has the most basic level of training, recognizing that individuals responding to an emergency may have different levels of training, could come from a variety of backgrounds, and may have different types of experience or speak different languages. FDA recommends that Fact Sheets accompany the EUA product in an accessible form (e.g., printable as a hard copy) when the product is distributed to the health care professional or authorized dispenser if practicable. To the extent consistent with other conditions of authorization, information on the EUA product also may be disseminated to health care professionals or authorized dispensers through mass media (including print, broadcast, radio, satellite, Internet, or other electronic means of dissemination), videos/DVDs, or direct communication from public health agencies.

For unapproved drug products, which do not have FDA-approved labeling for any indication, FDA recommends that, in addition to the brief summary information found in a Fact Sheet, the sponsor also develop more detailed information similar to what health care professionals are accustomed to finding in FDA-approved package inserts. For medical devices regulated, such as *in vitro* diagnostics, in addition to the brief summary information found in a Fact Sheet, FDA recommends the sponsor also develop separate Instructions for Use.[42]

With respect to an EUA that authorizes a change in labeling of an approved product, but for which the manufacturer chooses not to make such labeling change, the EUA may not authorize the product's distributor or any other person to alter or obscure the manufacturer's labeling (section 564(e)(2)(B)).[43] In such a situation, however, FDA must, to the extent practicable given the applicable circumstances, authorize a person acting pursuant to such EUA to provide, in

[41]For examples of Health Care Professional Fact Sheets, see FDA's website at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current.

[42] For examples of Instructions for Use, see FDA's website at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current.

[43] We note that this prohibition does not apply to changes in expiration dating permitted pursuant to section 564A(b). See section IV.B of this guidance.

addition to the manufacturer's labeling, appropriate information with respect to the product, such as that provided in the brief Fact Sheet described above.[44]

b. Information for Recipients

Although informed consent as generally required under FDA regulations[45] is not required for administration or use of an EUA product, section 564 does provide EUA conditions to ensure that recipients are informed about the MCM they receive under an EUA. For an unapproved product (section 564(e)(1)(A)(ii)) and for an unapproved use of an approved product (section 564(e)(2)(A)), the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances:

- That FDA has authorized emergency use of the product;
- Of the significant known and potential benefits and risks associated with the emergency use of the product, and of the extent to which such benefits and risks are unknown;
- That they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product;[46] and
- Of any available alternatives to the product and of the risks and benefits of available alternatives.

Therefore, FDA recommends that a request for an EUA include a “Fact Sheet" for recipients that includes essential information about the product. In addition to the above information, the Agency recommends that the content of the Fact Sheets for recipients include the following information:

- Product name and explanation of the intended use of the product;
- A description of the disease/condition;

[44] Additional information provided under section 564(e)(2)(B)(ii) as a condition of authorization is not considered "labeling" for purposes of section 502 of the FD&C Act while the EUA for the product is effective.

[45] See 21 CFR part 50.

[46] The President may under certain circumstances waive the option for members of the armed forces to accept or refuse administration of an EUA product (10 U.S.C. 1107a). In addition, the option to accept or refuse may not be practicable with regard to certain diagnostics because, for example, when a sample is taken from an individual it may be unknown, even to the health care professional, which diagnostic test will be used to test the sample. For this reason, Fact Sheets for both health care professionals and recipients may not accompany an EUA diagnostic product, but instead be publicly posted for reference when receiving test results.

- A description of items to discuss with a health care provider and adverse event information, including contact information for how to get more information and for reporting adverse reactions; and

- Dosing information (if applicable), including specific instructions for home use or preparation (if applicable).

FDA recommends that recipients be given as much appropriate information as possible given the nature of the emergency and the conditions of the authorization.[47] Ordinarily, FDA expects that some written form of information will be given to recipients with the MCM, similar to the Fact Sheet for health care professionals or authorized dispensers. FDA recognizes that these Fact Sheets, like those for health care professionals or authorized dispensers, will generally be brief. To ensure that individuals of varying educational levels comprehend the information provided, FDA recommends that all written information be stated in the simplest language possible using techniques to improve health literacy.[48] In addition, translations to other languages may be appropriate if practicable.[49] FDA recognizes that some flexibility may be needed for health care providers or authorized dispensers to make minor, nonsubstantive changes to the fact sheets for recipients such as adding local contact information, using specific letterhead or minor format changes.

FDA acknowledges that exigent circumstances may dictate the use of other appropriate dissemination methods. Therefore, FDA expects that information would be disseminated in the most effective and expeditious way possible to reach the recipient before administration or use of an EUA product.[50] If, however, taking the time needed to provide such information would diminish or negate the effectiveness of the product for the recipient, FDA may include as a condition of authorization that the information be provided to the recipient as soon as practicable after dispensing. Other methods of dissemination may include internet posting, mass media, videos/DVDs, or direct communication from health care professionals and public health agencies.

2. Monitoring and Reporting of Adverse Events

For an unapproved product (section 564(e)(1)(A)(iii)), EUA conditions for monitoring and reporting of adverse events are required to the extent practicable given the circumstances of the emergency; such conditions may be established for an EUA for an unapproved use of an approved product (section 564(e)(2)(A)), at the discretion of FDA.

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[47] For examples of Patient/Recipient Fact Sheets, see FDA's website at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current.

[48] See, e.g., http://www.health.gov/communication/literacy/quickguide/healthinfo.htm.

[49] When the translation of a fact sheet to a foreign language is determined to be appropriate and necessary, the party producing the translation is responsible for the accuracy and completeness of the translation; FDA does not intend to review translations to ensure their accuracy.

[50] As noted above, however, this may not be practicable or appropriate for certain diagnostic tests.

Conditions may be placed to enable the collection and analysis of information on the safety and effectiveness of the EUA product during the period when the authorization is in effect and for a reasonable time following such period. FDA expects that the primary focus of adverse event-related conditions will be capturing serious adverse events and applying appropriate mechanism(s) for the collection of follow-up clinical information. Some reporting may be directed to predefined mechanisms to capture adverse event data (e.g., FDA's Safety Information and Adverse Event Reporting System (MedWatch) or Vaccine Adverse Event Reporting System (VAERS)). FDA will work with product sponsors in some circumstances to develop proposals for more active data collection and follow-up mechanisms to capture adverse event information under the EUA. FDA encourages EUA sponsors to provide proposals for data collection and follow-up during pre-EUA interactions.

3. Records

To the extent practicable given the circumstances of the emergency, FDA must establish conditions for a manufacturer of an unapproved product to maintain records and to grant FDA access to records concerning the EUA product.[51] FDA anticipates that such conditions may relate to, for example, the number of doses, devices, or other unit(s) (including lot identification) that have been shipped or sold under an EUA; or the name and addresses of the facilities to and from which the EUA product was shipped. FDA may also impose comparable recordkeeping requirements on any person (e.g., an authorized distributor or dispenser) other than a manufacturer who carries out any activity for an unapproved EUA product (section 564(e)(1)(B)(iv)).

FDA may also impose recordkeeping and records access requirements on any person (including a manufacturer) engaged in an activity for which an EUA is issued for an unapproved use of an approved product (section 564(e)(2)(A)). In addition to the examples noted above for unapproved EUA products, examples may include conditions relating to actual use of the product and disposition of any unused product, and monitoring of patients who have been administered the product under an EUA.

4. Additional Conditions of Authorization

FDA, on a case-by-case basis and to the extent feasible given the circumstances of the emergency, may establish additional conditions that FDA finds to be necessary or appropriate to protect the public health (section 564(e)) [52], such as the following:

- *Distribution and administration*— conditions may be placed on which entities may distribute and who may administer the product, and how distribution and administration are to be performed. In addition, conditions may be placed on the

[51] Section 564(e)(1)(A)(iv).

[52] Section 564(e)(1)(B) (for unapproved products) and 564(e)(2)(A) (for unapproved uses of approved products).

categories of individuals to whom, and the circumstances under which, the product may be administered. FDA anticipates that distribution and administration of EUA products will be performed according to existing official government response plans, as practicable and appropriate. In some cases, administration of an MCM may go hand-in-hand with dispensing the MCM. In establishing conditions with respect to the distribution and administration of an approved product for an unapproved use, FDA may not impose conditions that would restrict distribution or administration of the product when distributed or administered for the approved use.[53]

- *Advertising*[54]— conditions (e.g., limitations) may be placed on advertisements and other promotional descriptive printed matter (e.g., press releases issued by the EUA sponsor) relating to the use of an EUA product, such as requirements applicable to prescription drugs under section 502(n) and requirements applicable to restricted devices under section 502(r).

5. Waivers or Limitations of Compliance With Other Requirements

a. CGMPs

FDA generally expects that EUA products will be produced, stored, and distributed in compliance with CGMPs; however, limits or waivers may be granted in an EUA on a case-by-case basis, after consideration of the circumstances and of any alternative proposed approach (section 564(e)(3)).[55]

b. Prescription Requirements

FDA may waive otherwise applicable prescription requirements, to the extent appropriate given the circumstances of an emergency (section 564(e)(3)). For example, operational considerations for a large-scale emergency response may demand that large numbers of individuals receive a medical product at centralized locations or locations that are not traditional health care settings, typically called "points of dispensing" (PODs). In such situations, the goal is to dispense medical product as quickly as possible to protect the public health, so it may not be practicable for each person to interact with a licensed practitioner before receiving a product authorized under an EUA (e.g., authorized dispensers may be responsible for dispensing or administering some or all MCMs). FDA also expects to include such waivers in EUAs on a case-by-case basis,

[53] Section 564(e)(2)(C).

[54] Section 564(e)(4).

[55] Section 564A(c) separately empowers FDA to authorize deviations from otherwise applicable CGMP requirements for the manufacture, processing, packing, or holding of eligible, FDA-approved products without issuing an EUA. This independent authority is discussed in section IV.C of this guidance.

after consideration of the anticipated or actual circumstances of an emergency and the operational plans for a response.[56]

c. REMS

FDA may waive otherwise applicable REMS requirements based on all CBRN emergencies that would trigger an EUA (section 505-1(k)). If it is determined that a waiver is needed, the waiver may apply to all REMS elements.[57]

F. CATEGORIZATION OF LABORATORY TESTS UNDER AN EUA

Section 564(m) allows FDA, if issuing an EUA for a diagnostic device, to indicate whether the test can be performed at a point-of-care setting or only in a laboratory able to handle more complex tests. FDA may determine that a laboratory examination or procedure associated with such a device shall be deemed, for purposes of section 353 of the PHS Act, to be in a particular category of examinations and procedures, including the category described by subsection (d)(3) of such section (commonly termed "waived" devices) if, based on the totality of scientific evidence available:

- The categorization would be beneficial to protecting the public health; and
- The known and potential benefits of such categorization under the circumstances of the authorization outweigh the known and potential risks of the categorization.

FDA may also establish appropriate conditions on the performance of the test. The complexity categorization made under this authority is effective for the same period as the EUA and is independent of that made under Clinical Laboratory Improvement Amendments (CLIA) regulations.

G. DURATION AND REVISION OF AN EUA

FDA will specify the effective date of an EUA issued under section 564. In general, an EUA will remain in effect for the duration of the EUA declaration under which it was issued (see section III.A.2 of this guidance, which describes termination of an EUA declaration and its impact on existing EUAs), unless the EUA is revoked because the criteria for issuance as described in section III.B of this guidance are no longer met or revocation is appropriate to protect public health or safety (section 564(f),(g)).

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[56] Section 564A(d) separately empowers FDA to issue an order authorizing emergency dispensing of eligible, FDA-approved products without issuing an EUA. This independent authority is discussed in section IV.D of this guidance.

[57] For further information on REMS, see FDA's draft *Guidance for Industry Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications* (October 2009) at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm184128.pdf.

1. Revision and Revocation

FDA will periodically review the circumstances and appropriateness of an EUA, including circumstances that might warrant revocation of the EUA. The review will include regular assessment based on additional information provided by the sponsor of the progress made with respect to the approval, licensure, or clearance of the unapproved product, or of the unapproved use of an approved product, for which an EUA was issued.

FDA may revise or revoke an EUA if the circumstances justifying its issuance (under section 564(b)(1)) no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.[58] Such circumstances may include significant adverse inspectional findings (e.g., when an inspection of the manufacturing site and processes has raised significant questions regarding the purity, potency, or safety of the EUA product that materially affect the risk/benefit assessment upon which the EUA was based); reports of adverse events (number or severity) linked to, or suspected of being caused by, the EUA product; product failure; product ineffectiveness (such as newly emerging data that may contribute to revision of the FDA's initial conclusion that the product "may be effective" against a particular CBRN agent); a request from the sponsor to revoke the EUA; a material change in the risk/benefit assessment based on evolving understanding of the disease or condition and/or availability of authorized MCMs; or as provided in section 564(b)(2), a change in the approval status of the product may make an EUA unnecessary.

2. Product Disposition and Continued Use

Upon revocation of an EUA or its termination as a result of the termination of the HHS EUA declaration supporting it, an unapproved product or its labeling, and product information for an unapproved use of an approved product, must be disposed of pursuant to section 564(b)(2)(B) and (b)(3).[59] Notwithstanding any such revocation or termination, under section 564(f)(2) an authorization shall continue to be effective to provide for continued use in any patient who began treatment before revocation or termination (to the extent found necessary by the patient's attending physician). Any study or future use of an EUA product beyond the term of a declaration is subject to investigational product regulations (e.g., IND regulations).

H. PUBLICATION

FDA will promptly publish in the Federal Register a notice of each EUA, including an explanation of the reasons for issuance, a description of the intended use, and any contraindications of the EUA product. The Agency also will promptly publish in the Federal Register each termination or revocation of an EUA and an explanation of the reasons for the decision. Although FDA is not required to publish notice of an EUA revision(s) in the Federal

[58] Section 564(g)(2).

[59] Section 564(b)(2)(B) provides that FDA shall consult with the manufacturer of the product with respect to the appropriate disposition.

Register, FDA plans to post any revisions to EUAs on FDA's website at http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm.[60]

I. OPTION TO CARRY OUT AUTHORIZED ACTIVITIES

If a manufacturer is the sole source of an unapproved product authorized for emergency use, that manufacturer must inform FDA, within a reasonable time after the authorization, if the manufacturer does not intend to make its product available for use under the EUA (section 564(l)). The Commissioner does not have the authority under section 564 to require a person to carry out any activity for which an EUA is issued. Section 564(l), however, does not limit FDA's authority to impose conditions on persons who carry out any activity for which an EUA is issued.

IV. EMERGENCY USE OF ELIGIBLE FDA-APPROVED MCMs WITHOUT AN EUA

Section 564A allows FDA to facilitate certain emergency activities involving FDA-approved MCMs without an EUA. This authority is independent of the EUA authority under section 564. In the past, to address concerns about potential FD&C Act violations related to the activities discussed in this section involving MCMs, FDA has either: (1) exercised its enforcement discretion with respect to the activity; or (2) issued an EUA to ensure that use of such MCMs remains covered under any otherwise applicable protections under the PREP Act [61] (discussed in section VII of this guidance). MCMs used under this authority qualify for applicable PREP Act protection.[62]

In some cases, FDA and CDC may coordinate activities under section 564A authorities including the issuance of an emergency dispensing order, waiver of cGMPs, waiver of REMS, extension of expiration dating, and/or issuance of EUI for specific MCMs.[63]

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[60] In publicly releasing information on an EUA, FDA will take necessary steps to protect nonpublic information and information otherwise protected by law, as appropriate.

[61] *See* 42 U.S.C. 247d-6d.

[62] *See* 42 U.S.C. 247d-6d(i)(1)(C), (i)(7)(B)(iii).

[63] See, e.g., Emergency Dispensing Information tables for doxycycline and ciprofloxacin at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#doxy http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#cipro.

A. ELIGIBLE PRODUCTS

The emergency authorities in section 564A apply only to those medical products that are "eligible" (as defined in section 564A(a)) (referred to in this document as "eligible MCMs"). Eligible MCMs must be:

- Approved by FDA;
- Intended for their approved use to prevent, diagnose, or treat a disease or condition involving a CBRN agent(s), or a serious or life-threatening disease or condition caused by a product used for such a purpose; and
- Intended for use during circumstances in which there has been either:
  - A determination of an emergency or a significant potential for an emergency made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary of HHS (as described in subparagraph (A), (B), or (C) , respectively, of section 564(b)(1)) (i.e., one of the three EUA determinations that may support issuance of an EUA declaration, as described in section III.A of this guidance); or
  - A material threat (described in subparagraph (D) of section 564(b)(1)) identified by the Secretary of Homeland Security pursuant to section 319F–2 of the PHS Act that is sufficient to affect national security or the health and security of U.S. citizens living abroad (i.e., a Department of Homeland Security (DHS) material threat determination, which may also support issuance of an EUA declaration, as described in section III.A of this guidance).[64]

B. EXPIRATION DATE EXTENSIONS WITHOUT AN EUA

FDA may extend the expiration date of an eligible, FDA-approved MCM stockpiled for use in a CBRN emergency if the extension is supported by an appropriate scientific evaluation that is conducted or accepted by FDA. An "expiration date" is defined as "the date established through appropriate stability testing…to ensure that the product meets applicable standards of identity, strength, quality, and purity at the time of use" (section 564A(b)(4)).

For each expiration date extension granted, FDA must identify the "specific lot, batch, or other unit of the product"[65] and the duration of the extension.[66] In addition, FDA must

[64] As noted previously with respect to EUAs, FDA has construed a material threat identification pursuant to section 319F-2 to apply to the health and security of U.S. citizens living abroad, even though that provision does not specifically focus on citizens outside the United States. Thus, a material threat determination may, in appropriate circumstances, serve as a basis for exercise of emergency authorities under section 564A(b),(c), and (d) and 505-1 as necessary for the protection of U.S. citizens living abroad.

[65] Section 564A(b)(2)(A).

identify any other requirements or conditions related to each expiration date extension that the Agency deems appropriate for the protection of the public health, which may include requirements for, or conditions on:

- Product sampling,
- Storage,
- Packaging or repackaging,
- Transport,
- Labeling,
- Notice to product recipients,
- Recordkeeping,
- Periodic testing or retesting, or
- Product disposition.[67]

The expiration date extension authority in section 564A applies to any eligible MCM, including eligible MCMs tested through the federal Shelf-Life Extension Program (SLEP). Since the mid-1980s FDA has engaged with federal partners in SLEP; DoD administers the program, while FDA tests the stability of certain federally stockpiled drug products to assess and extend, as appropriate, the useful shelf-life of such products. The explicit expiration date extension authority added by PAHPRA does not displace the longstanding federal SLEP, but eliminates any uncertainty about the legal status of eligible products for which FDA authorizes an extended expiration date, whether or not FDA also issues an EUA.

At this time FDA is not proposing or recommending any changes to SLEP or procedures for expiration date extensions for products tested through SLEP. For drugs tested within the SLEP program, federal participants should continue to submit requests to extend the expiration date of eligible MCMs using established processes. FDA is considering approaches for expiration extension for eligible products that are not tested within the SLEP program. Government stakeholders should consult with FDA via email or letter to the relevant Center and OCET points of contact identified in section III.D.3 of this guidance.[68]

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[66] Section 564A(b)(2)(B).

[67] Section 564A(b)(2)(C).

[68] For additional information about expiration dating extensions see http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411446.htm.

Although FDA may rely on section 564A to authorize an expiration date extension without issuing an EUA, if an EUA is requested for a product that is nearing or beyond its labeled expiration date, FDA may consider extending that expiration date and imposing conditions in connection with an EUA request as discussed in section III.D.2.a of this guidance.

1. In General

FDA may authorize deviations from otherwise applicable CGMP requirements for the manufacture, processing, packing, or holding of eligible, FDA-approved products without issuing an EUA (section 564A(c)). Products that receive a waiver from applicable CGMPs will not be considered adulterated or misbranded under the FD&C Act. This includes requirements under section 501 or 520(f)(1) or applicable conditions prescribed with respect to the eligible product by an order under section 520(f)(2).

Although FDA may rely on section 564A to waive CGMP requirements without issuing an EUA, if an EUA is requested for a product for which a CGMP waiver is also requested, FDA may consider waiving CGMP requirements and imposing conditions in connection with the EUA as discussed in section III.E.5 of this guidance.

2. Procedures for Request and Issuance

FDA may issue waivers on its own initiative, but expects that any such action will be uncommon. Since the need for a waiver will be driven by the exigencies and other demands of responding to a CBRN emergency, FDA expects that in most cases a waiver will be based on a request from a government stakeholder or other interested party. For example, government stakeholders or manufacturers of products intended for use in a CBRN emergency may submit a request for a CGMP waiver for eligible products based on actual or anticipated emergency response activities that necessitate the waiver. FDA recommends, however, that requests be submitted only after consultation with and among relevant government stakeholders (e.g., CDC, and government officials in adjacent jurisdictions) that are or eventually may be part of a coordinated or related response effort involving the CBRN agent(s) or MCM. For example, absent compelling justification and to maintain response consistency, FDA does not expect to grant multiple CGMP waivers for the same MCM or CBRN use. FDA generally will not issue a waiver based on a request from an individual state if FDA has already issued the same type of waiver for the same MCM on a nationwide basis. Similarly, if FDA receives CGMP waiver requests for a particular MCM from multiple states or federal partners at the same time, FDA generally anticipates it will issue a single waiver (if a waiver is appropriate). Advance consideration and coordination are critical to ensure appropriate consistency and avoid unnecessary duplication.

FDA intends to evaluate requests for CGMP waivers pursuant to section 564A(c) on a case-by-case basis. A waiver may be issued when, based on the information available, the Agency concludes it is reasonable to issue a waiver to facilitate a CBRN emergency response or preparedness efforts. Requests for waivers should include the following information:

- The identity and quantity of the medical product involved (e.g., product name(s); dosage form(s) and strength(s); number of doses, units, lots, or other unit(s); and unit/lot identifiers, as appropriate);

- The manufacturer's name, address, and contact information;

- The FDA application file number for the product, if known (e.g., NDA, BLA, IND, IDE);

- The actual or potential CBRN emergency for which the product is intended to be used;

- The anticipated conditions (e.g., storage, handling, transport, packaging) that will or may deviate from CGMP requirements and for which a waiver is being requested, including why such deviation may be necessary and the anticipated duration; and

- Available information about the potential impact of the deviation on the safety or efficacy of the product (e.g., strength, purity, quality).

FDA may request additional information to assess the request and decide whether to grant a waiver. A waiver of CGMP requirements pursuant to section 564A(c) may either (1) be issued independent of any other FDA action or, when appropriate, (2) be included with an emergency dispensing order under section 564A(d) (see section IV.D of this guidance).

Submit a request for a CGMP waiver for an eligible MCM via e-mail or letter to the relevant Center and OCET points of contact identified in section III.D.3 of this guidance.

D. EMERGENCY DISPENSING WITHOUT AN EUA

Emergency dispensing of eligible, FDA-approved products is allowed under section 564A(d) without adhering to the requirements of section 503(b) or 520(e). This authority includes dispensing such products without an individual prescription for each recipient (often referred to as "mass dispensing")[69] if: (1) permitted by state law where the product is dispensed (section 564A(d)(2)(A)) or (2) dispensed in accordance with an emergency dispensing order issued by FDA (section 564A(d)(2)(B)). This streamlined mechanism permits emergency response activities that involve an emergency dispensing strategy needed to meet immediate public health needs, but that otherwise may not comply with the FD&C Act's prescription requirements.[70] Like other provisions in section 564A, FDA may issue an emergency dispensing order to allow emergency dispensing of eligible products without having to issue an EUA. Products that are

[69] The term "emergency dispensing" includes, but is not limited to, the public health response activity of "mass dispensing" of MCMs (e.g., through points of dispensing).

[70] This may include dispensing without an individual prescription, or dispensing with an incomplete prescription, e.g., without all of the information otherwise required by FDA, such as the name and address of the dispenser, name of the prescriber, serial number, etc. (see, e.g., section 503(b)(2) (21 U.S.C. § 353(b)(2)). This also may include dispensing by a non-health care professional.

dispensed pursuant to section 564A(d) (i.e., under state law or under an FDA emergency dispensing order) will not be considered unapproved, adulterated, or misbranded under the FD&C Act.

Although FDA may rely on section 564A to allow emergency dispensing of FDA-approved products without issuing an EUA, if an EUA is requested for a product for which emergency dispensing is also requested, FDA may consider waiving prescription requirements and imposing conditions in connection with considering the EUA (as discussed in section III.E.5 of this guidance).

1. Procedures for Issuing Emergency Dispensing Orders

States may have in place provisions that facilitate emergency dispensing of eligible MCMs or may choose to take legal actions (e.g., pass laws, issue emergency orders) that facilitate emergency dispensing of eligible MCMs.[71]

Section 564A(d) provides a mechanism for FDA to fill any gaps in state law or to ensure adequate and consistent emergency response within and across state lines by issuing an order to allow emergency dispensing of eligible MCMs (i.e., an emergency dispensing order). FDA may issue such an order before or during an emergency. However, to receive the protections from potential violations of the FD&C Act under section 564A(d), eligible MCMs may only be dispensed during (not before) an emergency, as may be determined by relevant government stakeholders (see section IV.D.2 of this guidance).

FDA intends to issue orders to allow emergency dispensing when, based on available information about the MCM, emergency response plans, and operational needs, the Agency concludes that it is reasonable to permit emergency dispensing of eligible FDA-approved products. FDA anticipates that government stakeholders will submit a request for an emergency dispensing order. However, in the event that FDA deems it appropriate to issue an order without such a request, FDA will notify the relevant government stakeholders (e.g., ASPR, CDC, DHS, and/or DoD, regional authorities) as appropriate.

a. Federal requests

FDA expects that federal government stakeholders will initiate any requests relating to federally-maintained or federally-controlled MCMs, and to the extent possible, will consider emergency dispensing activities of the same MCMs at all jurisdictional levels including state, local, tribal, and territorial jurisdictions. For example, if both the CDC Strategic National Stockpile and state or local jurisdictions stockpile an antibiotic for use for post-exposure prophylaxis of inhalational

[71] Whether or not a particular state legal provision or action is sufficient to permit the government stakeholder's anticipated emergency dispensing strategy within their state rests in large part on the interpretation of that state's law, which is a matter that should first be directed to the appropriate legal authority within the relevant jurisdiction (e.g., the state Attorney General). To ensure clarity, and perhaps increase the likelihood that state laws, regulations, orders, or other legal actions to permit emergency dispensing are deemed legally sufficient, it is recommended that such actions address the same eligibility, scope, duration, and other elements that FDA intends to address in its emergency dispensing orders.

anthrax, FDA anticipates that a CDC request for an order to allow emergency dispensing for that antibiotic would address all other relevant government stakeholder stockpiles. FDA also expects that a federal stakeholder seeking an emergency dispensing order, or to which such an order is otherwise directed, will communicate with other government stakeholders as necessary to ensure a coordinated emergency response.

b. Non-federal requests

FDA also anticipates receiving requests relating to MCMs maintained or controlled solely by non-federal government stakeholders (e.g., public health officials at the state level or in major metropolitan areas that independently maintain MCM stockpiles) to address the possibility that such assets may be deployed independent of reliance on federal assets. FDA strongly recommends that such requests be submitted only after consultation with relevant federal government stakeholders (e.g., CDC), as well as other relevant government stakeholders (e.g., officials in adjacent jurisdictions) that are or may be part of a coordinated or related response effort involving the same CBRN agent(s) or MCM.

c. Content of requests

FDA anticipates that a request for an emergency dispensing order will include the following information:

- The CBRN agent(s) involved;
- The FDA-approved product(s) for which the order is requested (including the product name(s), manufacturer, quantity, dosage form(s), strength(s), dosing regimen(s), lot or batch number(s), expiration date(s), and any other identifying information);
- The intended use(s) of the product;
- The jurisdiction(s) to be covered (e.g., nationwide, state, region);
- How soon the order needs to be issued;
- The source of the product (e.g., Strategic National Stockpile (SNS), state or local MCM stockpile, multiple sources);
- The proposed duration of the order; and
- The relevant government stakeholders' roles in an anticipated response.

FDA may also request additional information to evaluate and make a decision on the request. Examples of additional information include: information about anticipated dispensing strategies, dispensing locations, dispensing personnel, recipient screening, or how health care professionals or authorized dispensers and recipients will be informed about product safety, efficacy, and use during an emergency (e.g., whether corresponding CDC-issued EUI will be needed to accompany the product).

d. Processing of Requests

Submit a request for an emergency dispensing order for an eligible MCM via email or letter to the relevant Center and OCET points of contact identified in section III.D.3 of this guidance.

2. Scope and Conditions of Emergency Dispensing Orders

An emergency dispensing order issued by FDA would authorize emergency dispensing, but not direct or require emergency dispensing to occur; government stakeholders typically will be responsible for determining when to commence emergency dispensing consistent with the conditions specified in the order. The Agency expects that in most cases, an emergency dispensing order will allow dispensing in all circumstances in which government stakeholders reasonably believe that a need exists because of their constituent recipients' known, suspected, or likely imminent exposure to the CBRN agent(s) identified in the order. FDA also expects that any dispensing contemplated within government stakeholder emergency response plans will, to the extent possible, involve guidance from licensed health care professionals in the dispensing of product. Nevertheless, an emergency dispensing order issued under section 564A(d) may also state that, in some circumstances, direct or immediate involvement or guidance by licensed health care practitioners may not be possible, and the emergency dispensing order may authorize others, provided the product is otherwise dispensed as part of the official government emergency response plan during a CBRN event.

FDA may specify in the emergency dispensing order who is responsible for contacting additional government stakeholders who may become engaged in a response to a CBRN event covered by the order (1) to ensure that relevant government emergency response plans are coordinated or revised as appropriate, (2) to specify different or additional conditions as appropriate, including information provided in support of a request for issuance of an emergency dispensing order (e.g., to accommodate or address specific response strategies or operational considerations), and (3) when appropriate, to waive CGMP requirements under section 564A(c), as discussed more fully in section IV.C of this guidance.

In appropriate cases, FDA may also coordinate with CDC so that FDA issuance of an emergency dispensing order accompanies CDC issuance of emergency use instructions for the same MCM, as discussed in section IV.E of this guidance.

3. Duration of an Emergency Dispensing Order

In most cases, an emergency dispensing order issued by FDA for preparedness purposes in advance of a CBRN event will remain in effect until it is revised or revoked by a subsequent FDA order. FDA may specify a duration (e.g., 1 year) for an emergency dispensing order, but, if it does so, may extend the order as appropriate.

E. EMERGENCY USE INSTRUCTIONS WITHOUT AN EUA

CDC may create, issue, and disseminate special emergency use instructions (EUI) concerning an eligible MCM's approved, licensed, or cleared conditions of use (section 564A(e)).[72] EUI are intended to be similar to "Fact Sheets" that have been authorized in past EUAs, and may be directed to health care professionals and authorized dispensers or to recipients of an eligible MCM. EUI may be created and disseminated both before a CBRN event occurs and during a response.

During past public health emergencies, there were concerns that instructions for administering MCMs, even those MCMs that were FDA-approved for the disease or condition (e.g., doxycycline for post-exposure prophylaxis of inhalational anthrax), that deviate from FDA-approved product labeling would violate the FD&C Act and thus invalidate any liability protection otherwise provided under the PREP Act. When an EUI is issued pursuant to this provision, that issuance would not deprive the product of otherwise-applicable PREP Act protection. Therefore, the EUI provisions offer enhanced flexibility for CDC to prepare and disseminate EUI concerning a disease or condition for which an MCM is FDA-approved, licensed, or cleared without further limitation. FDA and CDC interpret this provision as permitting the creation of EUI that describe how the approved drug may be used, for the disease or condition for which it is approved, but in ways that may deviate from or extend beyond the FDA-approved labeling. EUI would not, on the other hand, be permitted to describe uses of an FDA-approved product for diseases or conditions for which the product has not been approved.

V. GOVERNMENTAL PRE-POSITIONING OF MCMs

A new provision added by PAHPRA permits pre-positioning of MCMs without FDA approval when the product(s) is intended to be held (and not used) for emergency use (section 564B), allowing stakeholders to prepare for rapid deployment of MCMs during an emergency. This authority allows government stakeholders, or a person acting on behalf of a government stakeholder, e.g., an agent of the government stakeholder, to introduce into interstate commerce (e.g., stockpile or transport) a medical product intended for emergency use without violating the FD&C Act regardless of a product's regulatory status (i.e., without an IND, IDE, or any other acknowledgement by FDA), but in anticipation that use will be permitted under an appropriate regulatory mechanism (i.e., FDA approval, authorization, or for investigational use).

The authority to pre-position MCMs applies to all categories of medical products intended for emergency use, including those that are approved, unapproved, investigational, or authorized for use under an EUA. However, a government stakeholder may only rely on this authority if the

[72] Section 564A(e) allows a designated HHS official to create and issue EUI. Although EUI authority is part of the FD&C Act, on the joint recommendation of FDA, CDC, and the ASPR, the Secretary of HHS granted the authority to create EUI to the Director of CDC (or his/her designee). Allowing CDC to create and disseminate EUI is consistent with CDC's clinical expertise in providing event-driven treatment recommendations and facilitating emergency response with external stakeholders, as well as its front-line role in managing the SNS of medical products for which EUI may be most needed. See FDA and CDC's Memorandum of Understanding related to EUI coordination at FDA's website: http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm487464.htm.

MCMs are in fact held and not used to diagnose, treat, or prevent the CBRN-related disease or condition until permitted under one of these mechanisms. This means, for example, that even though a government stakeholder may stockpile an unapproved MCM, additional action likely will be required to ensure that any pre-positioned MCM can be used when needed. FDA, therefore, recommends that government stakeholders also consider and, if appropriate, initiate steps to ensure an approval can be granted, or that an IND/IDE or EUA is in place or can be readily put in place if necessary.

Those relying on this provision will have to maintain documentation that shows the product qualifies to be held for emergency use, including records reflecting the government stakeholder's initial intent to hold and not use the MCM until such time as it may be used under an appropriate regulatory mechanism. At this time, FDA is not specifying any additional recordkeeping methods relating specifically to pre-positioned MCMs. The Agency recommends, however, that to the extent feasible government stakeholders maintain sufficient records or other information to be able to readily identify their pre-positioned MCMs (e.g., by product name, manufacturer's name, dosage form and strength, quantity held, lot number) as well as the distribution, storage, and ultimate disposition of those MCMs.[73] For unapproved products, this information likely will be an element of the records required to be maintained for use under an IND/IDE or EUA. In addition, this information will help minimize the risks of misidentification, theft or other loss, and product deterioration. As an example, an MCM that a government stakeholder cannot verify has been properly stored might not qualify for use under an EUA or for an otherwise applicable extension of the product's shelf life because of a lack of information about the condition of the product.

VI. PREEMPTION

FDA anticipates that conflicts between federal and state law[74] may arise when FDA acts under sections 564, 564A, and 564B if states have existing requirements governing the shipment, holding, dispensing, administration, or labeling of unapproved medical products or approved medical products for unapproved uses.[75] Courts have stated that the Supremacy Clause of the U.S. Constitution can operate to nullify both state legislative requirements and state common-law

[73] Absent a CGMP waiver (see section III.E.5 of this guidance), government stakeholders, or person(s) acting on their behalf, should continue to store and handle pre-positioned MCMs to support their use according to CGMP standards.

[74] While FDA believes that preemption applies here, it recognizes that this is a controversial area of the law. Because attorneys advising some state response programs may take a different view than that expressed here, FDA encourages state programs to consult with their legal counsel as to whether they believe that their states would need to take complementary legal action to assure that their state laws would not conflict with actions that the Federal government might take pursuant to section 564 and 564A or that might affect pre-positioning under section 564B. If such state action is considered to be necessary, it will be important that any required changes in state law, or any steps necessary to implement state laws to permit emergency preparedness actions pursuant to these sections, be determined as part of the state's emergency planning.

[75] Such issues may also arise when FDA issues a waiver of CGMP requirements pursuant to section 564A(c), or an order to permit emergency dispensing pursuant to section 564A(d).

duties.[76] Under the legal principles of implied conflict preemption, courts have found state law preempted where it is impossible to comply with both federal and state law, or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[77] Consistent with this case law, section 4(a) of Executive Order 13132 states that "[a]gencies shall construe... a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."[78]

FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564. Similarly, an order or waiver issued under section 564A and pre-positioning under section 564B preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements related to the activity authorized under sections 564A or 564B.

To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular medical product within the scope of the declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” and “conflicts with the exercise of Federal authority under [§ 564].” The same rationale applies to an order or waiver issued under section 564A and pre-positioning of an MCM under section 564B.

Affected state laws may include, but are not limited to, laws governing the administration of investigational medical products, such as informed consent laws and laws requiring Institutional Review Board approval, and laws governing the prescribing or dispensing of medical products, such as laws limiting who may prescribe or dispense medical products and under what circumstances.

Moreover, the PREP Act, which expressly provides immunity from tort liability associated with certain MCM activities, preempts state laws that are different from, or in conflict with, any requirement applicable to a covered countermeasure under the PREP

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[76] Medtronic v. Lohr, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); id. at 510 (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992) (plurality opinion); id. at 548-49 (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part). Under the same reasoning, state regulations and local ordinances would also be preempted.

[77] See Arizona v. United States, 132 S. Ct. 2492, 2501, 2505, 2507 (2012); Crosby v. National Foreign Trade Council, 530 U.S. 363, 373 (2000); Geier v. American Honda Motor Company, Inc., 529 U.S. 861, 873 (2000); Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

[78] Exec. Order No. 13132, 64 FR 43255 (August 4, 1999).

Act and relating to, among other things, any matter applicable because of a requirement of the FD&C Act.[79] This includes actions taken to meet the terms of an EUA, an order or waiver issued under section 564A, pre-positioning of an MCM under section 564B, an IND or IDE, or any FDA approval of an MCM.

In an emergency, it is critical that the conditions that are part of the EUA or an order or waiver issued pursuant to section 564A—those that FDA has determined to be necessary or appropriate to protect the public health—be strictly followed, and that no additional conditions be imposed. To the extent there may be circumstances in which FDA would like people carrying out activities under an EUA to also comply with requirements contained in preempted state law, FDA anticipates incorporating such requirements into the terms and conditions of the EUA.

Similarly, an extension of expiration dating under section 564A(b), a waiver of CGMP requirements under section 564A(c), and an FDA order permitting emergency dispensing pursuant to section 564A(d) are actions intended to protect the public health by enabling rapid public access to potentially life-saving medical products during an emergency. State laws that govern CGMP requirements or the dispensing of products covered by an FDA extension of expiration dating, CGMP waiver, or emergency dispensing order and that impose different or additional conditions that would limit the access to eligible products covered by FDA's action, would be an obstacle to achieving that goal. Therefore, FDA believes that state laws within the jurisdictional coverage of an FDA extension of expiration dating, CGMP waiver, or emergency dispensing order that impose more restrictive conditions or requirements on dispensing products covered by the FDA order, or pre-positioning of MCMs under section 564B will be preempted.

As noted above, however, state laws may permit emergency dispensing of eligible MCMs. Under section 564A(d), such laws may provide another basis on which government stakeholders may be able to provide for emergency dispensing without a prescription or adherence to other prescription requirements that might otherwise apply.[80] An FDA order issued under section 564A(d) is not intended to replace those frameworks as long as they are not more restrictive than the FDA's order in providing for access to the FDA-approved product(s) that the order covers.

VII. LIABILITY PROTECTION

Apart from any applicable preemption principles, sections 564, 564A, and 564B do not confer explicit liability protections for stakeholders who carry out any activity under these authorities.

[79] 42 U.S.C. § 247d-6d(b)(8).

[80] Whether or not a particular state legal provision or action is sufficient to permit the emergency dispensing strategy that state or local government stakeholders anticipate conducting within their state rests in large part on the interpretation of that state law, which is a matter that should first be directed to the appropriate legal authority within the relevant jurisdiction (e.g., the state Attorney General). To ensure clarity, and perhaps increase the likelihood that state laws, regulations, orders, or other legal actions to permit emergency dispensing are deemed sufficient, it is recommended that such actions address the same eligibility, scope, duration, and other elements FDA intends to address in its emergency dispensing orders, as described above.

The PREP Act,[81] however, may provide for immunity from tort liability related to activities authorized under such authorities. More specifically, the PREP Act authorizes the HHS Secretary to issue a declaration (called a PREP Act declaration) that provides immunity (except for willful misconduct) for claims related to administration or use of countermeasures against CBRN agents to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures.[82] The PREP Act authority, including the authority to issue PREP Act declarations, resides with the Secretary of HHS and has not been delegated to FDA.

The PREP Act liability protections apply to "covered countermeasures" as defined by the statute.[83] Covered countermeasures include medical products that are approved, cleared, or licensed by FDA; authorized for investigational use under an IND or IDE by FDA; authorized for emergency use under section 564; or otherwise permitted to be held or used pursuant to sections 564A and 564B. As discussed in section IV of this guidance, in the past, EUAs have been issued in part to address concerns that certain activities related to MCMs potentially violated provisions of the FD&C Act, jeopardizing otherwise-applicable PREP Act protections. PAHPRA added sections 564A and 564B to the definitions of "covered countermeasure" in part to preserve these otherwise-applicable PREP Act protections.

VIII. IMPORTING AND EXPORTING MEDICAL PRODUCTS UNDER AN EUA

Although an EUA is not an FDA-approval, a medical product authorized for emergency use under an EUA may be introduced into interstate commerce during the effective period of the EUA declaration, and as such, contingent upon compliance with the terms and conditions of the authorization, may be legally imported and exported under section 801 of the FD&C Act (21 U.S.C. 381). The letter of authorization should serve as appropriate documentation or certification that the product may be legally imported or exported.

In the past, FDA has received EUA requests for which the primary emergency use of the investigational medical product would be in a foreign country (e.g. for use in West Africa during the Ebola crisis). The assessment of whether to issue an EUA in these cases is the same as for any other emergency use: FDA must determine whether the requisite EUA determination, declaration, and criteria (as described in section III.A and III.B of this guidance) are met and consider whether it is feasible or practicable in the foreign setting to comply with the necessary and appropriate conditions of use (as described in section III.E of this guidance).

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[81] 42 U.S.C. 247d-6d. For information on the PREP Act, see HHS's website at http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

[82] 42 U.S.C. 247d-6d(b).

[83] 42 U.S.C.247d-6d(i)(1) and (7).

IX. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 85 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection.

Send comments regarding this burden estimate or suggestions for reducing this burden to: Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

This guidance refers to previously approved collections of information found in FDA regulations. The collections of information for: adverse experience reporting for biological products is approved under OMB control number 0910-0308; adverse drug experience reporting is approved under OMB control number 0910-0230; adverse device experience reporting is approved under OMB control number 0910-0471; investigational new drug application regulations are approved under OMB control number 0910-0014; and investigational device exemption reporting is approved under OMB control number 0910-0078.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0595 (expires 08/31/2019).

List of Acronyms

Assistant Secretary for Preparedness and Response (ASPR)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Centers for Disease Control and Prevention (CDC)
Center for Drug Evaluation and Research (CDER)
Chemical, biological, radiological, and nuclear (CBRN)
Clinical Laboratory Improvement Amendments (CLIA)
Current Good Manufacturing Practice (CGMP)
Department of Health and Human Services (HHS)
Department of Homeland Security (DHS)
Department of Defense (DoD)
Emergency Use Authorizations (EUAs)
Emergency Use Instructions (EUI)
Federal Food, Drug, and Cosmetic Act (FD&C Act)
Federal Shelf-Life Extension Program (SLEP)
Food and Drug Administration (FDA)
Good Laboratory Practice for Nonclinical Laboratory Studies regulations (GLP)
Investigational Device Exemption (IDE)
Investigational New Drug Application (IND)
In Vitro Diagnostic (IVD)
Medical Countermeasure (MCM)
National Institutes of Health (NIH)
Office of Counterterrorism and Emerging Threats (OCET)
Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)
Points of Dispensing (PODs)
Public Health Service (PHS) Act
Public Readiness and Emergency Preparedness (PREP) Act
Risk Evaluation and Mitigation Strategy (REMS)
Safety Information and Adverse Event Reporting System (MedWatch)
Secretary of Health and Human Services (HHS Secretary or Secretary of HHS)
Strategic National Stockpile (SNS)
Vaccine Adverse Event Reporting System (VAERS)
World Health Organization (WHO)

Appendix A. EUA Conditions of Authorization: Required[a] vs. Discretionary[b]

Condition	Unapproved Product	Unapproved Use of an Approved Product	FD&C Act Section
Information ("fact sheets") for healthcare providers administering the product (significant known/potential benefits/risks of product and extent to which benefits/ risks are unknown; FDA has authorized emergency use)	Required	Required	§ 564(e)(1)(A)(i) § 564(e)(2)(A)
Information ("fact sheets") for product recipients (significant known/potential benefits/risks of product and extent to which benefits/ risks are unknown, option to accept or refuse product, consequences of refusing, available alternatives, FDA has authorized emergency use)	Required	Required	§ 564(e)(1)(A)(ii) § 564(e)(2)(A)
Adverse event monitoring and reporting	Required	Discretionary	§ 564(e)(1)(A)(iii) § 564(e)(2)(A)
Recordkeeping and reporting (by product manufacturers)	Required	Discretionary	§ 564(e)(1)(A)(iv) § 564(e)(2)(A)
Recordkeeping and reporting (by persons other than product manufacturers)	Discretionary	Discretionary	§ 564(e)(1)(B)(iv) § 564(e)(2)(A)
Product distribution (which entities may distribute product and how to perform distribution)	Discretionary	Discretionary[c]	§ 564(e)(1)(B)(i) § 564(e)(2)(A)
Product administration (who may administer product and categories of individuals to whom, and circumstances under which, product may be administered)	Discretionary	Discretionary[c]	§ 564(e)(1)(B)(ii) § 564(e)(2)(A)
Data collection and analysis (concerning product safety/effectiveness)	Discretionary	Discretionary	§ 564(e)(1)(B)(iii) § 564(e)(2)(A)
CGMP and prescription waiver or limit	Discretionary	Discretionary	§ 564(e)(3)
Advertising/other promotional material	Discretionary	Discretionary	§ 564(e)(4)
Other (any other condition FDA finds necessary or appropriate to protect the public health)	Discretionary	Discretionary	§ 564(e)(1)(B) § 564(e)(2)(A)

[a] Under section 564(e)(1)(A) of the FD&C Act, "required conditions" must be imposed by FDA in an EUA to the extent practicable given the applicable circumstances described in the HHS Secretary's EUA declaration under section 564(b)(1) of the FD&C Act. See also section 564(e)(2)(A) (same rule for unapproved uses of an approved drug).

[b] Discretionary conditions may be included in an EUA at FDA's discretion as deemed necessary to protect the public health. See section 564(e)(1)(B); section 564(e)(2)(A).

[c] Such conditions for an unapproved use of an approved product may not restrict distribution or administration of the product when it is distributed or administered for the approved use. See section 564(e)(2)(C).