[ORAL ARGUMENT NOT REQUESTED]

No. 22-1032

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

DAN ROBERT, SSGT, U.S. Army; HOLLIE MULVIHILL, SSGT, USMC and other similarly situated individuals,

Plaintiffs-Appellants,

v.

LLOYD AUSTIN, in his official capacity as Secretary of Defense, U.S. Department of Defense; XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; ROBERT CALIFF, U.S. Commissioner of Food and Drugs,

Defendants-Appellees.*

On Appeal from the United States District Court for the District of Colorado
District Court Case No. 1:21-cv-02228-RM-STV (Judge Moore)

BRIEF FOR APPELLEES

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*Robert Califf, U.S. Commissioner of Food and Drugs, has been automatically substituted for Janet Woodcock as a defendant, pursuant to Federal Rule of Appellate Procedure 43(c)(2).

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STATEMENT CONCERNING PRIOR OR RELATED APPEALS

Counsel for appellees are not aware of any prior or related appeals.

GLOSSARY

DoD	U.S. Department of Defense
EUA	Emergency Use Authorization
FDA	U.S. Food and Drug Administration
HHS	U.S. Department of Health and Human Services
Opening Br.	Brief of Appellants

STATEMENT OF JURISDICTION

Plaintiffs asserted jurisdiction in the district court under 28 U.S.C. §§ 1331, 1346, and 1361; 5 U.S.C. § 702; and 28 U.S.C. § 2201. The district court granted the government's motion to dismiss on standing and ripeness grounds and denied plaintiffs' motion for a preliminary injunction on January 11, 2022. ADD6.[1] Plaintiffs filed a timely notice of appeal on February 1, 2022, *see* A188, Fed. R. App. P. 4(a)(1)(B), and assert appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Plaintiffs are two military service members who object to the military's COVID-19 vaccination requirement on the basis that the currently available COVID-19 vaccines are, in their view, unsafe and ineffective. Plaintiffs have sued the Department of Defense (DoD), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Health and Human Services (HHS), alleging that DoD lacks authority to require them to receive a COVID-19 vaccine. But plaintiffs' assertions of injury are speculative and contingent. Not only was plaintiffs' suit instituted before COVID-19 vaccination was even required for service members, neither plaintiff is currently required to receive a COVID-19 vaccine: Plaintiff Hollie Mulvihill has a temporary medical exemption from the vaccination requirement, and plaintiff Dan Robert has a pending request for

[1] Citations to "ADD__" are to the addendum to plaintiffs' opening brief. Citations to "A__" are to plaintiffs' Appendix. Citations to "SA__" are to defendants' Supplemental Appendix.

an administrative exemption from the requirement. The district court dismissed plaintiffs' amended complaint, holding that plaintiffs' claims were not justiciable because they turned on speculative assertions of injury. The issue presented is:

Whether the district court correctly dismissed this action and denied a preliminary injunction on the ground that plaintiffs' claims are not justiciable.

PERTINENT STATUTES

Pertinent statutes are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Licensure and Emergency Use Authorization for Vaccines

The Public Health Service Act generally prohibits the introduction of biological products like vaccines into interstate commerce absent an approved biologics license from FDA. *See* 42 U.S.C. § 262(a)(1)(A), (i)(1); *see also* SA110 (Dkt. No. 37-11, Marks Decl. ¶ 4). To obtain a license, a manufacturer must submit an application to FDA, which then determines, among other things, whether the product is "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C); *see also* SA110-11 (Dkt. No. 37-11, Marks Decl. ¶ 5).

Separately, the Federal Food, Drug, and Cosmetic Act permits FDA to authorize the introduction of vaccines or other biological products that are "intended for use in an actual or potential emergency." 21 U.S.C. § 360bbb-3(a)(1). In the event of a current or impending public-health emergency, the HHS Secretary may declare that circumstances justifying an emergency use authorization (EUA) exist, *id.* § 360bbb-3(b)(1), (i), and FDA may then issue an EUA for vaccines or other products intended for use in

diagnosing, treating, or preventing the disease or condition that caused the emergency. *Id.* § 360bbb-3(c)(1); *see also* SA111-12 (Dkt. No. 37-11, Marks Decl. ¶ 7).

When issuing an EUA for a vaccine, FDA assesses whether it is reasonable to believe that the vaccine is effective "based on the totality of scientific evidence . . . , including data from adequate and well-controlled clinical trials, if available," and whether the vaccine's benefits outweigh its risks, 21 U.S.C. § 360bbb-3(c)(2), as well as whether there is any "adequate, approved, and available alternative to the product," *id.* § 360bbb-3(c)(3). FDA may revoke an EUA if either the emergency or the conditions required for an EUA are no longer present. *Id.* § 360bbb-3(g)(1), (2); *see id.* § 360bbb-3(f)(1).

The EUA statute empowers the HHS Secretary to impose conditions on EUAs that the Secretary "finds necessary or appropriate to protect public health," including "[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed" of "the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." 21 U.S.C. § 360bbb-3(e)(1)(A); *id.* § 360bbb-3(e)(1)(A)(ii)(III). Where an EUA product includes a condition that individuals be informed of their option to refuse the product, the condition may be waived as to members of the armed forces "only by the President" and "only if the President determines, in writing, that complying with such requirement

is not in the interests of national security." 10 U.S.C. § 1107a(a)(1). A similar requirement applies to the administration of "an investigational new drug or a drug unapproved for its applied use" to a member of the armed forces "in connection with the member's participation in a particular military operation." *Id.* § 1107(f)(1) (stating that a service member must provide prior consent to receive such a drug, unless the prior consent requirement has been waived by the President following the President's determination, "in writing, that obtaining consent is not in the interests of national security").[2]

B. The Development and Approval of the Pfizer Vaccine

In response to the COVID-19 pandemic, FDA has permitted the distribution of a vaccine manufactured by Pfizer and BioNTech, first pursuant to an EUA and now also pursuant to an approved biologics license application under the tradename Comirnaty. For ease, this brief refers to these products as the Pfizer vaccine.

1. In February 2020, the Secretary of Health and Human Services determined that a "public health emergency" existed "that involve[d] a novel (new) coronavirus . . . first detected in Wuhan City, Hubei Province, China in 2019," known as

[2] A drug unapproved for its applied use is "a drug administered for a use not described in the approved labeling of the drug under" 21 U.S.C. § 355. *See* 10 U.S.C. § 1107(g)(2). An investigational new drug is a "drug[] intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." 21 U.S.C. § 355(i); *see also* 10 U.S.C. § 1107(g)(1). The use of an EUA product within the scope of its authorization does not "constitute a clinical investigation for purposes of section 355(i)" or other enumerated statutory provisions. 21 U.S.C. § 360bbb-3(k).

SARS-CoV-2, the virus that causes COVID-19. *Determination of Public Health Emergency*, 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). The following month, the Secretary declared that "circumstances exist justifying the authorization of emergency use of drugs and biological products." *Emergency Use Authorization Declaration*, 85 Fed. Reg. 18,250, 18,250-51 (Apr. 1, 2020). The Secretary's determination and declaration remain in effect.

FDA issued an EUA in December 2020 for the then-unlicensed Pfizer vaccine for individuals 16 and older. *See* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* 6-8 (Dec. 11, 2020), https://go.usa.gov/xzpzn; *see also* SA111-12 (Dkt. No. 37-11, Marks Decl. ¶ 7). FDA has since reissued the EUA multiple times to update the vaccine's labeling with information on any safety issues and to incorporate EUA amendments. *See* FDA, *Emergency Use Authorization*, https://go.usa.gov/xzpuX (last updated May 25, 2022). Those amendments have, for instance, extended the authorization first to children 12 to 15 and then to children 5 to 11, and authorized administering booster doses in certain populations. *Id.*

2. On August 23, 2021, FDA approved a license for the Pfizer vaccine for individuals 16 and older. *See* A33; *see also* SA111 (Dkt. No. 37-11, Marks Decl. ¶ 6); FDA, *Summary Basis for Regulatory Action* 22-23 (Nov. 8, 2021), https://go.usa.gov/xzdcg (summarizing clinical studies on the vaccine's safety and effectiveness). FDA thus de-

termined that the vaccine met the "high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product." FDA News Release, *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://go.usa.gov/xuJqV.

When it licensed the Pfizer vaccine, FDA contemporaneously reissued an EUA for the product. *See* A45-46; SA112 (Dkt. No. 37-11, Marks Decl. ¶ 8); *see also* A49 & n.9. FDA explained that the licensed vaccine has "the same formulation" as the corresponding EUA-authorized vaccine and that they can be substituted for one another in a series of vaccine doses "without presenting any safety or effectiveness concerns," A46 n.8, although the agency recognized that a licensed vaccine and an EUA vaccine are "legally distinct," and subject to separate statutory regimes. *Id.*; *see* FDA, *Q&A for Comirnaty (COVID-19 Vaccine mRNA)*, https://go.usa.gov/xucdP (last updated Feb. 8, 2022) (detailing distinctions between licensed and EUA vaccine); SA112 (Dkt. No. 37-11, Marks Decl. ¶ 9).

3. Separately, FDA has issued an EUA and approved a license for the COVID-19 vaccine manufactured by ModernaTX, Inc. (under the tradename Spikevax), and issued an EUA for a vaccine manufactured by Janssen Biotech, Inc., a subsidiary of Johnson & Johnson.

C. The Military's COVID-19 Vaccination Requirement

The military has long required that service members receive a range of vaccinations. *See, e.g.*, SA106 (Dkt. 37-10, Defense Health Primer 1); *see also* Stanley M. Lemon, et al., *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military*

11-12 (2002), https://perma.cc/E545-TQ9G (recounting George Washington's instruction to inoculate the Continental Army against smallpox). Even before the COVID-19 vaccines were approved, nine vaccines were required for all service members, and eight others were required in the presence of certain risk factors. *See* SA76 (Dkt. No. 37-6, Army Regulation 40-562, Table D-1). This approach implements the directive of DoD Instruction 6205.02, which states that the military departments should, "[t]o the maximum extent practicable, provide for the immunization of personnel for protection against . . . naturally occurring infectious diseases of military or national importance, in time to develop sufficient immunity before deployment." SA32 (Dkt. No. 37-5, DoD Instruction 6205.02, at 12).

COVID-19 has taken a serious toll on the military. *See, e.g.*, SA133-37 (Dkt. No. 37-12, Rans Decl. ¶¶ 9-12). On August 9, 2021, after FDA had issued the Pfizer EUA but before FDA had approved the Pfizer license, Secretary of Defense Lloyd Austin announced that he would "seek the President's approval to make" the COVID-19 vaccination "mandatory no later than mid-September, or immediately upon the [FDA] licensure, whichever comes first." SA18 (Dkt. No. 37-2, DoD Message to the Force). On August 23, 2021, FDA licensed the Pfizer vaccine. The following day, Secretary Austin added COVID-19 vaccination to the required list of vaccines for active-duty and reserve service members. SA19 (Dkt. No. 37-3) (DoD Directive). That announcement

stated that "[m]andatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from" FDA, "in accordance with FDA-approved labeling and guidance." SA19 (Dkt. No. 37-3).

Following the DoD Directive, each military service provided specific guidance implementing the COVID-19 vaccination requirement. SA83 (Dkt. No. 37-7, Fragmentary Order "FRAGO" 5 to Army Executive Order 225-21) (implementing the requirement for the Army); SA96 (Dkt. No. 37-9, MARADMIN 462/21 and 533/21) (implementing the requirement for the Marine Corps).

As with other vaccination requirements, each service has a process through which service members can seek medical or administrative exemptions to the COVID-19 vaccination requirement. SA88-90 (Dkt. No. 37-7, FRAGO 5 to Army Executive Order 225-21, ¶ 3.D.8.B.6); SA98-99 (Dkt. No. 37-9, MARADMIN 462/21 ¶¶ 3j, 3k). Medical exceptions are granted to service members by medical personnel for medical reasons. SA156-57 (Dkt. No. 37-14, Soltis Decl. ¶¶ 10-12); SA167-69 (Dkt. No. 37-15, Huntley Decl. ¶¶ 6-8). Administrative exceptions cover a variety of situations from pending separation or retirement to religious accommodation. SA156, SA160 (Dkt. No. 37-14, Soltis Decl. ¶¶ 10, 18); SA171-72 (Dkt. No. 37-15, Huntley Decl. ¶ 12).

Each service also has an appeal process available to service members seeking exemptions if their initial requests are denied. SA157-61 (Dkt. No. 37-14, Soltis Decl. ¶¶ 13, 17, 19-20); SA172 (Dkt. No. 37-15, Huntley Decl. ¶ 12.b). A service member who refuses vaccination without an approved exemption may be subject to discipline

or adverse administrative action, but in no event would the vaccine be forcibly administered to the service member. SA166 (Dkt. No. 37-15, Huntley Decl. ¶ 4 n.2). In addition, no adverse action will be taken against a service member with a pending exemption request. SA155, SA159-61, SA163 (Dkt. No. 37-14, Soltis Decl. ¶¶ 8, 17, 20, 24); SA169 (Dkt. No. 37-15, Huntley Decl. ¶ 9 n.5).

D. Factual and Procedural Background

1. Plaintiffs are Dan Robert, a Staff Sergeant in the U.S. Army, and Hollie Mulvihill, a Staff Sergeant in the U.S. Marine Corps. They brought this suit on August 17, 2021 against DoD, HHS, and FDA—after Secretary Austin had announced that he would seek to require COVID-19 vaccination, but before the requirement had actually been implemented—preemptively challenging DoD's authority to require them to be vaccinated against COVID-19. *See* A5; SA3 (Dkt. No. 1, Original Compl. 1-2). In October 2021, Plaintiffs filed their second amended (and operative) complaint.

Plaintiffs have been infected with COVID-19 in the past but do not want to receive any COVID-19 vaccine. A13-15. Plaintiffs claim that the DoD Directive is contrary to DoD regulations, as well as various statutory provisions, and that it violates plaintiffs' equal protection rights by treating individuals with "naturally acquired immunity" (i.e., individuals who have previously been infected with COVID-19) differently from individuals with "artificially induced immunity through mRNA injectables" (i.e., individuals who have been vaccinated). A31; *see also* A27-30.

The complaint is filed on behalf of a putative class of all service members who have had COVID-19 or who have been ordered to take a COVID-19 vaccine, A16-18, but plaintiffs have not filed a motion for class certification.

2. In November 2021, plaintiffs moved for a preliminary injunction requiring DoD (1) "to stop [the] inoculation of [p]laintiffs and those similarly situated to them with . . . any unlicensed vaccines," (2) to exempt all service members who have had COVID-19 from the DoD Directive, and (3) to refrain "from retaliating against or in any other way professionally damaging" service members who refuse to comply with the DoD Directive. Dkt. No. 30, at 23. The government opposed the preliminary injunction motion and moved to dismiss. Dkt. No. 37.

The district court granted the government's motion to dismiss and denied plaintiffs' motion for a preliminary injunction. ADD1. The district court concluded that plaintiffs' claims were not justiciable and therefore must be dismissed on the ground that they rest on "uncertain and contingent events." ADD6. The district court observed that one plaintiff had obtained a temporary medical exemption and the other had a pending exemption request, and that if the exemptions were to expire or be denied, plaintiffs could appeal through the military's administrative processes. *See* ADD5-6; *see also* SA180-81 (Dkt. No. 37-16, Wilcox Decl. ¶¶ 3-4); Dkt. No. 37-17, at ¶ 9. As a result,

the district court reasoned, "[p]laintiffs' contention that they may be subject to discipline for refusing to take a vaccine appears to be based on nothing more than speculation." ADD6. The district court therefore dismissed the action. ADD6.[3]

SUMMARY OF ARGUMENT

On August 24, 2021, Secretary Lloyd Austin issued an order requiring all service members to be vaccinated against COVID-19. But plaintiffs brought this suit before DoD issued that directive and determined its parameters. And even now, plaintiffs are not subject to the COVID-19 vaccination requirement, as one plaintiff currently has an exemption and the other has a pending exemption request.

The district court thus rightly determined that plaintiffs' claims are not justiciable. Plaintiffs lack standing to challenge the DoD Directive. Their alleged injuries are not concrete, particularized, or imminent, but rather contingent and speculative. Plaintiffs do not yet know if the military will ever require them to receive a COVID-19 vaccine. And even if they were to receive such an order after exhausting the exemption request process, they can still challenge any potential adverse action through the military's administrative procedures. Plaintiffs' claims are not yet ripe for many of the same reasons. As long as plaintiffs' claims rely on "uncertain or contingent future events that may not occur as anticipated," *Southern Utah Wilderness All. v. Palma*, 707 F.3d 1143, 1158

[3] The district court also observed that there was a "complete lack of allegations pertaining to any conduct by" HHS or FDA "that could be deemed to state a claim against either entity." ADD6 n.1.

(10th Cir. 2013) (quoting *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1097 (10th Cir. 2006)), judicial intervention is premature. And enforcement of these justiciability principles is all the more critical where, as here, plaintiffs' requested relief would infringe on the military's professional judgment and ability to make significant operational decisions.

Even if the Court were to conclude that plaintiffs' claims against DoD were justiciable, it should affirm the district court's dismissal of those claims against FDA and HHS. Plaintiffs have not been injured by any action of FDA or HHS and plaintiffs do not demand any action from those defendants, let alone one that could redress their alleged harms. DoD's discretion to determine what vaccines are necessary for service members to receive, and under what circumstances, is independent of any action by FDA or HHS in authorizing or approving the use of a particular vaccine. Neither the EUA nor the license for the Pfizer vaccine requires DoD to take any action or requires any individual to be vaccinated. Plaintiffs therefore lack standing against FDA and HHS.

STANDARD OF REVIEW

The district court's dismissal for lack of subject-matter jurisdiction is reviewed de novo. *United States ex rel. Hafter D.O. v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1160 (10th Cir. 1999).

ARGUMENT

I. The district court correctly concluded that plaintiffs' claims challenging the future application of DoD's COVID-19 vaccination requirement are not justiciable.

Plaintiffs' claims turn on speculative and contingent claims of injury and are therefore not justiciable under both standing and ripeness doctrines. "Both standing and ripeness present the threshold jurisdictional question of whether a court may consider the merits of a dispute." *Southern Utah Wilderness All. v. Palma*, 707 F.3d 1143, 1152 (10th Cir. 2013). The doctrines "substantially overlap in many cases," and require plaintiffs to establish that their claims of injury do not rely on contingent future events. *Id.* at 1157-58. Indeed, because the ripeness inquiry asks whether an injury—even if sufficient to support standing were it to occur immediately—is imminent enough to warrant judicial intervention, it is often "characterized as standing on a timeline." *Id.* at 1157 (quoting *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1138 (9th Cir. 2000) (en banc)). Plaintiffs' claims must be dismissed under both doctrines. Moreover, because plaintiffs' claims are not justiciable, the district court correctly concluded that plaintiffs were not entitled to preliminary relief.

A. Plaintiffs lack standing to challenge the DoD Directive.

"To establish Article III standing, an injury must be 'concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.'" *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010)). Where a plaintiff's injury has not

yet occurred, the "threatened injury must be *certainly impending* to constitute injury in fact"; "'[a]llegations of *possible* future injury' are not sufficient." *Id.* (alteration in original) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). This is especially true when plaintiffs' suit touches on areas within the political branches' expertise. *Id.* at 408-09; *Orloff v. Willoughby*, 345 U.S. 83, 94 (1953) ("Orderly government requires that the judiciary be as scrupulous not to interfere with legitimate Army matters."); *Bois v. Marsh*, 801 F.2d 462, 468 (D.C. Cir. 1986) ("[C]ivilian courts must, at the very least, hesitate long before entertaining a suit which asks the court to tamper with the established relationship between enlisted military personnel and their superior officers." (quoting *Chappell v. Wallace*, 462 U.S. 296, 300 (1983))).

1. Plaintiffs have not alleged an actual or imminent injury. "[S]tanding is determined at the time the action is brought." *Southern Utah Wilderness All.*, 707 F.3d at 1152-53 (quoting *Mink v. Suthers*, 482 F.3d 1244, 1253 (10th Cir. 2007)); *see also Nova Health Sys. v. Gandy*, 416 F.3d 1149, 1154 (10th Cir. 2005). While a court may consider allegations from an amended complaint in assessing plaintiffs' standing, the "inquiry focuses on whether [plaintiffs] had standing when the original complaint was filed." *Southern Utah Wilderness All.*, 707 F.3d at 1152-53. When plaintiffs brought this suit on August 17, the DoD Directive had not yet been issued. SA3 (Dkt. No. 1, Original Compl.). The military had not yet implemented a COVID-19 vaccination requirement, and the parameters of any such requirement had not yet been determined. Plaintiffs could not do anything more than speculate about the contours of and exemptions to

any future vaccination requirement and its exemptions. And they could only speculate that they would be denied an exemption, that they would ultimately be ordered to receive the COVID-19 vaccine, and that they would then suffer adverse consequences from either taking or refusing the vaccine. Plaintiffs' alleged injury was not "certainly impending," *Clapper*, 568 U.S. at 409 (emphasis omitted) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 n.2 (1992)); it was quintessentially "conjectural" and "hypothetical," *Lujan*, 504 U.S. at 560 (quoting *Whitmore*, 495 U.S. at 155).

Nor would plaintiffs' purported injuries be redressed if they were to obtain a court order requiring the military to provide them with a vaccine available under an FDA license and not an EUA. Plaintiffs already have access to vaccines manufactured in compliance with an approved license. *See* SA114-15 (Dkt. No. 37-11, Marks Decl. ¶¶ 13-14); SA141 (Dkt. No. 37-12, Rans Decl. ¶ 18). And, in any event, the EUA and licensed vaccines are not medically distinct. *See* SA112 (Dkt. No. 37-11, Marks Decl. ¶ 9).

2. Subsequent developments have confirmed the contingent nature of plaintiffs' assertions of injury. Plaintiff Mulvihill sought and obtained a temporary medical exemption from the COVID-19 vaccination requirement, with the ability to periodically renew that exemption. Dkt. No. 37-17, at ¶ 9. And plaintiff Robert has sought an administrative exemption from the vaccination requirement. SA181-82 (Dkt. No. 37-16, Wilcox Decl. ¶ 3). That request is pending, and he will not be subject to the COVID-19 vaccination requirement during the pendency of that request, including during any

administrative appeal of an exemption denial. *Id.* Accordingly, neither plaintiff is facing a "direct and immediate dilemma" as a result of the challenged DoD directive. *Wyoming v. Zinke*, 871 F.3d 1133, 1143 (10th Cir. 2017) (quoting *Awad v. Ziriax*, 670 F.3d 1111, 1125 (10th Cir. 2012)). Nowhere in their opening brief do plaintiffs argue that anything has changed that makes their injuries more imminent. Nor could they, as Robert still has a pending administrative exemption request and Mulvihill still has a temporary medical exemption.

B. Plaintiffs' claims are not ripe.

Plaintiffs' lack of non-speculative injury also renders their claims unripe for review. The basic purpose of the ripeness doctrine "is to prevent the courts, through premature adjudication, from entangling themselves in abstract disagreements." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580 (1985) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967)); *see also Los Alamos Study Grp. v. U.S. Dep't of Energy*, 692 F.3d 1057, 1064 (10th Cir. 2012).

When a government policy is challenged, the ripeness doctrine protects the government "from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Southern Utah Wilderness All.*, 707 F.3d at 1158 (quoting *Abbott Labs.*, 387 U.S. at 148-49). The analysis focuses "on whether the case involves uncertain or contingent future events that may not occur as anticipated, or indeed may not occur at all." *Id.* (quoting *Initiative & Referendum Inst.*, 450 F.3d at 1097); *Los Alamos Study Grp.*, 692 F.3d at 1065; *see also Ohio*

Forestry Ass'n v. Sierra Club, 523 U.S. 726, 734 (1998) (explaining that a challenge was not ripe when the plaintiff would have "ample opportunity later to bring its legal challenge at a time when harm is more imminent and more certain"). The doctrine applies with particular force when a plaintiff asks the judiciary to review the actions of a co-equal branch of the federal government. *Raines v. Byrd*, 521 U.S. 811, 819-20 (1997); *see also Orloff*, 345 U.S. at 94.

Whether a claim is ripe depends on "1) whether delayed review would cause hardship to the plaintiffs; 2) whether judicial intervention would inappropriately interfere with further administrative action; and 3) whether the courts would benefit from further factual development of the issues presented." *Los Alamos Study Grp.*, 692 F.3d at 1065 n.1 (quoting *Sierra Club v. U.S. Dep't of Energy*, 287 F.3d 1256, 1262-63 (10th Cir. 2002)). Each factor demonstrates that plaintiffs' claims are not ripe.

First, delayed review would cause no hardship to plaintiffs, as they are not currently required to receive a COVID-19 vaccination and will have further opportunity to challenge any exemption denial or vaccination order that they might eventually receive. The military has extensive administrative procedures that offer plaintiffs multiple opportunities to present their arguments to their Service and for their Service to respond. *See* SA161-63 (Dkt. No. 37-14, Soltis Decl. ¶¶ 21-23); SA172-77 (Dkt. No. 37-15, Huntley Decl. ¶¶ 13-21). Any service member subject to discipline can challenge the lawfulness of the vaccination requirement in those military proceedings. *See United States v. Kisala*, 64 M.J. 50 (C.A.A.F. 2006). For an adverse action less than discharge, each

Service also has administrative procedures that can provide relief. *See* SA161-62 (Dkt. No. 37-14, Soltis Decl. ¶¶ 21-22); SA172-74 (Dkt. No. 37-15, Huntley Decl. ¶¶ 13-14). And if a service member is ultimately discharged following the initiation of separation proceedings, that discharge can be appealed to the applicable Discharge Review Board and Board of Correction of Military Records. *See* SA162-63 (Dkt. No. 37-14, Soltis Decl. ¶ 23); SA177-78 (Dkt. No. 37-15, Huntley Decl. ¶ 22). In the meantime, plaintiffs will suffer none of the harms that they allege will result from the COVID-19 vaccination requirement.

Second, judicial intervention would inappropriately interfere with further administrative action—a concern that is of particular importance in the military context. *Orloff*, 345 U.S. at 94; *Gilligan v. Morgan*, 413 U.S. 1, 10 (1973) ("The complex[,] subtle, and professional decisions as to the composition, training, equipping, and control of a military force are essentially professional military judgments, subject *always* to civilian control of the Legislative and Executive Branches."); *see also Rostker v. Goldberg*, 453 U.S. 57, 66 (1981) (noting the "healthy deference to legislative and executive judgments in the area of military affairs"). The military has not made a decision—much less a final decision—as to whether either plaintiff will be required to receive a COVID-19 vaccine. If such a decision were reached, plaintiffs could then avail themselves of further administrative procedures challenging that decision. Judicial intervention would short-circuit that process and "require the Court to adjudicate internal military affairs before the military chain of command has had full opportunity to consider" plaintiffs' requests.

Church v. Biden, 2021 WL 5179215, at *11 (D.D.C. Nov. 8, 2021). That would in turn "undermine the purpose of exhaustion and infringe on the military's expertise and interest in handling its own personnel matters." *Id.*

Third, and for similar reasons, the courts would benefit from further factual development of the issues presented. Any judicial review of plaintiffs' claims should wait until the military has had the opportunity to determine in the first instance whether plaintiffs will be subject to the vaccine requirement or whether their individual circumstances warrant an exemption.

C. Plaintiffs' arguments on justiciability are unavailing.

1. According to plaintiffs, it is "certain" that "the military [will] enforce its own Covid mandate." Opening Br. 21. But that argument fails to engage with the requirement that any injury must be imminent. It does not follow from the fact that the military has enforced and will continue to enforce the DoD Directive against other service members that plaintiffs, with their pending or granted exemption requests, are at imminent risk of injury. Nor does the fact that other service members have been "separated from the military after exhausting all of their appeals" (Opening Br. 28) advance plaintiffs' case. Plaintiffs have not been denied exemptions, much less exhausted all of their administrative appeals. Moreover, because the military's adjudication of exemption requests and (if necessary) separation proceedings is individualized, plaintiffs cannot generate a ripe claim for themselves based on other service members' circumstances.

2. Plaintiffs also contend that they are being "systematically den[ied]" "medical and other long-established exemptions from the (unlawful) Covid mandates." Opening Br. 21. But plaintiffs do not explain how they are harmed by that alleged denial in light of the fact that neither of them is currently subject to the COVID-19 vaccination requirement. *See* Dkt. No. 37-17, at ¶ 9; *see also* SA181-82 (Dkt. No. 37-16, Wilcox Decl. ¶ 3). Nor can plaintiffs salvage their claim with reference (Opening Br. 27) to the general principle that well-pleaded factual allegations in a complaint must be accepted as true at the pleading stage. The facts as alleged demonstrate that plaintiffs are not currently required to be vaccinated and are not currently at imminent risk of injury.

3. Plaintiffs' objection to the vaccine based on the "risk of permanent injury" from adverse vaccine reactions (Opening Br. 31-34) is likewise too speculative to confer standing or to establish a ripe claim. *See Clapper*, 568 U.S. at 414 n.5 (explaining that plaintiffs must at least allege "a 'substantial risk' that the harm will occur" (quoting *Monsanto Co.*, 561 U.S. at 153)). Plaintiffs are currently not required to receive a COVID-19 vaccine, nor would the military forcibly vaccinate service members even if their exemptions expire or are ultimately denied. SA166 (Dkt. No. 37-15, Huntley Decl. ¶ 4 n.2). In any event, plaintiffs' assertion in their opening brief that the vaccine poses an "ultra-high risk of harm or death" (Opening Br. 32; *see also id.* at 17) is not even supported by their complaint, which alleges only that the vaccine has an "unknown long-term safety profile." *See* A26-29.

4. Plaintiffs also claim that "[i]t is fully ripe that Defendant Austin violated the significant limitations on DOD's ability to involuntary inoculate service members." Opening Br. 29 (citing 10 U.S.C. §§ 1107, 1107a). Specifically, plaintiffs assert that a presidential waiver was required before any service member could be required to receive the vaccine. *Id.* These assertions are meritless: 10 U.S.C. § 1107 and 10 U.S.C. § 1107a do not apply here, because the Pfizer and Moderna vaccines have received full FDA licenses. In any event, plaintiffs are not injured by the alleged "involuntary inoculat[ion]" of other service members (Opening Br. 29); generalized grievances and policy disagreements are not sufficient to confer standing. *Lujan*, 504 U.S. at 560 n.1 (explaining that "the injury must affect the plaintiff in a personal and individual way").

The Sixth Circuit recently held as much in a suit challenging the FDA's restrictions on the use of hydroxychloroquine to treat COVID-19. *See Association of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 535 (6th Cir. 2021). The court explained that plaintiff did "nothing to establish an Article III 'case' merely by criticizing the wisdom or legality of the FDA's actions." *Id.* at 537. Plaintiffs' "belief that the FDA has engaged in wrongdoing [did] not prove its standing because its 'disagreement' with the FDA [was] not an injury, no matter how 'sharp and acrimonious' it may be." *Id.* (quoting *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013)). So too here.

Plaintiffs seek nothing less than for the Court to order DoD "to stop its universal vaccination policy of all personnel." Opening Br. 30. But plaintiffs lack standing to pursue relief on behalf of other service members; as the district court noted, plaintiffs

never moved for class certification. Plaintiffs' policy disagreements with the DoD Directive are not sufficient to confer standing or to render plaintiffs' claims ripe for judicial review.

5. Lastly, plaintiffs argue that other courts have not dismissed "[a]nalogous [c]ases" on justiciability grounds. Opening Br. 21; *see also id.* at 22-26, 30-31. But those cases provide no support for plaintiffs.

As an initial matter, plaintiffs largely rely on district court decisions and on cases that have been appealed, partially stayed, or vacated entirely. *See Feds for Med. Freedom v. Biden*, 2022 WL 188329 (S.D. Tex. Jan. 21, 2022), *vacated and remanded*, 30 F.4th 503 (5th Cir. 2022) (vacating preliminary injunction); *U.S. Navy SEALs 1-26 v. Biden*, 27 F.4th 336 (5th Cir. 2022) (per curiam), *rev'd in part*, *Austin v. U.S. Navy SEALs 1-26*, 142 S. Ct. 1301 (2022) (per curiam) (partially staying preliminary injunction pending appeal); *Navy SEAL 1 v. Austin*, 2022 WL 534459 (M.D. Fla. Feb. 18, 2022), *on appeal*, No. 22-10645 (11th Cir.) (preliminary injunction partially stayed pending appeal); *see also Air Force Officer v. Austin*, 2022 WL 468799 (M.D. Ga. Feb. 15, 2022), *on appeal*, No. 22-11200 (11th Cir.). District court decisions do not bind this Court, and the subsequent history of many of the cases cited by plaintiffs undermines any persuasive power they might have.

In any event, none of the cases that plaintiffs cite is analogous to this one. Some do not address the DoD Directive at all. *See National Fed'n of Indep. Bus. v. Department of Labor*, 142 S. Ct. 661 (2022) (per curiam) (Occupational Safety and Health Administra-

tion's vaccination or testing requirement); *Feds for Med. Freedom*, 2022 WL 188329 (federal civilian employee vaccination requirement); *Booth v. Bowser*, 2022 WL 823068 (D.D.C. Mar. 18, 2022) (District of Columbia's Minor Consent for Vaccination Act Amendment). And the cases that address the military's vaccination requirement involve different legal issues and facts: All involve challenges under the Religious Freedom Restoration Act and the First Amendment to the denial of religious exemption requests. *See U.S. Navy SEALs 1-26*, 27 F.4th at 341; *Navy SEAL 1*, 2022 WL 534459, at *1; *Air Force Officer*, 2022 WL 468799, at *1; *Poffenbarger v. Kendall*, 2022 WL 594810, at *1 (S.D. Ohio Feb. 28, 2022). Moreover, most of those cases involved religious exemption requests that had been administratively appealed and finally denied. *Navy SEAL 1*, 2022 WL 534459, at *2; *Air Force Officer*, 2022 WL 468799, at *4; *Poffenbarger*, 2022 WL 594810, at *4. Here, by contrast, plaintiffs claim no violation of their religious liberties, plaintiff Mulvihill currently possesses an exemption from the vaccination requirement, and plaintiff Robert's exemption request remains pending.

Plaintiffs' attempt to distinguish *Church v. Biden*, 2021 WL 5179215, is unavailing. In that case, the district court denied a preliminary injunction, holding that plaintiffs had failed to show that their claims were likely justiciable. *Id.* at *10. The fact that the court did not *sua sponte* dismiss those claims, in addition to denying a preliminary injunction, does not weaken the force of the court's analysis. The government has since moved to dismiss *Church* on justiciability and other grounds. *See* Defendants' Mot. to

Dismiss, *Church*, No. 21-cv-2815, 2021 WL 5179215 (D.D.C. Feb. 4, 2022), Dkt. No. 23. That motion is pending before the district court.[4]

In short, plaintiffs provide no plausible legal or factual basis to overturn the district court's conclusion that their claims are not justiciable. Because plaintiffs' claims turn on speculative and contingent claims of injury, those claims are unripe and plaintiffs lack standing to bring this suit.

II. In any event, the district court's dismissal of plaintiffs' claims against FDA and HHS should be affirmed.

Even if the Court were to conclude that plaintiffs' claims against DoD are justiciable, it should nevertheless affirm the dismissal of plaintiffs' claims against FDA and HHS. As the district court correctly recognized, plaintiffs' complaint contains a "complete lack of allegations pertaining to any conduct by" FDA or HHS that has affected plaintiffs. ADD6 n.1.[5]

Standing must be evaluated as to each defendant. *Town of Chester v. Laroe Estates*, 137 S. Ct. 1645, 1651 (2017); *see also, e.g.*, *Disability Rights S.C. v. McMaster*, 24 F.4th 893, 900 (4th Cir. 2022); *Daves v. Dallas County*, 22 F.4th 522, 542 (5th Cir. 2022); *Calzone v.*

[4] The district court dismissed the federal employee plaintiffs in that case for lack of jurisdiction on May 11 and stated that it intended to address the claims of the service member plaintiffs in a separate opinion. *See* Memorandum Opinion, *Church*, 2022 WL 1491100 (D.D.C. May 11, 2022), Dkt. No. 31.

[5] The district court observed that plaintiffs' complaint failed to state a claim as to FDA and HHS, a conclusion that was tantamount to concluding that plaintiffs lacked standing as to those defendants, as plaintiffs asserted no harms based on any alleged misconduct on the part of FDA or HHS.

Hawley, 866 F.3d 866, 869 (8th Cir. 2017). Plaintiffs cannot make such a showing with respect to FDA or HHS. Plaintiffs seek no relief governing the conduct of FDA or HHS, and they do not challenge either the EUAs or the licenses for COVID-19 vaccines.[6]

Put differently, even if plaintiffs were able to assert an injury, it would not be traceable to FDA or HHS. *See Association of Am. Physicians & Surgeons*, 13 F.4th at 546 ("Many cases . . . hold that a plaintiff failed to establish that an injury was traceable to a defendant when the injury would arise only if some third party decided to take the action triggering the injury."). Plaintiffs appear to concede that DoD is the true target of their complaint, stating that "[i]t was necessary to include the HHS and FDA officials as defendants to ensure the availability of complete relief, so that responsibility is not attributed to a non-party." Opening Br. 31 n.12. Plaintiffs' theory for suing FDA and HHS is that those entities' supposed "incomplete" authorization of the Pfizer vaccine "immediately led to the mandate imposed by Secretary Austin." *Id.* But neither the EUA nor the license requires anyone to receive the Pfizer vaccine. Nor do they require DoD to mandate COVID-19 vaccination for service members. To the contrary, DoD has independent discretion to decide when and whether to subject service members to a COVID-19 vaccination requirement, including when a vaccine is available only under

[6] Indeed, the issuance of an EUA is "committed to agency discretion" by the EUA statute and is therefore unreviewable. *See* 21 U.S.C. § 360bbb-3(i); *see also* 5 U.S.C. § 701(a)(2); *Association of Am. Physicians & Surgeons v. FDA*, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020).

an EUA. *See* 10 U.S.C. § 1107a. Plaintiffs' purported injuries are therefore not traceable to any decision by FDA or HHS.

Because plaintiffs' claims are not justiciable, the district court correctly denied plaintiffs' motion for a preliminary injunction and granted the government's motion to dismiss.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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STATEMENT REGARDING ORAL ARGUMENT

The government does not believe that oral argument is necessary in this case. Nevertheless, the government stands ready to present argument if the Court believes that it would be of assistance.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,417 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Sarah J. Clark
Sarah J. Clark

ADDENDUM

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10 U.S.C. § 1107

§ 1107. Notice of use of an investigational new drug or a drug unapproved for its applied use

(a) Notice Required.—

(1) Whenever the Secretary of Defense requests or requires a member of the armed forces to receive an investigational new drug or a drug unapproved for its applied use, the Secretary shall provide the member with notice containing the information specified in subsection (d).

(2) The Secretary shall also ensure that health care providers who administer an investigational new drug or a drug unapproved for its applied use, or who are likely to treat members who receive such a drug, receive the information required to be provided under paragraphs (3) and (4) of subsection (d).

(b) Time of Notice.—

The notice required to be provided to a member under subsection (a)(1) shall be provided before the investigational new drug or drug unapproved for its applied use is first administered to the member.

(c) Form of Notice.—

The notice required under subsection (a)(1) shall be provided in writing.

(d) Content of Notice.—The notice required under subsection (a)(1) shall include the following:

(1) Clear notice that the drug being administered is an investigational new drug or a drug unapproved for its applied use.

(2) The reasons why the investigational new drug or drug unapproved for its applied use is being administered.

(3) Information regarding the possible side effects of the investigational new drug or drug unapproved for its applied use, including any known side effects possible as a result of the interaction of such drug with other drugs or treatments being administered to the members receiving such drug.

(4) Such other information that, as a condition of authorizing the use of the investigational new drug or drug unapproved for its applied use, the Secretary of Health and Human Services may require to be disclosed.

(e) Records of Use.—The Secretary of Defense shall ensure that the medical records of members accurately document—

(1) the receipt by members of any investigational new drug or drug unapproved for its applied use; and

(2) the notice required by subsection (a)(1).

(f) Limitation and Waiver.—

(1) In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President. The President may grant such a waiver only if the President determines, in writing, that obtaining consent is not in the interests of national security.

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which prior consent for administration of a particular drug is required by reason of a determination by the Secretary of Health and Human Services that such drug is subject to the investigational new drug requirements of section 505(i) of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary of Defense may request the President to waive the prior consent requirement with respect to the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation. With respect to any such administration—

(A) the Secretary may not delegate to any other official the authority to request the President to waive the prior consent requirement for the Department of Defense; and

(B) if the President grants the requested waiver, the Secretary shall submit to the chairman and ranking minority member of each congressional defense committee a notification of the waiver, together with the written determination of the President under paragraph (1) and the Secretary's justification for the request or requirement under subsection (a) for the member to receive the drug covered by the waiver.

(4) In this subsection:

(A) The term "relevant FDA regulations" means the regulations promulgated under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

(B) The term "prior consent requirement" means the requirement included in the relevant FDA regulations pursuant to section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)).

(g) Definitions.—In this section:

(1) The term "investigational new drug" means a drug covered by section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

(2) The term "drug unapproved for its applied use" means a drug administered for a use not described in the approved labeling of the drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

10 U.S.C. § 1107a

§ 1107a. Emergency use products

(a) Waiver by the President.—

(1) In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act.

(b) Provision of Information.—

If the President, under subsection (a), waives the condition described in section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act, and if the Secretary of Defense, in consultation with the Secretary of Health and Human Services, makes a determination that it is not feasible based on time limitations for the information described in section 564(e)(1)(A)(ii)(I) or (II) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to

whom the product was administered as soon as possible, but not later than 30 days, after such administration. The authority provided for in this subsection may not be delegated. Information concerning the administration of the product shall be recorded in the medical record of the member.

(c) Applicability of Other Provisions.—

In the case of an authorization by the Secretary of Health and Human Services under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act based on a determination by the Secretary of Defense under section 564(b)(1)(B) of such Act, subsections (a) through (f) of section 1107 shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

21 U.S.C. § 360bbb-3

§ 360bbb-3. Authorization for medical products for use in emergencies

(a) In general

(1) Emergency uses

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) Approval status of product

An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title (referred to in this section as an "unapproved product"); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 360ccc of this title, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product").

(3) Relation to other uses

An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a section of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] referred to in paragraph (2)(A).

(4) Definitions

For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act [42 U.S.C. 262].

(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).

(C) The term "product" means a drug, device, or biological product.

(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).

(E) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).

(b) Declaration of emergency or threat justifying emergency authorized use

(1) In general

The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—

(A) 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 biological, chemical, radiological, or nuclear agent or agents;

(B) 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, including personnel operating under the authority of title 10 or title 50, of attack with—

(i) a biological, chemical, radiological, or nuclear agent or agents; or

(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;

(C) a determination by the Secretary 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 biological, chemical, radiological,

or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or

(D) the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b] sufficient to affect national security or the health and security of United States citizens living abroad.

(2) Termination of declaration

(A) In general

A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

(B) Disposition of product

If an authorization under this section with respect to an unapproved product ceases to be effective as a result of a termination under subparagraph (A) of this paragraph, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

(3) Advance notice of termination

The Secretary shall provide advance notice that a declaration under this subsection will be terminated. The period of advance notice shall be a period reasonably determined to provide—

(A) in the case of an unapproved product, a sufficient period for disposition of the product, including the return of such product (except such quantities of product as are necessary to provide for continued use consistent with subsection (f)(2)) to the manufacturer (in the case of a manufacturer that chooses to have such product returned); and

(B) in the case of an unapproved use of an approved product, a sufficient period for the disposition of any labeling, or any information under subsection (e)(2)(B)(ii), as the case may be, that was provided with respect to the emergency use involved.

(4) Publication

The Secretary shall promptly publish in the Federal Register each declaration, determination, and advance notice of termination under this subsection.

(5) Explanation by Secretary

If an authorization under this section with respect to an unapproved product or an unapproved use of an approved product has been in effect for more than 1 year, the Secretary shall provide in writing to the sponsor of such product an explanation of the scientific, regulatory, or other obstacles to approval, licensure, or clearance of such product or use, including specific actions to be taken by the Secretary and the sponsor to overcome such obstacles.

(6) Military emergencies

In the case of a determination described in paragraph (1)(B), the Secretary shall determine, within 45 calendar days of such determination, whether to make a declaration under paragraph (1), and, if appropriate, shall promptly make such a declaration.

(c) Criteria for issuance of authorization

The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (b)(1)), the Secretary concludes—

(1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

(A) the product may be effective in diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the

agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;

(4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and

(5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

(d) Scope of authorization

An authorization of a product under this section shall state—

(1) each disease or condition that the product may be used to diagnose, prevent, or treat within the scope of the authorization;

(2) the Secretary's conclusions, made under subsection (c)(2)(B), that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and

(3) the Secretary's conclusions, made under subsection (c), concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating such diseases or conditions, including, to the extent practicable given the circumstances of the emergency, an assessment of the available scientific evidence.

(e) Conditions of authorization

(1) Unapproved product

(A) Required conditions

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) Authority for additional conditions

With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

(ii) Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use.

(iii) Appropriate conditions with respect to collection and analysis of information concerning the safety and effectiveness of the product with respect to the use of such product during the period when the authorization is in effect and a reasonable time following such period.

(iv) For persons other than manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(2) Unapproved use

With respect to the emergency use of a product that is an unapproved use of an approved product:

(A) For a person who carries out any activity for which the authorization is issued, the Secretary shall, to the extent practicable given the applicable circumstances described in subsection (b)(1), establish conditions described in clauses (i) and (ii) of paragraph (1)(A), and may establish conditions described in clauses (iii) and (iv) of such paragraph or in paragraph (1)(B).

(B)

(i) If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change, such authorization may not authorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer, except as provided in section 360bbb–3a of this title with respect to authorized changes to the product expiration date.

(ii) In the circumstances described in clause (i), for a person who does not manufacture the product and who chooses to act under this clause, an authorization under this section regarding the emergency use shall, to the extent practicable given the circumstances of the emergency, authorize such person to provide appropriate information with respect to such product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). While the authorization under this section is effective, such additional information shall not be considered labeling for purposes of section 352 of this title.

(C) In establishing conditions under this paragraph with respect to the distribution and administration of the product for the unapproved use, the Secretary shall not impose conditions that would restrict distribution or administration of the product when distributed or administered for the approved use.

(3) Good manufacturing practice; prescription

With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the applicable circumstances described in subsection (b)(1)—

(A) requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including such requirements established under section 351 or 360j(f)(1) of this title, and including relevant conditions prescribed with respect to the product by an order under section 360j(f)(2) of this title;

(B) requirements established under subsection (b) or (f) of section 353 of this title or under section 354 of this title; and

(C) requirements established under section 360j(e) of this title.

(4) Advertising

The Secretary may establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), including, as appropriate—

(A) with respect to drugs and biological products, requirements applicable to prescription drugs pursuant to section 352(n) of this title; or

(B) with respect to devices, requirements applicable to restricted devices pursuant to section 352(r) of this title.

(f) Duration of authorization

(1) In general

Except as provided in paragraph (2), an authorization under this section shall be effective until the earlier of the termination of the declaration under subsection (b) or a revocation under subsection (g).

(2) Continued use after end of effective period

Notwithstanding the termination of the declaration under subsection (b) or a revocation under subsection (g), an authorization shall continue to be effective to provide for continued use of an unapproved product with respect to a patient to whom, or an animal to which, it was administered during the period described by paragraph (1), to the extent found necessary by such patient's attending physician or by the veterinarian caring for such animal, as applicable.

(g) Review and revocation of authorization

(1) Review

The Secretary shall periodically review the circumstances and the appropriateness of an authorization under this section. As part of such review, the Secretary shall

regularly review the progress made with respect to the approval, conditional approval under section 360ccc of this title, licensure, or clearance of—

(A) an unapproved product for which an authorization was issued under this section; or

(B) an unapproved use of an approved product for which an authorization was issued under this section.

(2) Revision and revocation

The Secretary may revise or revoke an authorization under this section if—

(A) the circumstances described under subsection (b)(1) no longer exist;

(B) the criteria under subsection (c) for issuance of such authorization are no longer met; or

(C) other circumstances make such revision or revocation appropriate to protect the public health or safety.

(h) Publication; confidential information

(1) Publication

The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, and an explanation of the reasons therefor (which may include a summary of data or information that has been submitted to the Secretary in an application under section 355(i) [1] 360b(j), or 360j(g) of this title, even if such summary may indirectly reveal the existence of such application). The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration.

(2) Confidential information

Nothing in this section alters or amends section 1905 of title 18 or section 552(b)(4) of title 5.

(i) Actions committed to agency discretion

Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

(j) Rules of construction

The following applies with respect to this section:

(1) Nothing in this section impairs the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution.

(2) Nothing in this section impairs the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law.

(3) Nothing in this section (including any exercise of authority by a manufacturer under subsection (e)(2)) impairs the authority of the United States to use or manage quantities of a product that are owned or controlled by the United States (including quantities in the stockpile maintained under section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b]).

(4) Nothing in this section shall be construed as authorizing a delay in the review or other consideration by the Secretary of any application or submission pending before the Food and Drug Administration for a product for which an authorization under this section is issued.

(k) Relation to other provisions

If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of section 355(i), 360b(j), or 360j(g) of this title or any other provision of this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262].

(l) Option to carry out authorized activities

Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall report to the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out any activity under the authorization. This section only has legal effect on a person who carries out an activity for which an authorization under this section is issued. This section does not modify or affect activities carried out pursuant to other provisions of this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262]. Nothing in this subsection may be construed as restricting the Secretary from imposing conditions on persons who carry out any activity pursuant to an authorization under this section.

(m) Categorization of laboratory tests associated with devices subject to authorization

(1) In general

In issuing an authorization under this section with respect to a device, the Secretary may, subject to the provisions of this section, determine that a laboratory examination or procedure associated with such device shall be deemed, for purposes of section 353 of the Public Health Service Act [42 U.S.C. 263a], to be in a particular category of examinations and procedures (including the category described by subsection (d)(3) of such section) if, based on the totality of scientific evidence available to the Secretary—

(A) such categorization would be beneficial to protecting the public health; and

(B) the known and potential benefits of such categorization under the circumstances of the authorization outweigh the known and potential risks of the categorization.

(2) Conditions of determination

The Secretary may establish appropriate conditions on the performance of the examination or procedure pursuant to such determination.

(3) Effective period

A determination under this subsection shall be effective for purposes of section 353 of the Public Health Service Act [42 U.S.C. 263a] notwithstanding any other provision of that section during the effective period of the relevant declaration under subsection (b).