(Slip Opinion)

Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization

Section 564(e)(1)(A)(ii)(III) of the Food, Drug, and Cosmetic Act concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for a vaccine that is subject to an emergency use authorization.

July 6, 2021

MEMORANDUM OPINION FOR THE
DEPUTY COUNSEL TO THE PRESIDENT

Section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3,[1] authorizes the Food and Drug Administration ("FDA") to issue an "emergency use authorization" ("EUA") for a medical product, such as a vaccine, under certain emergency circumstances. This authorization permits the product to be introduced into interstate commerce and administered to individuals even when FDA has not approved the product for more general distribution pursuant to its standard review process. Section 564 directs FDA—"to the extent practicable" given the emergency circumstances and "as the [agency] finds necessary or appropriate to protect the public health"—to impose "[a]ppropriate" conditions on each EUA. FDCA § 564(e)(1)(A). Some of these conditions are designed to ensure that recipients of the product "are informed" of certain things, including "the option to accept or refuse administration of the product." *Id.* § 564(e)(1)(A)(ii)(III).

Since December 2020, FDA has granted EUAs for three vaccines to prevent coronavirus disease 2019 ("COVID-19"). In each of these authorizations, FDA imposed the "option to accept or refuse" condition by requiring the distribution to potential vaccine recipients of a Fact Sheet that states: "It is your choice to receive or not receive [the vaccine]. Should you decide not to receive it, it will not change your standard medical care." *E.g.*, FDA, Fact Sheet for Recipients and Caregivers at 5 (revised June 25, 2021), https://www.fda.gov/media/144414/download

[1] Because it is commonly referred to by its FDCA section number, and for the sake of simplicity, we will refer to this provision as section 564, rather than by its United States Code citation.

("Pfizer Fact Sheet"). In recent months, many public and private entities have announced that they will require individuals to be vaccinated against COVID-19—for instance, in order to attend school or events in person, or to return to work or be hired into a new job. We will refer to such policies as "vaccination requirements," though we note that these policies typically are conditions on employment, education, receipt of services, and the like rather than more direct legal requirements.[2]

In light of these developments, you have asked whether the "option to accept or refuse" condition in section 564 prohibits entities from imposing such vaccination requirements while the only available vaccines for COVID-19 remain subject to EUAs. We conclude, consistent with FDA's interpretation, that it does not. This language in section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements.[3]

I.

A.

Federal law generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until FDA has approved the drug or product as safe and effective for its intended uses. *See, e.g.*, FDCA §§ 301(a), 505(a), 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C § 262(a). A vaccine is both a drug and a biological product. *See* FDCA § 201(g), 21 U.S.C § 321(g); 42 U.S.C. § 262(i)(1). Consistent with section 564, we will generally refer to it here as a "product." *See* FDCA § 564(a)(4)(C) (defining "product" to mean "a drug, device, or biological product").

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[2] For an example of the latter, see our discussion in Part II.B of a hypothetical military order to service members.

[3] We do not address whether other federal, state, or local laws or regulations, such as the Americans with Disabilities Act ("ADA"), might restrict the ability of public or private entities to adopt particular vaccination policies. *See, e.g.*, Equal Employment Opportunity Commission, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws* (updated June 28, 2021), https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws (discussing the ADA).

In 2003, Congress addressed a problem raised in emergency situations where "the American people may be placed at risk of exposure to biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents," but where, "[u]nfortunately, there may not be approved or available countermeasures to treat diseases or conditions caused by such agents," even though "a drug, biologic, or device is highly promising in treating [such] a disease or condition." H.R. Rep. No. 108-147, pt. 1, at 2 (2003). President George W. Bush had flagged this problem in his 2003 State of the Union Address, in which he proposed Project BioShield, a legislative initiative "to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague." *Address Before a Joint Session of the Congress on the State of the Union* (Jan. 28, 2003), 1 Pub. Papers of Pres. George W. Bush 82, 86 (2003). Among the principal components of the proposed Project BioShield legislation were provisions to enable FDA to authorize medical products for use during emergencies even before they are proven to be safe and effective under ordinary FDA review. *See, e.g.*, H.R. 2122, 108th Cong. § 4 (2003). At that time, the only alternative to ordinary FDA approval was 21 U.S.C. § 355(i), which authorizes FDA to exempt drugs from the ordinary approval requirements where the drug is "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." Such a cabined investigational new drug ("IND") exemption does not, however, allow the widespread dissemination of a drug for general public use in response to an emergency. *See* H.R. Rep. No. 108-147, pt. 1, at 2.

Congress enacted a version of the Project BioShield legislation's EUA provision in the National Defense Authorization Act for Fiscal Year 2004 as section 564 of the FDCA. *See* Pub. L. No. 108-136, § 1603(a), 117 Stat. 1392, 1684 (2003) (codified at 21 U.S.C. § 360bbb-3).[4] Section 564 authorizes the Secretary of Health and Human Services ("HHS")—who has delegated to FDA the authorities under the statute at issue here—to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency even though the product has not yet been generally approved as safe and

[4] The statute has been amended since, including when Congress enacted the Project BioShield Act the following year. *See* Pub. L. No. 108-276, § 4(a), 118 Stat. 835, 853 (2004).

effective for its intended use. FDCA § 564(a)(1)–(2); *see also* FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* at 3 n.6 (Jan. 2017) ("EUA Guidance") (noting delegation of most of the Secretary's authorities under section 564 to FDA).[5]

The most pertinent part of section 564 for purposes of your question has remained materially the same since Congress first enacted the statute in 2003. Subsection (e)(1)(A),[6] titled "Required conditions," provides:

> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable [emergency] circumstances . . . , 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 [certain specified conditions].

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[5] The current version of section 564(a)(1) provides in full:

> Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act, 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").

The "declaration under subsection (b)" refers to a declaration by the Secretary "that the circumstances exist justifying" an EUA, which must be made "on the basis" of one or more types of emergencies or threats. FDCA § 564(b)(1). FDA can grant an EUA where, "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available," FDA finds that "it is reasonable to believe," among other things, that "the product may be effective in diagnosing, treating, or preventing" a "serious or life-threatening disease or condition" caused by a "biological, chemical, radiological, or nuclear agent or agents" (a standard less onerous than for final approval of the product); 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 that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition." FDCA § 564(c).

[6] Subsection (e)(1) applies to a product that FDA has not approved as safe and effective for any intended use, whereas subsection (e)(2) applies to an unapproved use of an otherwise approved product. The COVID-19 vaccines fall under the former category, but the statute applies the condition at issue here to the latter category as well. *See* FDCA § 564(e)(2)(A).

The statute then lists a number of such conditions, including "[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed" of certain information. FDCA § 564(e)(1)(A)(ii). This information includes the fact that FDA "has authorized the emergency use of the product," "the significant known and potential benefits and risks of such use," and "the extent to which such benefits and risks are unknown." *Id.* § 564(e)(1)(A)(ii)(I)–(II). Most relevant here, section 564(e)(1)(A)(ii)(III) directs FDA to impose conditions on an EUA "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."

In the same section of the 2004 National Defense Authorization Act, Congress also enacted another provision, codified as 10 U.S.C. § 1107a, which is specific to the U.S. military and which expressly refers to the "option to accept or refuse" condition described in section 564(e)(1)(A)(ii)(III). Pub. L. No. 108-136, sec. 1603(b)(1), § 1107a, 117 Stat. at 1690. Subsection (a) of this law provides that when an EUA product is administered to members of the armed forces, "the condition described in section 564(e)(1)(A)(ii)(III) . . . 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" 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).

B.

In the years after Congress enacted section 564, FDA issued dozens of EUAs in response to various public-health emergencies. *See, e.g.*, Authorization of Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information; Availability, 74 Fed. Reg. 56,644 (Nov. 2, 2009) (antiviral drug to treat swine flu). The agency's use of EUAs increased dramatically with the onset of the COVID-19 pandemic in 2020. As of January 2021, the agency had issued more than 600 EUAs for products to combat COVID-19, including drugs, tests, personal protective equipment, and ventilators. *See* FDA, *FDA COVID-19 Pandemic*

Recovery and Preparedness Plan (PREPP) Initiative: Summary Report at 6 (Jan. 2021); *cf. id.* at 24 (noting that FDA issued 65 EUAs prior to COVID-19). More importantly for present purposes, the agency has granted EUAs for three COVID-19 vaccines manufactured by Pfizer, Moderna, and Janssen, respectively. *See* Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability, 86 Fed. Reg. 28,608 (May 27, 2021) (Janssen); Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic; Availability, 86 Fed. Reg. 5200 (Jan. 19, 2021) (Pfizer and Moderna).

As we have explained, section 564 of the FDCA contemplates that each EUA will be subject to various conditions. For the three COVID-19 vaccines, FDA implemented the "option to accept or refuse" condition described in section 564(e)(1)(A)(ii)(III) in the following manner: In each letter granting the EUA, FDA established as a "condition[] of authorization" that FDA's "Fact Sheet for Recipients and Caregivers" be made available to potential vaccine recipients. *See, e.g.*, Letter for Pfizer Inc. from RADM Denise M. Hinton, Chief Scientist, FDA at 6, 9 (updated June 25, 2021), https://www.fda.gov/media/150386/download ("Pfizer EUA Letter"). The Fact Sheet in question states (to take the Pfizer vaccine as an example): "It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care." Pfizer Fact Sheet at 5. We understand that this approach is consistent with FDA's general practice for EUAs. *See* EUA Guidance at 24–25 (discussing the use of fact sheets to inform recipients of EUA products "[t]hat they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product").

As access to the COVID-19 vaccines has become widespread, numerous educational institutions, employers, and other entities across the United States have announced that they will require individuals to be vaccinated against COVID-19 as a condition of employment, enrollment, participation, or some other benefit, service, relationship, or access.[7] For

[7] *See, e.g.*, Rukmini Callimachi, *For Colleges, Vaccine Mandates Often Depend on Which Party Is in Power*, N.Y. Times (May 22, 2021), https://www.nytimes.com/2021/05/22/us/college-vaccine-universities.html; Tracy Rucinski, *Delta will require COVID-19*

instance, certain schools will require vaccination in order for students to attend class in person, and certain employers will require vaccination as a condition of employment.

Some have questioned whether such entities can lawfully impose such requirements in light of the fact that section 564 instructs that potential vaccine recipients are to be informed that they have the "option to accept or refuse" receipt of the vaccine.[8] In the past few months, several lawsuits have also been filed challenging various entities' vaccination requirements on the same theory.[9] The only judicial decision to have addressed this issue so far summarily rejected the challenge. *See Bridges v. Houston Methodist Hosp.*, No. 4:21-cv-01774, 2021 WL 2399994, at *1–2 (S.D. Tex. June 12, 2021), *appeal docketed*, No. 21-20311 (5th Cir. June 14, 2021).

II.

A.

We conclude that section 564(e)(1)(A)(ii)(III) concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for vaccines that are subject to EUAs. By its terms, the provision directs only that potential vaccine recipients be "informed" of certain information, including "the option to accept or refuse administration of the product."

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vaccine for new employees, Reuters (May 14, 2021, 9:16 AM), https://www.reuters.com/world/us/delta-will-require-covid-19-vaccine-new-employees-2021-05-14/.

[8] *See, e.g.*, Letter for Thomas C. Galligan Jr., Interim President, Louisiana State University, from Jeff Landry, Attorney General of Louisiana (May 28, 2021); *see also* Advisory Committee on Immunization Practices, Summary Report at 56 (Aug. 26, 2020), https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf (reporting a CDC official as saying that EUA vaccines are not allowed to be mandatory).

[9] *See, e.g.*, Defendant's Notice of Removal, *Bridges v. Methodist Hosp.*, No. 4:21-cv-01774 (S.D. Tex. June 1, 2021), 2021 WL 2221293 (referencing complaint); Complaint, *Neve v. Birkhead*, No. 1:21-cv-00308 (M.D.N.C. Apr. 16, 2021), 2021 WL 1902937; Complaint, *Cal. Educators for Med. Freedom v. L.A. Unified Sch. Dist.*, No. 21-cv-2388 (C.D. Cal. Mar. 17, 2021), 2021 WL 1034618; Complaint, *Legaretta v. Macias*, No. 2:21-cv-00179 (D.N.M. Feb. 28, 2021), 2021 WL 909707; *see also* Complaint, *Health Freedom Defense Fund v. City of Hailey*, No. 1:21-cv-00212-DCN (D. Idaho May 14, 2021), 2021 WL 1944543 (making a similar argument about a face-mask requirement).

FDCA § 564(e)(1)(A)(ii)(III). In the sense used here, the word "inform" simply means to "give (someone) facts or information; tell." *New Oxford American Dictionary* 891 (3d ed. 2010); *see also, e.g.*, *Webster's Third New International Dictionary* 1160 (2002) (similar). Consistent with this understanding, the conditions of authorization that FDA imposed for the COVID-19 vaccines require that potential vaccine recipients receive FDA's Fact Sheet, *see, e.g.*, Pfizer EUA Letter at 6, 9, which states that recipients have a "choice to receive or not receive" the vaccine, *see, e.g.*, Pfizer Fact Sheet at 5. Neither the statutory conditions of authorization nor the Fact Sheet itself purports to restrict public or private entities from insisting upon vaccination in any context. *Cf. Bridges*, 2021 WL 2399994, at *2 (explaining that section 564 "confers certain powers and responsibilities to the Secretary of [HHS] in an emergency" but that it "neither expands nor restricts the responsibilities of private employers").[10]

The language of another provision of section 564 reflects the limited scope of operation of section 564(e)(1)(A)(ii)(III). Section 564(*l*) provides that "this section [i.e., section 564] only has legal effect on a person who carries out an activity for which an authorization under this section is issued." This provision expressly forecloses any limitation on the activities of the vast majority of entities who would insist upon vaccination requirements, because most do not carry out any activity for which an EUA is issued.

To be sure, the EUA conditions effectively require parties administering the products to do so in particular ways—including that they only administer the products to individuals after providing them the informational Fact Sheets that FDA prescribes—and some of those entities,

[10] Earlier-introduced versions of section 564(e)(1)(A)(ii)(III) in 2003 referred to "*any* option to accept or refuse administration of the product" (as opposed to "the" option), a formulation that might have even more clearly conveyed the informational nature of the condition. *See, e.g.*, S. 15, 108th Cong. § 204 (Mar. 11, 2003) (emphasis added). We have not found any explanation for why Congress revised the provision to refer to "the option," so we ascribe little significance to the change—either for or against our reading of the statute. *See Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989); *Trainmobile Co. v. Whirls*, 331 U.S. 40, 61 (1947) ("The interpretation of statutes cannot safely be made to rest upon mute intermediate legislative maneuvers."). In 10 U.S.C. § 1107a(a), moreover, Congress used the alternative formulation "*an* option to accept or refuse" in referring to the condition in section 564(e)(1)(A)(ii)(III) as it relates to the armed forces. (Emphasis added.) This discrepancy counsels further against assigning interpretive weight to the change from "any" to "the" in the legislative development of section 564.

such as universities, might also impose vaccination requirements (e.g., on their students and employees). There is no indication, however, that Congress intended to regulate such entities except with respect to the circumstances of their administration of the product itself. *See, e.g.*, FDCA § 564(e)(1)(B)(ii) (authorizing FDA to establish "[a]ppropriate 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*" (emphasis added)). And it would have been odd for Congress to have done so, for in that case the entities choosing to administer EUA products would be limited in their relations with third parties (e.g., students, employees) in ways that analogous entities that did not administer the products were not.

This reading of the "option to accept or refuse" condition to be informational follows not only from the plain text of the provision, but also from the surrounding requirements in section 564(e)(1)(A)(ii). *See, e.g.*, *Lagos v. United States*, 138 S. Ct. 1684, 1688–89 (2018) (relying on the canon of "*noscitur a sociis*, the well-worn Latin phrase that tells us that statutory words are often known by the company they keep"). In addition to requiring that potential recipients be informed of "the option to accept or refuse administration of the product," the statute also requires that they be informed 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." FDCA § 564(e)(1)(A)(ii)(III). Similarly, the two other provisions in subsection (e)(1)(A)(ii) require that individuals be informed of the fact that FDA "has authorized the emergency use of the product" and of "the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." *Id.* § 564(e)(1)(A)(ii)(I)–(II). These provisions all appear to require only that certain factual information be conveyed to those who might use the product.

Indeed, if Congress had intended to restrict entities from imposing EUA vaccination requirements, it chose a strangely oblique way to do so, embedding the restriction in a provision that on its face requires only that individuals be provided with certain information (and grouping that requirement with other conditions that are likewise informational in nature). Congress could have created such a restriction by simply stating that persons (or certain categories of persons) may not require others to

use an EUA product. *See Kloeckner v. Solis*, 568 U.S. 41, 52 (2012) (rejecting a statutory interpretation positing that Congress took a "roundabout way" and an "obscure path" to reach "a simple result"); *cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (Congress does not "hide elephants in mouseholes").

Our reading of section 564(e)(1)(A)(ii)(III) does not fully explain why Congress created a scheme in which potential users of the product would be informed that they have "the option to accept or refuse" the product. The legislative history of the 2003 statute does not appear to offer any clear explanation. Perhaps Congress viewed section 564(e)(1)(A)(ii)(III) as a variation on the "informed consent" requirement that applies to human subjects in "investigational drug" settings,[11] the only other context in which FDA may (in a limited fashion) authorize the introduction of unapproved drugs into interstate commerce. Or perhaps Congress included this condition to ensure that potential users of an EUA product would not misunderstand what the likely impact of declining to use that product would be.

The information conveyed pursuant to the "option" clause continues to be a true statement about a material fact of importance to potential vac-

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[11] Section 355(i)(4) of title 21 provides that an IND exemption to the premarket approval requirement may only apply if the manufacturer or sponsor of an expert investigation requires the experts in question to certify

> that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards.

Congress did not include this same "informed consent" requirement as part of the EUA provision in 2003, perhaps out of concern that it would not be practicable in emergency situations. *See Project BioShield: Contracting for the Health and Security of the American Public: Hearing Before the H. Comm. on Gov't Reform*, 108th Cong. 33 (Apr. 4, 2003) (statement of Mark B. McClellan, Commissioner, FDA, and Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases) ("Because urgent situations may require mass inoculations and/or drug treatments, such informed consent requirements may prove impossible to implement within the necessary time frame when trying to achieve the public health goal of protecting Americans from the imminent danger."); *see also infra* note 15 (explaining that the informed consent requirements contained in 21 U.S.C. § 355(i)(4) do not apply to EUA products).

cine recipients—virtually all such persons continue to have the "option" of refusing the vaccine in the sense that there is no direct legal requirement that they receive it. *See Bridges*, 2021 WL 2399994, at *2 (noting that an employer's vaccination policy was not "coercive" because an employee "can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work somewhere else"); Wen W. Shen, Cong. Research Serv., R46745, *State and Federal Authority to Mandate COVID-19 Vaccination* at 4 (Apr. 2, 2021) ("[E]xisting vaccination mandates—as they are typically structured—generally do not interfere with . . . an individual's right to refuse in that context. Rather, they impose secondary consequences—often in the form of exclusion from certain desirable activities, such as schools or employment—in the event of refusal." (footnote omitted)); *Black's Law Dictionary* 1121 (7th ed. 1999) (defining "option" as relevant here as "[t]he right or power to choose; something that may be chosen"); *The American Heritage Dictionary of the English Language* 1235 (4th ed. 2000) (similar); *cf.* FDCA § 564(e)(1)(A)(ii)(III) (directing that potential vaccine recipients be informed not only of "the option to accept or refuse administration of the product" but also of "the *consequences*, if any, of refusing administration of the product" (emphasis added)).

Importantly, however, and consistent with FDA's views, we also read section 564 as giving FDA some discretion to modify or omit "the option to accept or refuse" notification, or to supplement it with additional information, if and when circumstances change. As noted above, the statute directs FDA to establish the section 564(e)(1)(A) conditions "to the extent practicable given the applicable [emergency] circumstances" and "as the [agency] finds necessary or appropriate to protect the public health." FDCA § 564(e)(1)(A). Both of these phrases—"to the extent practicable" and "as the [agency] finds necessary or appropriate"—are generally understood to confer discretion on an agency. *See, e.g.*, *Gallegos-Hernandez v. United States*, 688 F.3d 190, 195 (5th Cir. 2012) (per curiam) ("to the extent practicable"); *Madison-Hughes v. Shalala*, 80 F.3d 1121, 1128 (6th Cir. 1996) (collecting cases on "necessary" and "appropriate"). Moreover, the portion of section 564 that deals specifically with informational conditions provides that FDA should establish "[a]ppropriate" conditions designed to ensure that potential vaccine recipients are informed of the "option to accept or refuse" an EUA product. FDCA § 564(e)(1)(A)(ii). These qualifiers indicate that FDA's responsibility to

impose the "option to accept or refuse" condition is not absolute and that the agency has some discretion to modify or omit the condition when the agency finds the notification would not be "practicable" given the emergency circumstances, or to determine that changes to the notification are "necessary or appropriate to protect the public health." *See* EUA Guidance at 24 n.46 (noting circumstances in which the "option to accept or refuse" notification might not be practicable).[12] In addition, section 564 gives FDA the authority to supplement the information that is conveyed to potential vaccine recipients, including information about "the consequences, if any, of refusing administration of the product." FDCA § 564(e)(1)(A)(ii)(III); *see also id.* § 564(e)(1)(B) (noting that FDA has the authority to impose additional conditions as the agency "finds necessary or appropriate to protect the public health"); EUA Guidance at 22 n.40, 26–27 (noting this point). Together, then, these provisions of section 564 give FDA the authority to adapt to changing circumstances and to ensure that the information conveyed to potential users of EUA products is accurate.[13]

Although many entities' vaccination requirements preserve an individual's ultimate "option" to refuse an EUA vaccine, they nevertheless impose sometimes-severe adverse consequences for exercising that option (such as not being able to enroll at a university). Under such circumstances, FDA could theoretically choose to supplement the conditions of authorization to notify potential vaccine recipients of the possibility of such consequences (or to make it even clearer that the consequences described

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[12] Indeed, FDA has recently exercised its discretion not to require certain of the statutorily specified conditions with respect to the current COVID-19 pandemic. We understand that FDA has amended or plans to amend the EUAs for the COVID-19 vaccines so as not to require compliance with several of the conditions—including the "option to accept or refuse" notification—when the vaccines are exported to other countries. *See, e.g.*, Pfizer EUA Letter at 10.

[13] Congress's use of the phrase "Required conditions" in the title of subsection (e)(1)(A) and its specification of certain conditions in the statute suggest that Congress may have presumed that FDA would generally find that the specified conditions are "necessary or appropriate" and thus impose them. As we discuss above, however, the operative text of section 564 indicates that FDA has some discretion to modify, omit, or supplement the conditions in some circumstances. *See Fulton v. City of Philadelphia*, 141 S. Ct. 1868, 1879 (2021) ("[A] title or heading should never be allowed to override the plain words of a text." (quoting A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 222 (2012)) (alteration in original)).

in the Fact Sheets are limited to consequences related to medical care). As we have noted, however, section 564 does not limit the ability of entities to impose vaccination requirements, and FDA would not be required to change the Fact Sheets in order to allow them to impose such requirements.[14]

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As noted above, FDA agrees with our interpretation of section 564. On a few occasions, however, FDA has made statements that could be understood as saying that the condition described in section 564(e)(1)(A)(ii)(III) prohibits entities (particularly the U.S. military) from requiring the use of EUA products. In 2005, for instance, FDA issued an EUA that permitted the use of a vaccine for the prevention of inhalation anthrax by individuals between 18 and 65 years of age who were deemed by the Department of Defense ("DOD") to be at heightened risk of exposure due to an attack with anthrax. As a condition of that authorization, the agency required DOD to inform potential vaccine recipients "of the option to accept or refuse administration of [the vaccine]." Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability, 70 Fed. Reg. 5452, 5455 (Feb. 2, 2005). That EUA continued:

> With respect to [the] condition . . . relating to the option to accept or refuse administration of [the vaccine], the [immunization program] will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation

[14] FDA further informs us that, wholly apart from FDA's own authority to change the Fact Sheet, nothing in the FDCA would prohibit an administrator of the vaccine who also has a relationship with the individuals to whom the vaccine is offered (e.g., students in a university that offers the vaccine) from supplementing the FDA Fact Sheet at the point of administration with factually accurate information about the possible nonmedical consequences of the person choosing not to use the product (e.g., that she might not be permitted to enroll).

> based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination.

Id.; *see also id.* (allowing DOD to inform recipients that "military and civilian leaders strongly recommend anthrax vaccination, but . . . individuals [subject to the vaccination program] may not be forced to be vaccinated" and that "the issue of mandatory vaccination will be reconsidered by [DOD] after FDA completes its administrative process."). FDA included the same information in its later extension of that EUA. *See* Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Extension; Availability, 70 Fed. Reg. 44,657, 44,659–60 (Aug. 3, 2005).

In addition, although it is less than clear, certain FDA guidance could be read as saying that section 564 confers an affirmative "option" or "opportunity" to refuse EUA products. *See* EUA Guidance at 24 n.46 (implying that the condition in section 564(e)(1)(A)(ii)(III)—which is subject to waiver for the armed forces under 10 U.S.C. § 1107a—protects "the option for members of the armed forces to accept or refuse administration of an EUA product"); *Guidance Emergency Use Authorization of Medical Products*, 2007 WL 2319112, at *15 (July 1, 2007) (stating that "[r]ecipients must have an opportunity to accept or refuse the EUA product").

These statements do not affect our conclusion. Neither the 2005 anthrax vaccine EUA nor the later FDA guidance articulated a legal interpretation of section 564(e)(1)(A)(ii)(III)'s text. And FDA appears to have insisted upon the voluntariness requirement for DOD in the anthrax vaccine EUA because of then-recent litigation in which a court enjoined DOD from implementing a mandatory vaccination program based upon a different statutory provision that is inapplicable to EUAs. *See Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) (relying on 10 U.S.C. § 1107); *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) (same); *see also* 70 Fed. Reg. at 44,660 (requiring DOD to tell vaccine recipients the following: "On October 27, 2004, the U.S. District Court for the District of Columbia issued an Order declaring unlawful and prohibiting mandatory anthrax vaccinations to protect against inhalation anthrax, pending further FDA action. The *Court's injunction* means you have the right to refuse to take the vaccine without fear of retaliation." (emphasis added)); 70 Fed. Reg.

at 5454 (discussing litigation); *see also infra* note 15 (explaining that 10 U.S.C. § 1107(f) is inapplicable to EUAs).

B.

Section 564(e)(1)(A)(ii)(III) also raises a question about how to understand its cognate provision regarding the use of EUA products by the armed forces. As we noted above, in the same 2003 legislation that first created section 564, Congress also added the following provision to title 10 of the United States Code:

> In the case of the administration of [an EUA] product . . . to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) . . . 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.

10 U.S.C. § 1107a(a)(1).[15] On its own terms, this provision appears to be consistent with—and even to support—our reading of section 564, as it likewise describes the "option to accept or refuse" condition in purely informational terms. The language refers to the President's authority to

[15] Section 1107(f) of title 10—an earlier-enacted provision—contains a similar, but importantly different, waiver authority. Specifically, that provision authorizes the President, "[i]n the case of the administration of an [IND] 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," to waive "the prior consent requirement imposed under [21 U.S.C. § 355(i)(4)]." 10 U.S.C. § 1107(f)(1). That "prior consent requirement," which is imposed for purposes of the human clinical trials for which FDA authorizes "investigational" use of unapproved drugs, *see* 21 U.S.C. § 355(i)(4), does not apply to EUA products, which typically are more widely available, *see* FDCA § 564(k); EUA Guidance at 24 ("informed consent as generally required under FDA regulations is not required for administration or use of an EUA product" (footnote omitted)). Thus, the waiver provision in section 1107(f) is inapplicable to EUA products. *See* 10 U.S.C. § 1107(f)(2) (explaining that this waiver authority applies only in cases in which "prior consent for administration of a particular drug is required" because the Secretary of HHS determines that the drug "is subject to the [IND] requirements of [21 U.S.C. § 355(i)]"); *see also id.* § 1107(f)(4) (defining the relevant consent requirements as those in 21 U.S.C. § 355(i)).

waive a requirement to provide certain information, not to waive any right or affirmative "option" to refuse administration of the product itself.

On the other hand, the conference report on the legislation that created both section 564 of the FDCA and section 1107a of title 10 described the latter provision in the following way:

> [This provision] would authorize the President to waive *the right of service members to refuse administration of a product* if the President determines, in writing, that affording service members the right to refuse the product is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

H.R. Rep. No. 108-354, at 782 (2003) (Conf. Rep.) (emphasis added). This language indicates that the conferees may have believed that section 1107a concerns some "right" of members of the armed forces to refuse the use of EUA products. And that belief may help to explain why section 1107a allows only the President to exercise the waiver authority.

Consistent with this legislative history and the vesting of the waiver authority in the President, DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section 1107a. *See* DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008) ("In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients *are provided an option* to refuse administration of the product, the President may . . . waive *the option* to refuse for administration of the medical product to members of the armed forces." (emphasis added)). Moreover, we understand that DOD's position reflects the concern that service members, unlike civilian employees, could face serious criminal penalties if they refused a superior officer's order to take an EUA product. *See* 10 U.S.C. § 890; *see also United States v. Kisala,* 64 M.J. 50 (C.A.A.F. 2006) (upholding a soldier's punishment for refusing to take a vaccine). In this way, service members do not have the same "option" to refuse to comply with a vaccination requirement as other members of the public.

As noted above, it does appear that certain members of Congress thought that section 1107a concerned a prohibition against requiring service members to take an EUA product—perhaps on the view that the

waiver authority in section 1107a paralleled the one in 10 U.S.C. § 1107(f), which does effectively prohibit the administration of an IND product in a clinical trial without first obtaining the individual's affirmative, informed *consent*. *See supra* note 15 (distinguishing these waiver authorities).[16] As explained, however, that intent or expectation is not realized in the text of section 564(e)(1)(A)(ii)(III), which section 1107a expressly cross-references. *Cf. Steinle v. City & Cty. of San Francisco*, 919 F.3d 1154, 1164 n.11 (9th Cir. 2019) ("[T]he plain and unambiguous statutory text simply does not accomplish what the Conference Report says it was designed to accomplish."); *Goldring v. Dist. of Columbia*, 416 F.3d 70, 75 (D.C. Cir. 2005) ("A sentence in a conference report cannot rewrite unambiguous statutory text[.]").[17] We therefore conclude that section 1107a does not change our interpretation of section 564 of the FDCA.

As for DOD's concern about service members who would lack a meaningful option to refuse EUA products because of the prospect of sanction, including possibly prosecution, we note that any difference between our view and the assumption reflected in the conference report should have limited practical significance. Given that FDA has imposed the "option to accept or refuse" condition for the COVID-19 vaccines by requiring

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[16] It is possible the conferees assumed that the new EUA legislation would, in effect, carry over from the earlier IND provision of the FDCA, *see supra* Part I.A and note 11, the condition that a covered product may not be administered to an individual without that person's express, informed consent—a condition that applies to the military when it undertakes the sort of clinical trial with an IND that 21 U.S.C. § 355(i) governs, *see supra* note 11. Congress did not include such a consent requirement in section 564, however, perhaps because EUA products are not limited, as INDs are, to use in human clinical trials, but are instead authorized for more widespread use in the case of a declared emergency. *See supra* Part I.A and notes 11 & 15.

[17] Moreover, the legislative history as a whole is not uniform on this point. The earlier House report, for instance, described the condition in purely informational terms. *See* H.R. Rep. No. 108-147, pt. 3, at 33 (2003) ("New section 564(k) [an earlier but similarly worded version of what became 10 U.S.C. § 1107a] pertains to members of the Armed Forces and, among other things, it specifies that the President may waive requirements designed to ensure that such members are *informed* of the option to accept or refuse administration of an emergency use product, upon certain findings[.]" (emphasis added)); *see also Milner v. Dep't of the Navy*, 562 U.S. 562, 574 (2011) (noting that "[l]egislative history, for those who take it into account, is meant to clear up ambiguity, not create it," and thus, "[w]hen presented, on the one hand, with clear statutory language and, on the other, with dueling committee reports, we must choose the language").

distribution of its Fact Sheet containing the "[i]t is your choice to receive or not receive" language, DOD is required to provide service members with the specified notification unless the President waives the condition pursuant to 10 U.S.C. § 1107a. And because DOD has informed us that it understandably does not want to convey inaccurate or confusing information to service members—that is, telling them that they have the "option" to refuse the COVID-19 vaccine if they effectively lack such an option because of a military order—DOD should seek a presidential waiver before it imposes a vaccination requirement.

III.

For the reasons set forth above, we conclude that section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs.

DAWN JOHNSEN
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August 4, 2021

VIA EMAIL AND FEDERAL EXPRESS

The Honorable Dawn Johnsen
Acting Assistant Attorney General
Office of Legal Counsel
United States Department of Justice
Washington, DC 20530
dawn.johnsen@usdoj.gov

Re: Slip Opinion: *Whether Section 564 of the FDCA Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization*

Dear Ms. Johnsen:

We write on behalf of our client, the Informed Consent Action Network, regarding your Slip Opinion to the Deputy Counsel to the President, titled "Whether Section 564 of the FDCA Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization," (the "**Slip Opinion**") released to the public on July 26, 2021.

Section 564 of the Food, Drug, and Cosmetic Act ("**FDCA**"), codified at 21 U.S.C. § 360bbb-3 ("**Section 564**"), permits the Food and Drug Administration ("**FDA**") to issue an emergency use authorization ("**EUA**") for a medical product prior to licensure by the FDA. In your Slip Opinion, you conclude that Section 564 "does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs."[1] This conclusion runs contrary to the text of Section 564, its statutory framework, the history surrounding its passage and its consistent interpretation by the FDA, Centers for Disease Control and Prevention ("**CDC**"), the Department of Defense ("**DOD**"), and other federal agencies. Our client strongly urges you to reconsider your interpretation and guidance regarding Section 564, revise your Slip Opinion, and enforce Section 564 by making clear that it prohibits entities from requiring the use of an EUA product.

The Question Answered by Your Slip Opinion

Your Slip Opinion states that the Deputy Counsel to the President asked "whether the 'option to accept or refuse' condition in section 564 prohibits entities from imposing …

[1] https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf.

vaccination requirements while the only available vaccines for COVID-19 remain subject to EUAs." The "option to accept or refuse" refers to one of the "[r]equired conditions" in Section 564 for each EUA product. As provided in Section 564:

> the Secretary … shall … establish … [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.

Section 564, 21 U.S.C. § 360bbb-3(e)(1)(A) (emphasis added). The Department of Justice ("**DOJ**") is the entity primarily tasked with enforcing Section 564. *See* 21 U.S.C. § 337. Nevertheless, your Slip Opinion circumvents any enforcement of the foregoing required condition by concluding that the "language of section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements."[2] As discussed below, this conclusion is incorrect.

Entrenched Principle to Not Coerce Acceptance of Unlicensed Medical Products

To be licensed, the FDA must find that a medical product is "safe for use and … effective in use."[3] Until licensed, a medical product remains investigational, even after issuance of an EUA. As the National Institutes of Health ("**NIH**") explains with regard to a vaccine granted EUA: "The issuance of an EUA is different than an FDA approval (licensure) of a vaccine. A vaccine available under emergency use authorization is still considered investigational."[4] And as the FDA explains, "an investigational drug can also be called an experimental drug" because these two terms are synonymous.[5] For example, the EUA fact sheet for an intravenous drug to treat H1N1 granted EUA by the FDA explains that it is "an experimental drug."[6] Similarly, after an EUA was granted

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[2] *Id*.

[3] 21 U.S.C. § 355(b)(1)(A)(i) (an application for licensure requires "full reports of investigations which have been made to show that such drug is safe for use and whether such drug is effective in use").

[4] https://www.niaid.nih.gov/diseases-conditions/covid-19-vaccine-faq.

[5] Until a medical product's Investigational New Drug Application is approved by the FDA, and hence licensed, it is considered experimental. https://www.fda.gov/media/138490/download ("an investigational drug can also be called an experimental drug"); https://www.northwell.edu/coronavirus-covid-19/vaccine/frequently-asked-questions ("Vaccines that receive EUA are considered experimental until the FDA formally approves it.").

[6] https://web.archive.org/web/20100222172129/http:/www.cdc.gov/h1n1flu/eua/pdf/patient_fact_sheet_peramivir_IV_23Oct2009.pdf. Peer review studies found that using the term "experimental" in reference to an EUA medical product reduced their uptake and hence advised against informing the public that these products are still "experimental." *See, e.g.*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7893369/ ("A 2010 survey examining the acceptance of peramivir, approved as an EUA, found that use of the term 'experimental' on the fact sheet decreased willingness across the board. … FDA and the sponsor must … avoid language that stimulates negative responses (i.e., experimental)."); https://pubmed.ncbi.nlm.nih.gov/25882123/ ("In late 2009, peramivir was granted an EUA" and its "CDC fact sheet" stated it is an "experimental drug" but the study found that "the use of the term experimental, while necessary and accurate, presented real impediments for willingness" to take the EUA product.).

for the COVID-19 vaccine co-developed by the NIH and Moderna, it was described by the NIH as an "[e]xperimental coronavirus vaccine."[7]

Long settled legal precedent establishes that it is not legal to coerce an individual to accept an unlicensed, and hence experimental, medical product. An individual must voluntarily agree, free from any undue influence, to accept same. This principle was first codified long-ago by American jurists.[8] It was then incorporated into the United States Code, the Code of Federal Regulations, and guidance from federal health agencies. *See e.g.*, 21 U.S.C. § 360bbb-0a (Even for patients with a life-threatening condition, an unlicensed medical product cannot be coerced, rather Congress required obtaining the patient's "written informed consent.") 42 U.S.C. § 9501 (Same for mental health patients);[9] 45 C.F.R. § 46.116 (For an unlicensed medical product, the "Basic elements of informed consent" include that "participation is voluntary," "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled" and that consent be obtained without "coercion or undue influence.");[10] FDA *Information Sheet: Informed Consent* ("Coercion occurs when an overt threat of harm [such as expulsion from school or employment] is intentionally presented by one person to another in order to obtain compliance.")[11]

The principle that individuals should not be coerced to receive an unlicensed medical product is also codified in the law of at least 84 countries and is an accepted principle of international common law. *See, e.g.*, *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 184 (2nd Cir. 2009) ("We have little trouble concluding that a norm forbidding nonconsensual human medical experimentation [which includes unlicensed medical products] is every bit as concrete – indeed even more so – than the norm prohibiting piracy…. The Nuremberg Code, Article 7 of the ICCPR, the Declaration of Helsinki, the Convention on Human Rights and Biomedicine, the Universal Declaration on Bioethics and Human Rights, the 2001 Clinical Trial Directive, and the domestic laws of at least eighty-four States all uniformly and unmistakably prohibit medical experiments on human beings without their consent, thereby providing concrete content for the norm.").

In your Slip Opinion, you assert that expulsion from a job, school, and civil society are only "secondary consequences" which does not remove the "option to accept or refuse." Not only does this argument defy common sense, but Section 564's history, statutory framework, and

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[7] https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective.

[8] "The Nuremberg Code is the most important document in the history of the ethics of medical research. The Code was formulated 50 years ago, in August 1947 … by American judges … It served as a blueprint for today's principles that ensure the rights of subjects in medical research [which includes unlicensed medical products]." https://www.nejm.org/doi/full/10.1056/NEJM199711133372006. *See also* https://history.nih.gov/display/history/Nuremberg+Code, 313 BMJ 1448 (1996) ("The voluntary consent of the human subject is absolutely essential [for unlicensed medical interventions]. This means that the person … [is] able to exercise free power of choice, without the intervention of any element of … coercion.").

[9] *See also* 38 U.S.C. § 7331 (Same for veterans); 42 U.S.C § 300ff-61 ("in testing for HIV/AIDS, the applicant will test an individual only after the individual confirms that the decision of the individual with respect to undergoing such testing is voluntarily made").

[10] *See also* 21 C.F.R § 50.20 (sets forth conditions for obtaining informed consent for use of an unlicensed medical product and reiterating that consent should be free from "coercion or undue influence")

[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#coercion

implementation all reflect that "the option to accept or refuse" was intended to continue the longstanding principle that it is not permissible to coerce anyone to receive an unlicensed medical product.

Section 564 Incorporates the Principle that Unlicensed Medical Products Cannot be Mandated

Section 564 was enacted after the United States experienced September 11, 2001, and subsequent acts of terror, including envelopes with anthrax being sent through the United States Postal Service.[12] To create a legal route to distribute an unlicensed and therefore, experimental, medical product in the event of bioterrorism, or a similar emergency, and create a narrow exception to allow mandates of such a product to members of the military, Congress passed Section 564 (permitting an EUA) and 10 U.S.C. § 1107a ("**Section 1107a**") (permitting the President to waive "the option to accept or refuse" requirement in Section 564 for members of the military under limited circumstances of national security).

i. Congress' Intent When Passing Section 564

There is no indication that Congress, in passing Section 564 and Section 1107a, intended to deviate from the long-standing principle and entrenched state, federal, and international principle that unlicensed medical products generally cannot be anything but completely voluntary. That this principle was carried forward when Congress included the words "the right to accept or refuse" in Section 564 is reinforced by the legislative discussions surrounding the passing of Section 564. On July 16, 2003, in deliberating Section 564, Representative Hays said, without any objection, that:

> …any authority to actually use experimental drugs or medical devices in emergency situations has to be defined and wielded with nothing less than surgical precision. Prior informed consent in connection with the administration of experimental therapy is a basic human right, a right no one should be asked to surrender…[13]

Similarly, on May 19, 2004, Senator Kennedy said while deliberating regarding Section 564 that "[t]he authorization for the emergency use of unapproved products also includes strong provisions on informed consent for patients."[14]

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[12] *See* https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article (detailing "the need for and genesis of the EUA, its requirements, its broad application to civilian and military populations, and its features of particular importance to physicians and public health officials.").

[13] https://www.congress.gov/congressional-record/2003/7/16/house-section/article/h6908-1.

[14] https://www.congress.gov/congressional-record/2004/05/19/senate-section/article/S5744-1. This same Senator also reiterated that Section 564 "allows the FDA to authorize the emergency use of medicines under the tightly controlled conditions outlined in this legislation." *Id.* Those conditions are, of course, specifically outlined in Section 564. In a congressional hearing on Section 564 held a few months later, Representative Maloney added that "unapproved drugs and devices, whose risks and benefits are not fully tested, impose an unprecedented responsibility on the government. The FDA must be vigilant in protecting the public against unnecessary risks from these products. In part because of these concerns, the bill has been modified to require that health care providers and patients be informed that the products have not been approved and of their risks. … These conditions [in Section 564] are essential

ii. The Exception that Proves the Rule

That Congress intended "the option to accept or refuse" as a prohibition on mandating an unlicensed medical product comes into sharp focus by the fact that Congress specifically carved out only one exception for when an individual would not have "the option to accept or refuse administration of the product." Congress permitted required use of an EUA product when the President of the United States finds that providing an individual in the military with the option to accept or refuse the product would not be in the interests of national security. As provided in Section 1107a:

> 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.

Thus, Congress so highly valued the right to individual choice that it allowed only a threat to national security to trump that right, and even then, only with regard to military personnel. As your Slip Opinion admits, this is how members of Congress understood Section 564 and Section 1107a when they were enacted. *See* Slip Opinion at 16-17. It is also how the DOD understood these sections following their enactment, stating in DOD Instruction 6200.02 § E3.4, adopted February 27, 2008:

> In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients **are provided an option** to refuse administration of the product, the President may … waive **the option** to refuse … administration of the medical product to members of the armed forces.[15]

Your interpretation of Section 564 renders Section 1107a meaningless and nonsensical. If the military was permitted to create any consequences it deemed appropriate in the event an armed forces member refused an EUA vaccine, it would be unnecessary to create a separate statute and require a written presidential national security finding to remove a requirement that, in your words, "concerns only the provision of information[.]"

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for the safe use of unapproved products, and they should be imposed in all cases, except in truly extraordinary circumstances." https://www.congress.gov/congressional-record/2004/07/14/house-section/article/H5721-3

[15] https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620002p.pdf (emphasis added).

iii. Consistent Agency Interpretation of Section 564

The FDA likewise viewed Section 564 as providing a substantive right to refuse when it explained the military exception:

> [A]s a general rule, persons **must be made aware of their right to refuse the product** (or to refuse it for their children or others without the capacity to consent) and of the potential consequences, if any, of this choice. An exception to this rule is that the president, as commander in chief, **can waive military personnel's right to refuse this product**. If the right is not specifically waived by the president for a particular product given under EUA, military personnel **have the same right to refuse as civilians**.[16]

The FDA thus makes clear that Section 564 provides a substantive right to refuse, and this right does not exist in the presence of a requirement that imposes negative consequences for refusing.

Similarly, the CDC's Advisory Committee on Immunization Practices ("**ACIP**") has interpreted Section 564 as a consent provision and not merely a requirement to inform. When responding to an inquiry regarding whether the COVID-19 vaccines can be required, the Executive Secretary of ACIP publicly stated that "under an EUA, vaccines are not allowed to be mandatory. Therefore, early in the vaccination phase individuals **will have to be consented** and **cannot be mandated to be vaccinated**."[17] ACIP's Executive Secretary then reaffirmed to the FDA's Vaccine and Related Biological Products Advisory Committee that no organization, public or private – including hospitals – can mandate the EUA COVID-19 Vaccines:

> Organizations, such as hospitals, with licensed products do have [the] capability of asking their workers to get the vaccine. But in the setting of an EUA, patients and individuals will have **the right to refuse** the vaccine.[18]

Consistent with the foregoing, the U.S. General Services Administration's ("**GSA**") Safer Federal Workforce website, applicable to all federal employees and contractors, expressly provided that the EUA COVID-19 vaccines cannot be mandatory, stating:

> Employees should receive paid time off to be vaccinated and to deal with any side effects. At present, COVID-19 vaccination should generally not be a pre-condition for employees or contractors at executive departments and agencies … to work in-person in Federal buildings, on Federal lands, and in other settings as required by their job duties. Federal employees and contractors may voluntarily share

[16] Nightingale SL, Prasher JM, Simonson S. Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States. *Emerging Infectious Diseases*. 2007;13(7):1046. doi:10.3201/eid1307.061188 available at https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article#r1 (emphasis added).

[17] https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf at 56 (emphasis added).

[18] https://www.fda.gov/media/143982/download at 156 (emphasis added).

> information about their vaccination status, but agencies should not require federal employees or contractors to disclose such information.[19]

The GSA only changed this interpretation *after* you released your Slip Opinion.

The foregoing consistent guidance from the FDA, CDC, DOD, and GSA all reflect the fact that federal agencies have long understood that an EUA product cannot be mandatory.

iv. Section 564 Prohibits Consequences Beyond Those Authorized by the Secretary

In line with the foregoing, Congress provided in Section 564 that only the Secretary of the U.S. Department of Health and Human Services (the "**Secretary**") may provide consequences for refusing an EUA product. As provided in that section, "the Secretary … shall … establish … the consequences, if any, of refusing administration of the product." The FDA makes plain that "the option to accept or refuse" and the "consequences" for refusing an EUA product established by the Secretary cannot be modified or added to:

> … section 564 does provide EUA conditions to ensure that recipients are informed about the MCM [medical countermeasure] they receive under an EUA. For an unapproved product … the statute requires that FDA ensure that recipients are informed … [t]hat they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product. The President may under certain circumstances waive the option for members of the armed forces to accept or refuse administration of an EUA product…
>
> In an emergency, **it is critical that the conditions that are part of the EUA … be strictly followed, and that no additional conditions be imposed**.[20]

The authorized labeling (the "**Fact Sheets**") for each EUA COVID-19 vaccine includes a question and answer section that expressly asks the question: "What if I decide not to get the … COVID-19 vaccine?," and the response reflects that the Secretary chose to not provide any "consequences" for refusing these products when it states: "Should you decide to not receive it, it will not change your standard of medical care."[21] Consistent with Section 564, and as reflected in the FDA's guidance, the required conditions on the Fact Sheets for each EUA COVID-19 vaccine are to "be strictly followed" and "no additional conditions [may] be imposed." And the Secretary's

[19] https://web.archive.org/web/20210727233714/https:/www.saferfederalworkforce.gov/faq/vaccinations/.

[20] https://www.fda.gov/media/97321/download (emphasis added).

[21] https://www.fda.gov/media/144414/download (Pfizer); https://www.fda.gov/media/144638/download (Moderna); https://www.fda.gov/media/146305/download (Janssen).

conditions for each EUA COVID-19 vaccine provide that there will not be any consequences for refusing this product.[22]

The interpretation of Section 564 that you apply in your Slip Opinion is therefore incorrect in stating that "[n]either the statutory conditions of authorization nor the Fact Sheet itself purports to restrict public or private entities from insisting upon vaccination in any context." The Slip Opinion runs directly counter to Section 564 and the FDA's guidance by permitting additional conditions on a person's refusal to receive an EUA product. For example, it would permit public or private entities to impose conditions such as a person's continued employment, or their right to receive certain benefits, on that person's acquiescence to receive an EUA product. These are obviously additional conditions beyond those established by the EUA for the COVID-19 vaccines, and as such, these conditions are not permitted. [23]

v. The Dictionary and Common Sense

Your Slip Opinion cites to the dictionary definition of "inform" but ignores the definition of the more important word "option" in Section 564 which the dictionary defines as "the power or right to choose; freedom of choice."[24] The Slip Opinion's interpretation of Section 564 would permit eliminating any real "freedom of choice." It is illogical that Congress would require that individuals be informed of a freedom of choice if that choice is illusory at the whim of any public or private entity.

If not clear on its face from Section 564, it is certainly made clear by the fact that Congress found it necessary to craft an exception to this freedom of choice for the military. If the "option to accept or refuse" were not a substantive right, there would be no need for the President to make a national security finding to require the military to receive an EUA product. The military exception was also unnecessary if Congress intended to permit any entity to impose its own "consequences" for refusing an EUA product.

vi. Putting it All Together

In sum, your reading of Section 564 as a requirement that an individual be informed that they have a "choice" while at the same time allowing the product to be mandated is illogical and contrary to the plain meaning, intent, and history of Section 564. There is no logical way to interpret Section 1107a other than as creating the only exception to the general rule in Section 564 that no one can be mandated to receive an EUA product except for the military in the event of a national security threat. Section 564 requires that this be an actual choice, which is incompatible

[22] *Id*. While the Secretary may include "consequences," consistent with the remainder of Section 564 and its statutory framework, those consequences cannot be coercive or unduly influence consent to an EUA product.

[23] The Slip Opinion focuses on the language "to the extent practicable given the applicable circumstances" to indicate the Secretary could potentially even eliminate the "required condition" of informing of "the option to accept or refuse." However, the "to the extent practicable" language plainly modifies the words "appropriate conditions" that the Secretary can impose, but those appropriate conditions must still "ensure that individuals to whom the product is administered are informed … of the option to accept or refuse."

[24] https://www.merriam-webster.com/dictionary/option.

with levying serious adverse consequences if someone refuses an EUA product, such as expulsion from school, employment, or the armed forces.

Your Slip Opinion did not meaningfully consider the foregoing in concluding that the "language of section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements."[25]

Conclusion

Rights exist to limit those in power. Congress entrusts the DOJ with the duty to enforce the long-standing principal that no individual should be coerced or unduly influenced to accept an unlicensed medical product. Whatever short term gain the Office of the President and the DOJ officials who authored the Slip Opinion believe will be achieved by casting aside this fundamental right pales in comparison to the harm likely to result from its elimination over the long arc of our great nation.[26]

We live in an unprecedented time, making it all the more important to hold tight to the principles that we have learned from history. We respectfully request that the DOJ officials that drafted the Slip Opinion reconsider their interpretation and guidance regarding Section 564, that you revise the Slip Opinion to accord with the foregoing, and that the DOJ fulfill its duty by enforcing this provision which prohibits mandates of an EUA product, rather than casting this important and longstanding right aside.

Sincerely Yours,

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cc: Danielle Conley, Deputy Counsel to the President

[25] https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf.

[26] Most medical products have historically been given to a small segment of the population, and hence when an unexpected result occurs, only a small segment of the population is impacted. Recent innovations have made it feasible and affordable to deploy drugs to large portions of the population. Unexpected consequences from an EUA product can therefore have far wider implications. This makes it even more important to hold fast to the longstanding principal that nobody should be coerced to take an unlicensed medical product.