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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-mmdl-vaa.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/20160222172129/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/NEJM199711333372006. *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/H5721-2

[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

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[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://www.wnc.edu/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

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[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

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[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,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.
Allison Lucas, Esq.
Gabrielle Palmer, Esq.
Jessica Wallace, Esq.

cc: Danielle Conley, Deputy Counsel to the President

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[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.