ELIDING CONSENT IN THE CASE OF PANDEMIC COUNTERMEASURES AUTHORIZED ONLY FOR EMERGENCY USE

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ABSTRACT

Four months after the first vaccines against Covid-19 became available to the public, and just as some universities announced plans to require inoculations, the Boston Globe *quoted me as (alone) suggesting that mandates would conflict with federal law. When Congress created a special mechanism for the emergency use of still investigational products, it directed providers to reveal, among other things, that individuals remained free to decline such an intervention; only after full FDA approval of a medical countermeasure would this disclosure obligation become inapplicable. I have watched with dismay over the last three years as nearly everyone—including Executive branch officials, federal and state judges, and various academic commentators—cavalierly dismissed an entirely valid statutory objection. This Article probes what accounts for the universal rejection of an argument that, on further reflection, continues to strike me as far from frivolous.*

TABLE OF CONTENTS

> *So all a man could win in the conflict between plague and life was knowledge and memories.*
> —Albert Camus, *The Plague* (1947)

INTRODUCTION

As promising vaccines became widely available just one year into the

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Covid-19 pandemic, questions arose about the legality of possible immunization mandates then under consideration by various entities. In particular, would a federal statute that had authorized the "emergency use" of unapproved countermeasures, which included a requirement for informing individuals of "the option to . . . refuse administration of the product,"[1] stand in the way of premature vaccination orders?[2] When some such immunization mandates took hold, challenges quickly followed in the courts, raising a range of objections including but hardly limited to this statutory question.[3] Now that the pandemic phase of Covid-19 has passed, and before we confront another such emergency, the time has come for a less hurried appraisal of this seeming technicality.

Meatier constitutional objections to immunization requirements need not detain us. More than a century ago, the U.S. Supreme Court upheld a municipality's smallpox vaccination mandate even though questions existed about the safety of that vaccine,[4] which had undergone no federal licensing

1. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

2. At the time, I shared my doubts with a couple of media outlets, while other commentators expressed rather more confidence on this score. *See* Deirdre Fernandes, *A New College Prerequisite: Vaccinations; As Some Schools Adopt Mandate, Concerns Arise*, BOS. GLOBE, Apr. 20, 2021, at A1; Daniel Funke, *Fact Check: Federal Law Does Not Prevent States, Businesses, Employers from Requiring COVID-19 Vaccines*, USA TODAY, May 25, 2021, https://www.usatoday.com/story/news/factcheck/2021/05/25/fact-check-federal-law-doesnt-prohibit-covid-19-vaccine-mandates/5062104001/ [perma.cc/2RQW-P9JG]. I found only a few academic commentators expressing similar qualms at that time. *See, e.g.*, Amy Goldstein, *For Health-Care Industry, an Agonizing Debate*, WASH. POST, Apr. 6, 2021, at A1 (quoting a leading public health law expert, Professor Larry Gostin at the Georgetown University Law Center, as saying that "the government 'mandating a vaccine that's only authorized for emergency use is a gray area of legality and may be unlawful'"); *see also* Lawrence O. Gostin et al., *Mandating COVID-19 Vaccines*, 325 JAMA 532, 532 (2021) (calling the idea "legally and ethically problematic," though offering little elaboration); Efthimios Parasidis & Aaron S. Kesselheim, *Assessing the Legality of Mandates for Vaccines Authorized Via an Emergency Use Authorization*, HEALTH AFF. BLOG (Feb. 16, 2021), https://www.healthaffairs.org/content/forefront/assessing-legality-mandates-vaccines-authorized-via-emergency-use-authorization [perma.cc/V7GP-4PTH] (concluding that Congress had not contemplated mandates in such circumstances).

3. *See* Isaac Stanley-Becker, *Group's Legal Blitz Deters Vaccine Mandates*, WASH. POST, May 27, 2021, at A1; *see also* Molly Hennessy-Fiske & Emily Baumgaertner, *153 Houston Hospital Workers Lose Jobs After Refusing Vaccine; Healthcare Employees Go to Court, Saying an Experimental Drug Was Being Forced on Them*, L.A. TIMES, June 23, 2021, at A1; Lauren Weber, *Nonprofits Hit It Big with Claims About Covid*, WASH. POST, Feb. 24, 2024, at A1 (reporting that the pandemic brought substantial increases in donations to libertarian health advocacy organizations, helping "to finance lawsuits seeking to roll back vaccine requirements"). Part III.B canvasses the disposition of the numerous court cases that arose.

4. *See* Jacobson v. Massachusetts, 197 U.S. 11, 26-39 (1905); *see also* Zucht v. King, 260 U.S. 174, 176 (1922) (relying primarily on *Jacobson* in the course of upholding a school smallpox vaccination requirement); *cf.* Buck v. Bell, 274 U.S. 200, 207 (1927) (relying exclusively on *Jacobson* in the course of allowing a state to sterilize individuals institutionalized for "feeble mindedness"). *See generally* Josh Blackman, *The Irrepressible Myth of* Jacobson v. Massachusetts, 70 BUFF. L. REV. 131 (2022).

process at the time.[5] Before the ruling, Congress made these biological agents subject to regulatory scrutiny.[6] Decades passed before the Supreme Court would recognize a fundamental right to decline unwanted medical interventions,[7] though that still allowed for government infringements if premised on sufficiently compelling reasons.[8] This Article focuses instead on a newer and seemingly less forgiving statutory safeguard for a patient's freedom of choice applicable to only a narrow subset of vaccines and related interventions though potentially limiting private actors as well.

I. EMERGENCY USE AUTHORIZATION MEETS COVID-19

In 2003, prompted by the attacks of 9/11 and the mailing of anthrax spores one month later, Congress authorized the waiver of federal licensing and other

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5. *See* LARS NOAH, LAW AND THE PUBLIC'S HEALTH: CASES, CONTROVERSIES, AND COVID-19, at 24 (2023) ("Fears about the smallpox vaccine would have been fresh on people's minds at the time. One year before Mr. Jacobson's refusal, nine children in Camden, New Jersey, died from tetanus-contaminated doses that they had received in school.").

6. *See id.* ("Congress responded by passing the Biologics Act of 1902, the first ever federal licensing requirement. Even with greater supervision of product quality, however, this vaccine remains one of the most likely to trigger side effects in recipients."); *see also* Ross E. DeHovitz, *The 1901 St. Louis Incident: The First Modern Medical Disaster*, 133 PEDIATRICS 964, 965 (2014) (discussing the deaths of thirteen children after they received diphtheria antitoxin contaminated with tetanus as prompting Congress to act, making passing reference to "a similar incident in Camden"); *cf.* Tess Lanzarotta & Marco A. Ramos, *Mistrust in Medicine: The Rise and Fall of America's First Vaccine Institute*, 108 AM. J. PUB. HEALTH 741, 742 (2018) (explaining that a federal initiative ended in 1822 after its leader accidentally sent smallpox instead of cowpox material for vaccination to a town in North Carolina, which resulted in ten deaths).

7. *See* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 270 (1990) ("The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment."); *see also* Washington v. Glucksberg, 521 U.S. 702, 720 (1997) ("We have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment."); *id.* at 725 ("Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation's history and constitutional traditions."); Winston v. Lee, 470 U.S. 753, 765-67 (1985) (holding that the surgical removal of a bullet from a suspect without consent constituted an unreasonable search); NOAH, *supra* note 5, at 24 ("Over time, . . . the personal rights given relatively short shrift in *Jacobson* have become far more jealously protected.").

8. *See, e.g.*, Washington v. Harper, 494 U.S. 210, 227-36 (1990) (rejecting constitutional objections to the forced treatment of a schizophrenic prison inmate with antipsychotic drugs). The *Jacobson* decision predated the modern tiers of constitutional scrutiny, which has prompted growing questions about its continued authoritativeness. *See, e.g.*, Roman Cath. Diocese of Brooklyn v. Cuomo, 592 U.S. 14, 23-25 (2020) (Gorsuch, J., concurring); Calvary Chapel Dayton Valley v. Sisolak, 140 S. Ct. 2603, 2608 (2020) (Alito, J., dissenting) ("[I]t is a mistake to take language in *Jacobson* as the last word on what the Constitution allows public officials to do during the COVID-19 pandemic."); Big Tyme Invs., L.L.C. v. Edwards, 985 F.3d 456, 470-71 (5th Cir. 2021) (Willett, J., concurring). Even if eventually abandoned as a precedent, *Jacobson* would still serve as evidence that any claimed (and more specifically defined) right to refuse vaccination does not have deep roots in our nation's history and traditions (as courts must determine whenever asked to recognize new fundamental rights). *See, e.g.*, Boone v. Boozman, 217 F. Supp. 2d 938, 956 (E.D. Ark. 2002).

applicable requirements for medical countermeasures to a life-threatening chemical, biological, radiological, or nuclear (CBRN) danger for the duration of a declared emergency and for which no adequate alternatives exist.[9] Although initially designed solely for a "military emergency," subsequent amendments expanded this new power for granting emergency use authorization (EUA) to include a "public health emergency."[10] The Food and Drug Administration (FDA), which resides within the sprawling U.S. Department of Health and Human Services (HHS), exercises this authority,[11] though so far neither of these agencies has promulgated any formal rules to further define how it would implement the EUA provision.[12]

Used only a handful of times previously, EUAs became commonplace during the Covid-19 pandemic.[13] The FDA made repeated use of this

9. *See* National Defense Authorization Act for Fiscal Year 2004, Pub. L. No. 108-136, § 1603(a), 117 Stat. 1392, 1684-89 (2003) (codified as amended at 21 U.S.C. § 360bbb-3). This legislation added new section 564 to the federal Food, Drug & Cosmetic Act (FDCA). One year earlier, Congress took other steps to address such fears, including efforts to speed the approval of countermeasures. *See* Public Health Security and Bioterrorism Preparedness and Response Act, Pub. L. No. 107-188, § 122, 116 Stat. 594, 613 (2002) (codified as amended at 21 U.S.C. § 356-1).

10. *See* Project BioShield Act of 2004, Pub. L. No. 108-276, § 4(a), 118 Stat. 835, 854 (codified as amended at 21 U.S.C. § 360bbb-3(b)(1)(C)). Such an emergency would still need to potentially affect "national security," or, as added almost a decade later, "the health and security of United States citizens living abroad," Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, § 302(a)(2)(B)(iv), 127 Stat. 161, 180-81. The 2013 amendments also added a new section (FDCA § 564A) for the emergency use of fully approved products to allow for, among other things, extensions of expiration dates, waivers of good manufacturing practice (GMP) requirements, and dispensing without a prescription. *See id.* § 302(b), 127 Stat. at 183-85 (codified at 21 U.S.C. § 360bbb-3a).

11. *See* FDA, EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES 3 n.6 (Jan. 2017), https://www.fda.gov/media/97321/download [perma.cc/7G33-KJAP] [hereinafter FDA's 2017 EUA Guidance] (explaining that the Secretary of HHS had subdelegated to it most of these functions); *see also* 21st Century Cures Act, Pub. L. No. 114-255, § 3088, 130 Stat. 1033, 1148-49 (2016) (titling one set of amendments as "Clarifying Food and Drug Administration emergency use authorization"); Guidance, Emergency Use Authorization of Medical Products, 72 Fed. Reg. 41,083 (July 26, 2007), *superseded*, 82 Fed. Reg. 4362, 4363 (Jan. 13, 2017). The U.S. Centers for Disease Control and Prevention (CDC), also figuratively housed within HHS though headquartered in Atlanta, play a supporting role.

12. Congress had expressly delegated the power to issue regulations designed to implement this provision. *See* 21 U.S.C. § 360bbb-3(c)(5). This agency has increasingly shifted to issuing technically nonbinding guidance documents. *See* Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 97-109, 113-22 (2014); *see also* Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, 85 Fed. Reg. 16,949 (Mar. 25, 2020) (explaining that, given the pressing nature of the pandemic, the agency would skip the limited procedures that govern its issuance of guidance). *See generally* Guidance Documents Related to Coronavirus Disease 2019, 85 Fed. Reg. 46,641 (Aug. 3, 2020) (listing some of the earliest ones).

13. In just the first year of the pandemic, the agency issued almost ten times as many EUAs as it had during the preceding seventeen years. *See* FDA COVID-19 PANDEMIC RECOVERY AND PREPAREDNESS PLAN (PREPP) INITIATIVE: SUMMARY REPORT 24 (Jan. 2021), https://www.fda.gov/media/145129/download [perma.cc/G24L-BGZ9] (counting more than 600 EUAs issued in

mechanism to facilitate the introduction of *in vitro* diagnostic (IVD) tests,[14] vaccines,[15] treatments (e.g., monoclonal antibodies),[16] and face masks.[17] As the Covid-19 public health emergency began to wind down, EUAs also figured prominently in the federal government's response to a worrisome outbreak of

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2020 compared to 65 previously); Jonathan L. Iwry, *FDA Emergency Use Authorization from 9/11 to Covid 19: Historical Lessons and Ethical Challenges*, 76 FOOD & DRUG L.J. 337, 355-59 (2021) (summarizing this upsurge in use); *see also id.* at 380 ("There is hardly any precedent to refer to in making EUA-related decisions; even the use of EUAs in the H1N1 [swine flu] crisis of 2009 pales in comparison."). Before 2020, the FDA only sporadically used this authority, in connection with countermeasures to anthrax, Ebola, H1N1 flu, MERS, and Zika. *See id.* at 350-55; Kirstiana Perryman, Note, *Agents of Bioshield: The FDA, Emergency Use Authorizations, and Public Trust*, 56 GA. L. REV. 341, 356-60 (2021).

14. *See* FDA, POLICY FOR CORONAVIRUS DISEASE-2019 TESTS (REVISED), GUIDANCE FOR DEVELOPERS AND FOOD AND DRUG ADMINISTRATION STAFF 5 (Jan. 12, 2023), https://www.fda.gov/media/135659/download [perma.cc/32GS-9HME] ("As of August 15, 2022, FDA has issued EUAs for more than 439 tests for COVID-19, including more than 354 diagnostic and 85 serology or other immune response tests."); *see also* Jeffrey N. Gibbs & Gail H. Javitt, *A Test of the Emergency (Use Authorization) System: Challenges in FDA Regulation of COVID-19 Diagnostics*, 76 FOOD & DRUG L.J. 398 (2021) (providing a detailed catalog of the various delays, missteps, and confusion that have plagued this process); *id.* at 435 ("[F]ocusing on the EUAs that were granted overlooks the numerous EUAs that were unsuccessful."); *id.* at 427 n.173 ("As of May 14, 2021, FDA had received an estimated 6,604 EUAs for devices overall; . . . only 372 tests have been granted EUAs.").

15. *See* Authorization of Emergency Use of a Biological Product During the COVID-19 Pandemic, 87 Fed. Reg. 52,790, 52,792-93 (Aug. 29, 2022) (vaccine from Novovax); Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic, 86 Fed. Reg. 28,608, 28,619-20 (May 27, 2021) (vaccine from Johnson & Johnson's Janssen Biotech subsidiary); Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic, 86 Fed. Reg. 5200 (Jan. 19, 2021) (mRNA vaccines from Pfizer-BioNTech and Moderna).

16. *See, e.g.*, Authorization of Emergency Use of a Biological Product During the COVID-19 Pandemic, 87 Fed. Reg. 16,201, 16,203-04 (Mar. 22, 2022) (monoclonal antibody bebtelovimab); Authorizations of Emergency Use of Certain Drugs and Biological Products During the COVID-19 Pandemic, 87 Fed. Reg. 6578, 6580-81, 6590-91 (Feb. 4, 2022) (monoclonal antibody Evusheld® for prevention and antiviral Paxlovid® for treatment); Authorizations of Emergency Use of Certain Drug and Biological Products During the COVID-19 Pandemic, 86 Fed. Reg. 10,290 (Feb. 19, 2021); Authorizations and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic, 85 Fed. Reg. 56,231, 56,250-55 (Sept. 11, 2020) (antiviral remdesivir).

17. In April 2020, the FDA posted a letter directed to manufacturers and other stakeholders in order to clarify that an EUA it had issued a week earlier authorized the use of various types of "face masks" (as distinct from more closely regulated respirators and surgical masks then in short supply) by health care personnel as well as the general public for purposes of "source control" (as distinct from personal protective equipment (PPE) that would also guard against the risks of exposure by inhalation) during the Covid-19 public health emergency. *See* Letter from Denise M. Hinton, Chief FDA Scientist (Apr. 24, 2020), https://www.fda.gov/media/137121/download [perma.cc/R6HD-4HRA]. Although it specified permissible claims in labeling, *see id.* at 3-4, the "conditions of authorization" set forth elsewhere in that letter made no mention of any requirement to inform users of an option to decline, *see id.* at 5-6; *see also* Lloyd v. Sch. Bd. of Palm Beach Cnty., 570 F. Supp. 3d 1165, 1174 (S.D. Fla. 2021) ("The Mask EUA does not include any provision regarding informed consent."). The FDA later issued separate EUAs for respirators and related devices. *See, e.g.*, Authorization of Emergency Use of Certain Medical Devices During COVID-19, 85 Fed. Reg. 74,346, 74,350-52 (Nov. 20, 2020).

monkeypox (later redesignated as mpox).[18] The remainder of this Article focuses on disclosure requirements that may accompany an FDA decision to authorize the emergency use of medical countermeasures, particularly vaccines.

II. CONSTRUING THE EUA CHOICE CLAUSE

Congress had dictated certain "required conditions" when a previously unapproved product secured an EUA. In pertinent part, the statute provided as follows:

> [T]he Secretary, to the extent practicable given the applicable circumstances [of a declared emergency], shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following: . . . (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed— . . . (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.[19]

Even as truncated to isolate the effort to ensure that recipients make a free and informed choice, this language requires some unpacking and hardly represents a model of clarity. Indeed, Congress did not call for securing "consent" as such. Perhaps it thought that this provision would create a quick-and-dirty mechanism for getting permission by acquiescence, so "assent" (or "consent lite") might better capture the issue.[20] In taking care to avoid misrepresenting the intentions of Congress, I will hereinafter refer to this statutory language as the "EUA

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18. *See, e.g.*, Authorization of Emergency Use of a Biological Product in Response to an Outbreak of Monkeypox, 87 Fed. Reg. 61,054, 61,056-57 (Oct. 7, 2022) (allowing for the use of lower doses—by a different route of administration—of the previously approved vaccine Jynneos®); *see also* Policy for Monkeypox Tests to Address the Public Health Emergency, 87 Fed. Reg. 56,064, 56,065 (Sept. 13, 2022) (issuing guidance on EUAs for IVDs).

19. 21 U.S.C. § 360bbb-3(e)(1)(A); *see also id.* § 360bbb-3(e)(2)(A) (requiring likewise for unapproved uses of previously approved products). Other conditions required for previously unapproved products related to informing health care professionals, reporting of adverse events, and recordkeeping by manufacturers. *See id.* § 360bbb-3(e)(1)(A).

20. *Cf.* O'Brien v. Cunard S.S. Co., 28 N.E. 266, 266 (Mass. 1891) ("There was nothing in the conduct of the plaintiff [a disembarking passenger] to indicate to the [ship's] surgeon that she did not wish to obtain a card which would save her from detention at quarantine, and to be vaccinated [against smallpox], if necessary, for that purpose."); Alexander Morgan Capron, *Where Did Informed Consent for Research Come From?*, 46 J.L. MED. & ETHICS 12, 15 (2018) ("Compliance and acquiescence, that is, the absence of objection, provide a form of consent, in medicine as in the rest of our lives."). For instance, research involving children generally requires securing "assent" from the subjects coupled with written "permission" from their parents. *See* 21 C.F.R. § 50.55 (FDA); 45 C.F.R. § 46.408 (HHS).

choice clause."

First, Congress allowed for the possibility that a sufficiently pressing emergency might make these conditions impracticable for the Department to impose. Second, the statute obligated HHS to establish these conditions based on a finding of necessity that linked back to public health protection. What happens, however, if the Department failed to make such a finding when it issued an EUA and imposed no conditions?[21] What if, instead, it made a threshold finding of impracticability or a more focused finding that one or more of the enumerated conditions did not strike HHS as "necessary or appropriate"?[22] Finally, what if the agency imposed conditions that simply parroted the language of this provision, including the above-quoted clause regarding the choice available to recipients, but a person carrying out an activity covered by the EUA neglected to comply with these terms?[23] As it happens, anyone alleging an injury from such a failure would lack any meaningful opportunity for recourse under state tort law because of special immunities granted to suppliers and providers of countermeasures during a declared emergency.[24]

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21. *Cf.* 21 U.S.C. § 360bbb-3(h)(1) (requiring publication of each EUA in the *Federal Register* and on the FDA's website).

22. For instance, IVD test kits did not include such a statement. *See, e.g.*, FACT SHEET FOR PATIENTS, GNOMEGEN COVID-19 RT-DIGITAL PCR DETECTION KIT (Apr. 6, 2020), https://www.fda.gov/media/136737/download?attachment [perma.cc/V99H-P94E]. The FDA previously had suggested a reason based on uncertainty over whether collected samples might undergo a fully approved test. *See* FDA's 2017 EUA Guidance, *supra* note 11, at 24 n.46. During the pandemic, however, all tests initially lacked approval, making this rationale inapt. Since 2006, and entirely apart from the use of the EUA mechanism, the agency has allowed for the waiver of informed consent requirements for investigational IVDs to identify CBRN agents in an emergency. *See* Medical Devices; Exception from General Requirements for Informed Consent, 71 Fed. Reg. 32,827, 32,833 (June 7, 2006) (codified as amended at 21 C.F.R. § 50.23(e)).

23. *Cf.* Antunes v. Rector & Visitors of Univ. of Va., 627 F. Supp. 3d 553, 561 (W.D. Va. 2022) (holding that a nurse fired by a state university for refusing to get vaccinated lacked standing to challenge federal agencies for an alleged failure to ensure that she would enjoy a genuine option to decline such an employer mandate under the EUA statute).

24. *See* Public Readiness and Emergency Preparedness (PREP) Act, Pub. L. No. 109-148, Div. C, § 2, 119 Stat. 2818, 2818-29 (2005) (codified as amended at 42 U.S.C. § 247d-6d) (generally authorizing lawsuits only in cases of "willful misconduct"); *see also* 42 U.S.C. § 247d-6d(c)(5) (providing that, in order to establish willful misconduct by a manufacturer or distributor, a plaintiff first would have to await successful enforcement action for a violation of the FDCA); Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 Fed. Reg. 30,769 (May 12, 2023) (issuing likely the last in a series of announcements that triggered such immunity during the pandemic). The only reported tort cases alleging that providers had failed to secure informed consent to the use of a countermeasure (both involving the H1N1 flu vaccine) took contrary positions on the availability of immunity under the PREP Act. *Compare* Kehler v. Hood, No. 4:11CV1416, 2012 WL 1945952, at *4 (E.D. Mo. May 30, 2012) (suggesting that the provision did not apply because the breach of duty would have occurred prior to the vaccination), *with* Parker v. St. Lawrence Cnty. Pub. Health Dep't, 954 N.Y.S.2d 259, 262-63 (App. Div. 2012) (dismissing such a claim as federally preempted).

A. Confronting the Text

The language of the statute plainly expressed a congressional aim of ensuring that individuals offered an unapproved product subject to an EUA would comprehend their options. Although the FDA enjoyed some flexibility in implementing this provision, it presumably could not entirely ignore these obligations.[25] In fact, the agency had demanded disclosing that recipients enjoyed freedom of choice when it issued EUAs for the Covid-19 vaccines.[26] The downstream consequences of this condition remain unclear, partly because Congress provided that "[t]his section only has legal effect on a person who carries out an activity for which an authorization under this section is issued."[27] Plainly it meant to constrain actors other than the agency that grants an EUA, but would "the option to . . . refuse administration of the product" prevent the imposition of immunization mandates before the FDA fully approved a vaccine?

Some commentators have understood the immediately following reference

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25. Congress separately provided, however, that actions under this provision "are committed to agency discretion," 21 U.S.C. § 360bbb-3(i), which would appear to preclude review under the Administrative Procedure Act, *see* 5 U.S.C. § 701(a)(2). Unlike express preclusion of judicial review, this language does not invariably foreclose intervention by the courts. *See* Lars Noah, *Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law*, 41 WM. & MARY L. REV. 1463, 1501 (2000) ("[T]he Supreme Court has applied this provision grudgingly, finding preclusion of review on this basis in only quite limited cases."). At a minimum, however, it would suggest more deferential judicial review only for "an abuse of discretion." 5 U.S.C. § 706(2)(A); *see also* Ass'n of Am. Physicians & Surgeons v. FDA, 479 F. Supp. 3d 570, 579 n.6 (W.D. Mich. 2020) ("The agency's decisions under the APA would be subject to a deferential standard of review, for example, assuming the Court even had authority to review them."), *aff'd*, 13 F.4th 531, 535-36, 544-47 (6th Cir. 2021) (sustaining the dismissal for lack of standing of claims objecting to the limited scope of the subsequently revoked EUA for hydroxychloroquine). In contrast, a different provision applicable to pandemic countermeasures expressly precluded judicial review of HHS actions. *See* 42 U.S.C. § 247d-6d(b)(7).

26. *See, e.g.*, FACT SHEET FOR RECIPIENTS AND CAREGIVERS: EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER, at 1 (Dec. 2020), http://www.gtbindians.org/downloads/covidinfo.pdf [perma.cc/LY8U-9L8Y] ("It is your choice to receive [this vaccine] . . . . There is no FDA-approved vaccine to prevent COVID-19."); *id.* at 4 ("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."); *see also* FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF EVUSHELD™ (TIXAGEVIMAB CO-PACKAGED WITH CILGAVIMAB) FOR CORONAVIRUS DISEASE 2019 (COVID-19), at 1, 5 (2023), https://www.fda.gov/media/154702/download [perma.cc/Q5V9-5S9J] (providing similar language for a monoclonal antibody treatment). As few people went to their regular physicians in order to get inoculated early in the pandemic, the reassurance that refusal would not negatively impact their medical care serves no particular purpose unless it meant that a provider could not later hold their unvaccinated status against them. Of course, many people would not have read or understood the Fact Sheets. *See* Luke S. Bothun et al., *Readability of COVID-19 Vaccine Information for the General Public*, 40 VACCINE 3466, 3468 (2022) (concluding that the Fact Sheets "fail to meet acceptable readability standards"). The EUAs for devices typically did not require any language about freedom to choose. *See supra* note 17 (explaining the failure to do so for face masks); *supra* note 22 (same for IVDs).

27. 21 U.S.C. § 360bbb-3(*l*); *see also infra* note 38 (elaborating on this point).

in the statute to any potential "consequences" of refusal as limiting the freedom of choice.[28] A more natural reading would take it to mean a need to reveal only potential health (as opposed to legal) consequences of declining.[29] Such disclosures arguably play a more central role for products designed to prevent illness in large swaths of healthy individuals than to treat particular patients already in dire straits.[30] This obligation had particular importance during the Covid-19 public health emergency given the amount of dangerous misinformation circulating at that time,[31] and these vaccines promised meaningful and immediate reductions in risk.

An affiliated statutory provision seems to support interpreting "consequences" narrowly. When administering any products governed by an EUA to members of the armed forces, this disclosure requirement, which was "designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived . . . only if the President determines, in writing, that complying with such requirement is not in the interests of

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28. *See* Dorit R. Reiss & John DiPaolo, *COVID-19 Vaccine Mandates for University Students*, 24 N.Y.U. J. LEGIS. & PUB. POL'Y 1, 52 (2021). These commentators asked, for instance, "why add the consequences here, when any health impacts should be covered by the disclosure of benefits and risks" required separately by the statute. *Id.* at 52 n.240. The simple answer: the latter relate to the potential health consequences of using the product, while the former address the health consequences of declining to use it. Their rebuttal to that construction, arguing that to decline a countermeasure covered by an EUA would invariably pose a risk of adverse health consequences, *see id.*, hardly makes much sense either, evidently reflecting their excessive confidence in the utility of these investigational agents and of the assessments by health care providers of a patient's particular circumstances, to say nothing of subsequent shifts in the external threat environment. I pointedly critique many of their other arguments later herein where relevant.

29. *Cf.* Nikolao v. Lyon, 875 F.3d 310, 314 (6th Cir. 2017) (reviewing objections to the application of a state rule obligating health workers to "certify that the parent had 'received education on the risks of not receiving the vaccines being waived and the benefits of vaccination to the individual and the community'"); *id.* at 318-19 (elaborating on the limited purposes of this requirement); Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 366 (2002) (As held by a few courts resolving tort claims alleging a failure to secure informed consent, physicians "may have an obligation to describe the benefits of a diagnostic or therapeutic procedure—in other words, the health risks associated with the failure to follow the physician's recommendation—in order to ensure that, if the patient declines to consent, the decision is also a fully informed (even if unwise) one.").

30. *See* Iwry, *supra* note 13, at 373 ("Vaccines are especially hard to evaluate: rather than being used on already-sick patients with perhaps somewhat less to lose, they impose new risks on the majority of the public who have yet to contract the illness and who, in many cases, might be expected to remain healthy otherwise."); *see also id.* at 374 (summarizing with little elaboration an "autonomy-based approach: an EUA should be granted so that members of the public can freely decide whether or not to take a vaccine, and as long as informed consent is provided, those that choose to take the vaccine accept the risk"); *id.* at 376-77 (discussing a range of policy issues posed by mandating the use of such vaccines without, however, noting the possible relevance of the EUA choice clause).

31. *See* NOAH, *supra* note 5, at 229, 247, 783, 790, 816; Lars Noah, *Censorship Is So Last Century: Therapeutic Products, Propaganda, and Compelled Speech*, 66 ST. LOUIS U. L.J. 79, 97 n.80 (2021).

national security."[32] If dishonorable discharge could qualify as a "consequence" of refusal,[33] why would Congress have added this provision?[34] Relatedly, if only the United States government enjoys standing to enforce the EUA choice clause, as some courts have recently emphasized,[35] then how would it ever in practice serve to protect service members from the nonconsensual administration of unapproved countermeasures?

If the disclosure of "consequences" instead served to qualify the purported option to refuse, then it could mean having to make the non-health repercussions of declining unmistakably clear in order to guard against any complaints about unfair surprise as to the potentially negative impact of so choosing.[36]

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32. 10 U.S.C. § 1107a(a)(1). The FDA seemingly understood this provision to have more content than simply about what information the Pentagon would have to share with soldiers. *See* FDA's 2017 EUA Guidance, *supra* note 11, at 24 n.46 ("The President may under certain circumstances waive the option for members of the armed forces to accept or refuse administration of an EUA product (10 U.S.C. 1107a)."). After all, the statute that created the EUA mechanism consciously paired it with § 1107a. *See* National Defense Authorization Act for Fiscal Year 2004, Pub. L. No. 108-136, § 1603(b)(1), 117 Stat. 1392, 1690 (2003) (codified as amended at 10 U.S.C. § 1107a).

33. *See* Lars Noah, *Coerced Participation in Clinical Trials: Conscripting Human Research Subjects*, 62 ADMIN. L. REV. 329, 338 (2010) ("Perhaps military officials realized that consent to research secured under [threatened discharge otherwise] would not pass muster as genuinely voluntary."); *see also id.* at 338-39 ("[O]nce the FDA approves a medical product for a particular use, the special consent requirements . . . become inapplicable, and the Pentagon then could force military personnel to get inoculated or face discharge in the event of refusal.").

34. *See* H.R. REP. NO. 108-354, at 782 (2003) (explaining that it "would authorize the President to waive the *right* of service members to refuse administration of a product" (emphasis added)); *see also* DOD Instruction No. 6200.02, § E3.4 (Feb. 27, 2008), https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620002p.pdf [perma.cc/WDN9-FBET] ("In the event that an EUA . . . 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)). In the civilian context, imagine a physician threatening to drop a patient for declining to get immunized, as some frustrated pediatricians have done when parents reject recommended vaccines for their children. *See* Sean T. O'Leary et al., Letter, *Policies Among US Pediatricians for Dismissing Patients for Delaying or Refusing Vaccination*, 324 JAMA 1105, 1106 (2020); *cf.* Noah, *supra* note 33, at 363-64 (discussing the ethical propriety of a proposal that physicians use such leverage to encourage their adult patients to participate in medical research).

35. *See infra* note 138; *see also* Navy SEAL 1 v. Biden, 574 F. Supp. 3d 1124, 1130-31 (M.D. Fla. 2021) (holding that § 360bbb-3 provided no private right of action, while adding that 10 U.S.C. § 1107a offered no assistance to the plaintiffs because the FDA had by that time fully approved Pfizer's Covid-19 vaccine).

36. *See* United States v. Brown, 539 F. Supp. 3d 489, 501 n.10 (W.D. Pa. 2021) (noting, in the course of ordering the compassionate release of a prisoner at heightened risk of Covid-19 even though she declined to get vaccinated, that the prospect of categorical ineligibility for such relief in cases of vaccine refusal otherwise might have to get disclosed in advance as one of the "consequences" pursuant to the EUA choice clause); *cf.* Dorit Rubinstein Reiss & Nili Karako-Eyal, *Informed Consent to Vaccination: Theoretical, Legal, and Empirical Insights*, 45 AM. J.L. & MED. 357, 381 n.172 (2019) ("While these [threatening] techniques should be avoided, parents should be informed in an objective manner of the legal implications of not vaccinating their child, i.e. school entry vaccination requirements . . . . [T]he task of providing such information to parents should not be imposed on health providers.").

Understanding the EUA choice clause as necessitating the clear communication of threats would, however, further erode the more plausible goal of ensuring genuine voluntariness![37]

Even if "consequences" meant solely the foregone health benefits of refusal, some have argued that the statute only requires providing a statement about the theoretical freedom to decline even if divorced from the reality of the matter.[38] In short, it would suffice to make an empty gesture, rendering the disclosed freedom of choice entirely illusory.[39] That strikes me as far too cramped a reading of what Congress had in mind,[40] as attention to the clause's drafting history and broader statutory context makes evident. Even if only a form of

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37. *Cf.* Allison v. Merck & Co., 878 P.2d 948, 961 (Nev. 1994) (recognizing that in such circumstances a vaccine recipient "had no real choice"); Maureen C. Kelley & Samuel J. Tilden, *Ethical and Legal Oversight of Human Subjects Research in Emerging Infections and Biodefense Research: A Review of Recent Changes and Call for Policy Reform*, 8 HOUS. J. HEALTH L. & POL'Y 1, 30 (2007) ("[R]efusals in the context of a public health emergency may be accompanied by consequences such as quarantine. There is a predictable element of strong persuasion, if not coercion, inherent in the informed consent process in the context of a serious disease outbreak."); *id.* at 43 (elaborating). A similar concern has arisen in the context of suspicionless drug testing. *See* Ferguson v. City of Charleston, 532 U.S. 67, 90-91 (2001) (Kennedy, J., concurring in judgment) ("[T]he usual voluntariness analysis is altered because adverse consequences (*e.g.*, dismissal from employment or disqualification from playing on a high school sports team) will follow from refusal.").

38. *See* Reiss & DiPaolo, *supra* note 28, at 52 & n.240 (emphasizing that the clause only speaks to what HHS must do); *id.* at 53 (making light of suggestions that this "requirement extends to parties beyond the federal government," which might entail "massive federalization of privately-ordered relationships"); *cf. id.* at 55 (conceding that it might limit the authority of other federal agencies, at least the military, to mandate use). Although it may have spoken solely to HHS (and its constituent units), Congress thereby had charged those agencies with a duty of speaking to both the suppliers of these products and the health providers delivering them to patients in precisely the same manner as many other parts of the FDCA, to say nothing of innumerable other statutory provisions that delegate authority to regulatory agencies.

39. *Cf.* Anna Zagaja et al., *Informed Consent in Obligatory Vaccinations?*, 24 MED. SCI. MONITOR 8506, 8508 (2018) ("[I]n the case of obligation, voluntariness might be lacking and thus from an ethical and legal perspective, the whole informed consent is invalid and, in reality, becomes a legal fiction.").

40. It also reflects a decidedly legalistic way of approaching questions about bioethics. *Cf.* Noah, *supra* note 33, at 354-56 (criticizing on similar grounds some of the published defenses of the "coverage with study participation" (CSP) policy adopted by the Centers for Medicare and Medicaid Services (CMS)); *id.* at 366 ("The CSP policy appears to run afoul of federal research regulations, which only represent ethical minima in any event. Indeed, the agency's effort to skirt those regulations and justify its ethically dubious initiative rather than to steer well clear of existing restrictions itself sets a poor example for the broader research community."). Then again, having perused dozens of cookie-cutter EUA notices, the FDA's rote approach would coincide with viewing the provision as demanding little more than boilerplate. The disclosures provided to individuals plainly get recycled. *See supra* note 26; *see also* FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT JYNNEOS (SMALLPOX AND MONKEYPOX VACCINE, LIVE, NON-REPLICATING) TO PREVENT MONKEYPOX DISEASE IN INDIVIDUALS DETERMINED TO BE AT HIGH RISK FOR MONKEYPOX INFECTION, at 1 (Aug. 9, 2022), https://www.fda.gov/media/160773/download [perma.cc/7PNN-D8V2] ("Under the EUA, there is an option to accept or refuse JYNNEOS."); *id.* at 4 ("Under the EUA, there is an option to accept or refuse JYNNEOS. Should you decide not to receive it or for your child not to receive it, it will not change your standard medical care.").

"consent lite," it exceeds what the legislature or agency dictate for fully approved products.[41]

B. Exploring Its Origins

As for the history behind this provision, Congress addressed similar concerns in the context of military service members five years before it enacted the EUA provision. The controversial intervening actions of both the U.S. Department of Defense (DOD) and the FDA, which prompted several rounds of litigation, meant that the special clause adopted in 2003 had not emerged from an entirely blank slate.[42] Understanding this backdrop takes on added significance because, while Congress amended the broader statutory provision repeatedly, the EUA choice clause has remained unchanged since 2003.

In 1990, the FDA granted a request from the DOD for an exemption to informed consent requirements during the Gulf War in order to inoculate military personnel with unapproved treatments for biowarfare agents.[43] Military officials feared that some soldiers would refuse, which then might create difficulties in the field in the event of exposure to biological and chemical weapons, so the DOD claimed that this made it "not feasible" to secure informed consent.[44] The federal courts soon rejected a challenge to the FDA's waiver of

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41. A few years after Congress delegated this authority, a group of authors affiliated with HHS expressed similar views in a professional journal produced by the CDC. *See* Stuart L. Nightingale et al., *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States*, 13 EMERGING INFECTIOUS DISEASES 1046, 1049 (2007) ("[P]ersons must be made aware of their right to refuse the 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."); *id.* ("EUA products do not require the detailed, formal, informed-consent process used for human research study participants. However, to the extent practicable given the circumstances of the emergency, prospective patients will always be informed about the opportunity to accept or refuse an EUA product . . . ."). In other words, these officials construed the statute as granting recipients a meaningful "right to refuse" even if communicated with less formality than required for subjects enrolled in clinical trials of investigational products.

42. *See* Daniel Walsh, Note, *COVID-19: A Crisis and an Opportunity to Improve the Emergency Use Authorization Process*, 22 MINN. J.L. SCI. & TECH., no. 2, 2021, at 169, 199 (explaining that this legislation was "originally intended to be used only in the context of military operations . . . [with] provisions allowing EUAs to be used in the context of public health emergencies tacked on"); *id.* at 179-80 (elaborating on this drafting history); *see also* Iwry, *supra* note 13, at 380 ("The history of EUAs reflects a gradual shift from counterterrorism in the post-9/11 period to naturally occurring infectious diseases in the wake of the H1N1 crisis of 2009.").

43. *See* Informed Consent for Human Drugs and Biologics; Determination That Informed Consent Is Not Feasible, 55 Fed. Reg. 52,814, 52,817 (Dec. 21, 1990), *revoked and replaced*, 64 Fed. Reg. 54,180, 54,188-89 (Oct. 5, 1999) (codified as amended at 21 C.F.R. § 50.23(d)).

44. *See* 21 U.S.C. § 355(i)(4). Congress also had imposed separate consent requirements on the DOD for "research involving a human being as an experimental subject." Department of Defense Authorization Act of 1985, Pub. L. No. 98-525, § 1401(c)(1), 98 Stat. 2492, 2615 (1984) (codified at 10 U.S.C. § 980); *see also* Elliott J. Schuchardt, *Distinguishing Between Research and Medical Practice During Operation Desert Storm*, 49 FOOD & DRUG L.J. 271, 277-89 (1994) (concluding that the DOD had not conducted research in violation of this statute).

informed consent requirements.[45] In 1998, expressing evident displeasure with these rulings, Congress mandated that the DOD secure informed consent from military personnel before administering an investigational drug (whether or not done in connection with genuine experimentation), including an approved drug for an unapproved use, and it provided that only the President could waive this requirement.[46]

These issues returned after 2001, with concerns about bioterrorist attacks in the United States. Under a program begun in 1998 but not fully implemented until mid-2002 (shortly before invading Iraq), the DOD inoculated service members and certain employees of civilian contractors with anthrax vaccine adsorbed (AVA).[47] The FDA previously had licensed this biological product for the prevention of cutaneous anthrax while expressing doubts about its efficacy against inhalation anthrax,[48] and, in 1996, the manufacturer submitted an investigational new drug (IND) application to undertake research that would support adding that indication to the labeling.[49] The military's Anthrax Vaccine Immunization Program (AVIP) did not, however, make any provision for securing informed consent before inoculating soldiers with AVA for this still unapproved use.[50]

A group of service members and civilian employees challenged the

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45. *See* Doe v. Sullivan, 756 F. Supp. 12, 16 (D.D.C.) ("The fact that the DoD will collect information on the efficacy of the drugs does not transform the strategic decision to use the unapproved drugs in combat into research."), *aff'd*, 938 F.2d 1370, 1379-83 (D.C. Cir. 1991); *see also* Robyn Pforr Ryan, *Should Combat Troops Be Given the Option of Refusing Investigational Drug Treatment?*, 52 FOOD & DRUG L.J. 377, 393 (1997) (criticizing the waiver, noting that, although "DOD did not administer the treatment with the primary intent of generating new knowledge," the drugs were experimental in the sense that uncertainty remained about their safety and efficacy); Claire A. Milner, Comment, *Gulf War Guinea Pigs: Is Informed Consent Optional During War?*, 13 J. CONTEMP. HEALTH L. & POL'Y 199, 223-31 (1996).

46. *See* Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, Pub. L. No. 105-261, § 731(a), 112 Stat. 1920, 2070-71 (1998) (codified as amended at 10 U.S.C. § 1107(f)) (establishing a "Process for Waiving Informed Consent Requirement for Administration of Certain Drugs to Members of Armed Forces for Purposes of a Particular Military Operation"); *see also* Exec. Order No. 13,139, 64 Fed. Reg. 54,175, 54,176 (Oct. 5, 1999) (announcing that the President would evaluate waiver requests using the criteria set forth in the FDA's regulation); H.R. REP. NO. 106-556, at 55-58 (2000) (discussing these changes to the DOD's "not exemplary" previous approach).

47. *See* Guy Gugliotta, *Pentagon to Resume Anthrax Vaccinations*, WASH. POST, June 29, 2002, at A3; *see also* Ruth K. Miller, Note, *Informed Consent in the Military: Fighting a Losing Battle Against the Anthrax Vaccine*, 28 AM. J.L. & MED. 325, 339-43 (2002) (defending the DOD's program).

48. *See* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51,002 (Dec. 13, 1985).

49. *See* Randall D. Katz, Note, *Friendly Fire: The Mandatory Military Anthrax Vaccination Program*, 50 DUKE L.J. 1835, 1853-54, 1859 (2001). Although technically a "biological product," 42 U.S.C. § 262(i)(1), ultimately needing to secure approval for a biologics license application (BLA), *id.* § 262(a), IND rules apply to investigational vaccines and other biologics, *see id.* § 262(a)(3), (j); 21 C.F.R. § 312.2(a); *see also* Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. art. 4, ¶ 21 (2006).

50. *See* Doe v. Rumsfeld, 297 F. Supp. 2d 119, 125 (D.D.C. 2003).

program, arguing that the use of this vaccine to protect against the risk of inhalation anthrax but licensed only to guard against cutaneous exposure remained investigational and therefore required informed consent under statute unless waived by a presidential order.[51] A federal judge issued a preliminary injunction, first finding that AVA remained "investigational" against inhalation anthrax,[52] and then rejecting the DOD's claims of necessity.[53] One week after the court's order (and eighteen years after issuing its proposal), the FDA published a final rule that found AVA safe and effective for protection against inhalation anthrax.[54]

Agency approval did not, however, settle the matter. The district court invalidated this rule on procedural grounds and then issued a permanent injunction against implementation of the AVIP.[55] In response, the government invoked the newly enacted EUA provision.[56] In doing so, the FDA emphatically directed the DOD to allow service members to decline: "[T]he AVIP 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 adverse personnel action. . . . There may be no penalty or loss of entitlement for refusing anthrax vaccination."[57] Finally, just as the authorization for emergency use of AVA expired, the FDA reissued its rule concluding that

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51. *See id.* at 122-23.

52. *See id.* at 131-34; *see also id.* at 135 ("Absent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs.").

53. *See id.* at 134; *see also id.* at 126-31 (rejecting the government's threshold justiciability arguments).

54. *See* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 69 Fed. Reg. 255, 259 (Jan. 5, 2004).

55. *See* Doe v. Rumsfeld, 341 F. Supp. 2d 1, 19 (D.D.C. 2004); *cf.* Ammend v. BioPort, Inc., 322 F. Supp. 2d 848, 870-73 (W.D. Mich. 2004) (rejecting constitutional claims against entities that supplied anthrax vaccine to the DOD); Bates v. Rumsfeld, 271 F. Supp. 2d 54, 63-64 (D.D.C. 2002) (dismissing for lack of standing a complaint filed on behalf of a group of discharged service members, pointing out, for instance, that one of the named plaintiffs "can not demonstrate that the ultimate relief he is seeking, namely, reversal of the court martial decision, will be redressed by a declaration by this Court that AVA was in IND status at the time he refused to be vaccinated").

56. *See* Marc Kaufman, *Pentagon Boosts Plan for Anthrax Inoculations: Emergency Provisions Invoked to Revive Use*, WASH. POST, Feb. 2, 2005, at A3 (reporting that soldiers would have the right to refuse).

57. 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, 70 Fed. Reg. 5452, 5455 (Feb. 2, 2005); *see also id.* (detailing exactly how the DOD had to revise the brochure that it supplied to service members); *id.* (reiterating the language from the statutory clause but replacing its commas with semicolons to separate these disclosure obligations, which arguably would weaken suggestions that the reference to "consequences" served as a limitation on the immediately preceding mention of an option to "refuse"); 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, 70 Fed. Reg. 44,657, 44,660 (Aug. 3, 2005) (reiterating these directives verbatim when granting a six-month extension of the EUA, but adding language for the brochure to include a reference to a modification of the court's injunction).

the vaccine worked against inhalation anthrax,[58] which removed it from IND (and EUA) status and thereby avoided application of the consent (and choice) requirements imposed by Congress.[59]

At some level, the Pentagon's attempts to dodge informed consent requirements seem odd. After all, presumably it could have discharged (dishonorably or otherwise) any service member who refused, which would mean that only rarely would a soldier decline to participate.[60] Nonetheless, military officials undoubtedly realized that consent secured under such circumstances would not count as truly voluntary,[61] which only a formal waiver from the Commander-in-Chief could excuse. In connection with civilians, however, the President enjoyed no express power to waive consent requirements before full approval,[62] and the EUA choice clause seems to represent a disavowal of the FDA's previously exercised power to waive it for investigational products in such circumstances.

C. Comparing Adjacent Provisions

It may help to situate EUAs among the range of other federal controls over

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58. *See* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed, 70 Fed. Reg. 75,180, 75,183 (Dec. 19, 2005); *see also* Rempfer v. Sharfstein, 583 F.3d 860, 866-68 (D.C. Cir. 2009) (rejecting a substantive challenge to the FDA's approval decision).

59. *See* Termination, by Expiration, of Declaration of Emergency Justifying Emergency Use Authorization of Anthrax Vaccine Adsorbed, 71 Fed. Reg. 5341 (Feb. 1, 2006); *see also* Doe v. Rumsfeld, 172 F. App'x 327, 328 (D.C. Cir. 2006) (per curiam) (rejecting the government's appeal as moot because FDA approval satisfied the district court's injunction).

60. *See* Neely Tucker, *Anthrax Vaccine Challenged: Two Suing Defense Department over Inoculation Policy*, WASH. POST, May 15, 2002, at A10 (reporting that approximately 500 service members had declined anthrax vaccinations and that some of those faced courts martial). After the FDA approved a vaccine for a particular use, of course, the Pentagon could force military personnel to get inoculated or face discharge in the event of refusal. *See* George J. Annas, *Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat*, 24 AM. J.L. & MED. 245, 250, 257 & n.47 (1998); Katz, *supra* note 49, at 1848; *Pentagon Set to Vaccinate Troops, Assist in Flu Crisis*, WASH. POST, Sept. 30, 2009, at A6.

61. *See* Keri D. Brown, Comment, *An Ethical Obligation to Our Servicemembers: Meaningful Benefits for Informed Consent Violations*, 47 S. TEX. L. REV. 919, 935 (2006) (calling the "voluntariness" element "arguably the biggest problem for the military and the reason that they have procedures for informed consent waivers").

62. *Cf.* Efthimios Parasidis, *Justice and Beneficence in Military Medicine and Research*, 73 OHIO ST. L.J. 723, 762 (2012) ("While the EUA is available for both civilian and military use, only military populations are subject to forced use of experimental products and informed consent waivers."); *id.* at 778 ("[W]hereas civilians may opt-out of emergency use of an investigational medical product, service members do not have this option in instances where the President has issued an informed consent waiver . . . ."). This statutory asymmetry might have come in response to reports circulating at the time that "some Bush administration officials had suggested widespread vaccination of U.S. civilians against smallpox for essentially tactical purposes (e.g., to take some of the steam out of threats of bioterrorism, including Saddam Hussein's supposed weapons of mass destruction, by effectively hardening the population against such an attack)." NOAH, *supra* note 5, at 24.

the introduction of therapeutic products in the channels of interstate commerce.[63] Of particular relevance, one decade after it first created the EUA pathway Congress added section 564A to the FDCA to govern the emergency use of fully approved products, which allowed but did not require the distribution of "emergency use instructions" and made no mention of reminding recipients of an option to refuse.[64] The contrasting approach to disclosure in these adjacent provisions of the statute speaks volumes.

More broadly, investigational drugs and devices face stringent conditions on availability, primarily for restricted use in clinical trials though special pathways exist to allow early access by desperate patients not able to enroll as subjects, and federal law insists that sponsors secure informed consent in these circumstances.[65] Although focused on subjects enrolled in clinical trials, federal consent obligations attach to the narrow exceptions that allow the use of not-yet-approved products in treating patients as well.[66] More than a decade ago, for instance, the FDA authorized "expanded access" to the investigational vaccine Bexsero® for students at one prominent university during an outbreak of a rare strain of meningitis, but the successful immunization campaign conducted on this campus did not involve compulsion and secured signed consent forms from

63. In writing about the first EUA issued for an unapproved drug, FDA officials included a chart that compared, in turn, EUAs, INDs, emergency INDs, and approved NDAs along several dimensions. *See* Debra Birkrant & Edward Cox, *The Emergency Use Authorization of Peramivir for Treatment of 2009 H1N1 Influenza*, 361 NEW ENG. J. MED. 2204, 2205 (2009) (indicating in the "informed consent" row "no" for the first and last columns but "yes" for the middle two columns); *cf. id.* at 2206 (explaining that health care providers must "include documentation in the medical record that the patient and caregivers have been given the 'Peramivir Fact Sheet for Patients and Parents/Caregivers,' informed of alternatives to receiving peramivir, and told that peramivir is an unapproved drug to be used only under the EUA"). Emergency INDs represent a fairly obscure variant of treatment INDs. *See* FDA, EMERGENCY USE OF AN INVESTIGATIONAL DRUG OR BIOLOGIC; GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS (Jan. 1998), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-investigational-drug-or-biologic [perma.cc/2MN7-8L85].

64. *See* Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, § 302(a)(2)(B)(iv), 127 Stat. 161, 180-81 (codified at 21 U.S.C. § 360bbb-3a(e)). Indeed, HHS delegated the authority over the preparation of such instructions to the CDC. *See* FDA's 2017 EUA Guidance, *supra* note 11, at 3 n.6, 4 & n.10.

65. *See* 21 U.S.C. § 355(i)(4); 21 C.F.R. §§ 50.20, 312.60; *see also id.* § 50.25(a)(8) (listing as a basic element of informed consent to research the following: "A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time . . . ."); 45 C.F.R. § 46.116(b)(8) (identical language in the HHS regulation known as the "Common Rule" because more than a dozen other federal agencies follow it). The IND provision seemed to distinguish between a duty to "inform" subjects of certain things and to "obtain" their "consent," while the EUA provision lumped the disclosure conditions into a duty to "inform" and did not use the language of consent.

66. Patients given an unapproved new drug under expanded access mechanisms must consent in the same manner as would a subject enrolled in a clinical trial of that investigational product. *See* 21 C.F.R. § 312.305(c)(4); *see also* FDA, EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE—QUESTIONS AND ANSWERS; GUIDANCE FOR INDUSTRY 6 (Oct. 2017), https://www.fda.gov/media/85675/download [perma.cc/B2JU-NBJA] (explaining the need to secure informed consent under the IND expanded access program).

recipients.[67] In 2018, Congress enacted a broader "right to try law," which allowed desperate patients to use certain investigational drugs outside of clinical trials, but again it conditioned such access on securing their written consent.[68]

Conversely, mechanisms for the accelerated approval of drugs and devices on weaker evidence of safety and effectiveness than typically demanded by the FDA may call for disclosing that fact but stop short of imposing consent requirements.[69] Similarly, a statutory obligation to supply information about childhood and other vaccines does not go so far as to specify any right of refusal.[70] On rare occasions, the FDA has insisted that manufacturers call on prescribers to secure patient consent when fully approved products pose exceptionally serious risks,[71] but even these aim to underscore the importance

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67. *See* Lucy A. McNamara et al., *First Use of a Serogroup B Meningococcal Vaccine in the US in Response to a University Outbreak*, 135 PEDIATRICS 798, 800-02 (2015); *id.* at 799 ("Written informed consent was obtained from all vaccine recipients . . . ."); *Princeton to Use Foreign Vaccine*, N.Y. TIMES, Nov. 19, 2013, at A23. More recently, in response to an outbreak of mpox, the FDA relied on its expanded access program to allow for the use of the antiviral TPOXX® (tecovirima), which it had previously approved to treat smallpox, for any patients infected with this milder orthopox. *See* Dominique Mosbergen, *Monkeypox Patients Scramble for Care*, WALL ST. J., Aug. 3, 2022, at A3. This also necessitated securing patient consent. *See* CDC, INFORMED CONSENT/PARENTAL PERMISSION FORM FOR TECOVIRIMAT TREATMENT UNDER AN EXPANDED ACCESS INVESTIGATIONAL NEW DRUG (IND) PROGRAM (last updated May 5, 2023), https://www.cdc.gov/poxvirus/mpox/pdf/Attachment-1-Informed-Consent.pdf [perma.cc/626G-9GVZ].

68. *See* Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, Pub. L. No. 115-176, § 2(a), 132 Stat. 1372, 1372 (2018) (codified at 21 U.S.C. § 360bbb-0a(a)(1)(C)) (requiring that a patient "has provided to the treating physician written informed consent regarding the eligible investigational drug"). Utah amended its right-to-try law early in the pandemic to allow for the use of investigational products during a public health emergency, which it also premised on securing patient consent. *See* UTAH STAT. ANN. § 58-85-106(2)(c)(i) (2022).

69. *See, e.g.*, 21 C.F.R. § 314.610(b)(3) (calling for disclosures in labeling for patients given drugs approved based only on efficacy testing in animals); Lars Noah, *Growing Organs in the Lab: Tissue Engineers Confront Institutional "Immune" Responses*, 55 JURIMETRICS J. 297, 327-28 (2015) (explaining that the FDA requires the following disclaimer for so-called humanitarian use devices: "Authorized by Federal law for use in the treatment of [specify disease or condition]. The effectiveness of this device for this use has not been demonstrated."). The FDA rejected a suggestion that products reviewed through its accelerated approval mechanism call for patient consent. *See* New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58,942, 58,957 (Dec. 11, 1992).

70. *See* 42 U.S.C. § 300aa-26; *see also* New Vaccine Information Materials, 59 Fed. Reg. 31,888 (June 20, 1994).

71. *See* Lars Noah, *Turn the Beat Around?: Deactivating Implanted Cardiac-Assist Devices*, 39 WM. MITCHELL L. REV. 1229, 1284 n.218 (2013) ("Recently, the [FDA] has mandated that physicians secure written informed consent from patients . . . in order to ensure against inappropriate use that carries serious risks of injury."); Noah, *supra* note 29, at 381-82 ("[I]n the course of approving particular drugs that pose special risks to women, the FDA has gone a step further and called on physicians to supply their patients with an enclosed informed consent form and request their signature, as it did in the case of Accutane® (isotretinoin), Mifeprex® (mifepristone), and Thalomid® (thalidomide)." (footnotes omitted)); Marc Kaufman, *FDA Reapproves Bowel Drug After Pulling It for Safety*, WASH. POST, June 8, 2002, at A4 (reporting

of communicating information to promote safe use (and guard against inappropriate use) rather than to attest that users have voluntarily assumed these dangers.

Countermeasures introduced under an EUA seem to fall closer to the "investigational" end of the spectrum than to FDA-approved drugs and medical devices posing well understood risks,[72] which suggests that the statutory choice clause had more to do with the freedom to decline than to fully inform.[73] Imagine problems with under enrollment in studies of a promising vaccine for a new infectious agent; could the corporate sponsor of such an investigational drug order its employees to participate as subjects in ongoing clinical trials run at a

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that, after first withdrawing its approval of Lotronex® (alosetron), a drug used to treat irritable bowel syndrome, the agency reversed course but made reapproval contingent on a special informed consent requirement); *cf.* General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products, 80 Fed. Reg. 79,493, 79,504 (Dec. 22, 2015) (proposed 21 C.F.R. § 878.4635(c)(4)) (planning to require that adult users of tanning equipment first sign a "risk acknowledgment" form).

72. Indeed, the EUAs for the Covid-19 vaccines directed sponsors to continue making submissions to the still open IND files for these investigational products. *See, e.g.*, Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic, 86 Fed. Reg. 5200, 5206-07, 5216-17 (Jan. 19, 2021); *see also id.* at 5202, 5211 (calling each "an investigational vaccine not licensed for any indication"); *id.* at 5209, 5219 (requiring that all promotional material state conspicuously that the "product has not been approved or licensed by FDA"); *cf.* 21 U.S.C. § 360bbb-3(k) (providing that "use of such product within the scope of the [emergency] authorization shall not be considered to constitute a clinical investigation for purposes of section 355(i)," which governs INDs). For more on the use of a sliding scale to make sense of varied obligations to secure consent in the medical setting, see Noah, *supra* note 29, at 370-79, 382-94 (contrasting tort duties and regulatory obligations to secure informed consent in connection with the use of investigational products and procedures); *id.* at 372 ("A few courts have held that the lack of approval by the [FDA] might itself represent material information that a physician would have to disclose to a patient."); *id.* at 396 ("[T]he FDA only rarely imposes informed consent requirements after it approves a product, notwithstanding the fact that research continues in a more or less structured fashion after approval.").

73. *See* Noah, *supra* note 33, at 343 ("Even in the absence of deception, however, subjects may object if their participation was nonconsensual. At its core, informed consent requires both knowledge and volition, and research violates these norms where subjects participate knowingly but involuntarily." (footnote omitted)); *id.* at 344 ("It may be easier to discern and criticize instances of inadequate disclosure, but we also must guard against situations where researchers take advantage of the constrained choices available to fully informed individuals."); *id.* at 362-66 (cautioning against a turn to communitarianism in research ethics); *id.* at 342-66 (discussing different forms of volitional impairment that might invalidate consent in the research setting). Even for fully approved drugs and devices, patients generally enjoy a right to decline or discontinue use of an intervention. *See* Noah, *supra* note 71, at 1275-80 (elaborating on the right to refuse treatment as an essential aspect of informed consent). It does not, however, necessitate that product suppliers or health care providers disclose that patients retain this freedom of choice. *Cf.* Lars Noah, *Doctors on the Take: Aligning Tort Law to Address Drug Company Payments to Prescribers*, 66 BUFF. L. REV. 855, 879-80 (2018) (explaining that, though the courts in a couple of states have suggested otherwise when resolving medical malpractice litigation, the administration (e.g., injection) of a pharmaceutical agent qualifies as an invasive procedure that requires first securing permission from the recipient). That said, providing a noninvasive sample (e.g., saliva) for testing—or donning a mask in public—is still further removed from the type of medical encounter normally subject to informed consent duties.

nearby medical school without vitiating its obligations to secure consent to research?[74] Could state or local officials anxious to do their part but not otherwise involved in running the trials demand that citizens sign up to serve as guinea pigs in a way that did not fundamentally undermine the consent process?

If private or public entities could not mandate the use of Covid-19 vaccines while still undergoing clinical trials, for instance in younger age groups that did not become eligible under EUAs until months after adults, then why allow them to do so pursuant to emergency authorizations similarly conditioned on disclosing to recipients the freedom to decline?[75] Although the degree of volitional impairment undoubtedly varies by context, the imposition of mandates sought to secure greater vaccine uptake and coverage than achieved under a wholly voluntary system.[76] Lack of access and simple inertia accounted for a sizeable number of the unvaccinated, but others claimed to have strong reservations.[77] Indeed, employer immunization mandates prompted fears of widespread resignations; it appears that relatively few workers actually quit in

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74. *See infra* note 130 (posing a similar question about universities conditioning enrollment on students consenting to participation in medical research conducted by their faculty); *cf.* Johnson v. Brown, 567 F. Supp. 3d 1230, 1248 (D. Or. 2021) ("Plaintiffs here do not contend that they are being forced to be part of the *clinical trials* for the Pfizer-BioNTech Vaccine . . . ."). Could a private employer order workers diagnosed with Covid-19 to use unorthodox treatments (not even covered by an EUA) in the hopes of currying favor with like-minded politicians? *Cf.* NOAH, *supra* note 5, at 745-46 (discussing the persistent misuse of the antiparasitic drug ivermectin); Heather Murphy, *The Pitch for a Proposed Covid-19 Cure Ignores Its Risks*, N.Y. TIMES, Aug. 25, 2020, at D7 (reporting that the CEO of My Pillow (and major Trump donor), Mike Lindell, had touted oleandrin, an extract of the toxic oleander plant, as a promising treatment during a White House meeting).

75. Some states did mandate the immunization of certain groups of adults shortly before any of the vaccines had gone to full approval, though it seems that the plaintiffs challenging these requirements had not raised any objections premised on the EUA choice clause. *See, e.g.*, Does 1-6 v. Mills, 566 F. Supp. 3d 34, 58 (D. Me.) (declining to preliminarily enjoin Maine's emergency rule to require health care worker immunization effective on August 12, more than a week before the FDA fully approved the first of the Covid-19 vaccines, finding no merit in objections to the failure to allow for religious exemptions), *aff'd*, 16 F.4th 20, 37 (1st Cir.), *emergency stay denied*, 142 S. Ct. 17 (2021). Similarly, some public universities had done so even earlier. *See* Nanette Asimov, *UC Students, Faculty, Staff Will Need Shots; UC Reverses Course, Will Require All Students, Faculty and Staff to Be Vaccinated This Fall*, S.F. CHRON., June 16, 2021, at A11 (reporting that the public universities in California decided not to hold off until full FDA approval after initially hesitating to mandate the use of vaccines subject to EUAs). Indiana University was among the campuses to do so. *See infra* note 130 (discussing the resulting litigation).

76. *See, e.g.*, Joseph G. Allen, Opinion, *The Vaccination Campaign Has Hit Its Limit*, WASH. POST, Aug. 3, 2021, at A23 ("[W]e have hit a wall with this voluntary approach. The only way out of our Covid-19 morass is to mandate vaccines . . . [even though] the FDA has still granted it only authorization for an emergency use.").

77. *See, e.g.*, Dan Diamond et al., *In New Season of Mandates, Social Fabric Is Further Frayed*, WASH. POST, Aug. 15, 2021, at A1; David Sharp et al., *Vaccine Mandates Fuel Conflict with Defiant Workers*, L.A. TIMES, Oct. 24, 2021, at A1.

protest,[78] but this pattern could demonstrate either that many who had expressed objections did not mean it or else that they only consented under protest. If employees rarely left their jobs notwithstanding serious qualms about getting vaccinated, then such a pattern might show that in practice they enjoyed little genuine choice in the matter.[79]

Although some commentators viewed the Covid-19 vaccines as closer to fully approved from the outset,[80] and they could have pointed to the endorsements issued by the U.S. Centers for Disease Control and Prevention (CDC) to buttress such a claim,[81] the EUA statute made no provision for such subtle gradations.[82] With the benefit of hindsight given their eventual approval,

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78. *See* Nat'l Fed'n of Indep. Bus. v. Dept' of Labor, 595 U.S. 109, 136 (2022) (Breyer, J., dissenting) ("According to OSHA, employers that have implemented vaccine mandates have found that far fewer employees actually quit their jobs than threaten to do so."); Florida v. HHS, 19 F.4th 1271, 1277 (11th Cir. 2021) ("[T]he Secretary cited evidence showing that after a large hospital system in Texas imposed a vaccine mandate, . . . [o]nly a very small number of workers—53 out of more than 26,000 (or 0.6%)—resigned rather than receive the vaccine."); Ezekiel J. Emanuel & David J. Skorton, Opinion, *Mandating COVID-19 Vaccination for Health Care Workers*, 174 ANNALS INTERNAL MED. 1308, 1309 (2021) (finding no basis for concerns about mass resignations based on the experience of hospitals that adopted mandates even before any vaccines had received full FDA approval).

79. *See* Liam Drew, *Did COVID Vaccine Mandates Work? What the Data Say*, 607 NATURE 22, 24 (2022); James T. Lee et al., *Employer Requirements and COVID-19 Vaccination and Attitudes Among Healthcare Personnel in the U.S.*, 40 VACCINE 7476, 7481 (2022). Contrast losing the opportunity take a cruise or visit a theme park. *See* NOAH, *supra* note 5, at 265-66, 465-67 (discussing litigation over cruise line vaccination requirements and restrictions on sailing, making light of these and other forms of escapism).

80. *See* Reiss & DiPaolo, *supra* note 28, at 56-57; *see also* Carolyn Y. Johnson et al., *Questions About Vaccines, Answered*, WASH. POST, Mar. 30, 2021, at E6 ("Peter Marks, director of the FDA center that oversees vaccines, has pledged to use an emergency standard roughly equivalent to what is needed for a full licensure. Even so, the available safety data—two months of follow-up on half the trials' participants after their second shots—is shorter than in traditional trials."); *infra* note 86 (referencing the issuance of a guidance document that focused on EUAs for Covid-19 vaccines).

81. *See, e.g.*, Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 Fed. Reg. 30,769, 30,771 (§ V(d)) (May 12, 2023) (conditioning PREP Act coverage for pharmacists on adherence to CDC vaccination recommendations); Lena H. Sun & Fenit Nirappil, *U.S. Youths 12 to 15 Now Eligible for Pfizer Shot*, WASH. POST, May 13, 2021, at A1 (explaining the reasons for awaiting the CDC's endorsement of a new vaccine even after the FDA has granted authorization); *see also* Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 878 (2009) ("[A] vaccine licensed by the FDA but not yet blessed by the CDC might as well not exist.").

82. *See* E-mail from author to Dorit R. Reiss, Professor of Law, U.C. Hastings (Mar. 26, 2021, 10:49 AM) (on file with author) ("I was struck that you even suggested these vaccines are 'EUA plus,' as if that matters . . . ."). Although limited to school immunization mandates, a couple of jurisdictions adopted restrictions based on a recognition that vaccines granted EUAs do not enjoy full FDA approval. In the summer of 2021, for instance, the Ohio legislature enacted the following provision:

> [A] public school or state institution of higher education shall not do either of the following: (1) Require an individual to receive a vaccine for which the [FDA] has not

the emergency authorizations for the Covid-19 vaccines merit praise,[83] but let us not forget about significant initial doubts,[84] and the EUAs issued for some other pandemic countermeasures hardly inspired confidence.[85] Once such products secure full FDA approval, of course, the special disclosure requirements would have no impact on immunization or comparable mandates, whether adopted by federal, state, or local governments or imposed by private entities. Even before full FDA approval, some immunization requirements allowed instead for testing and/or masking, which meant that the vaccine option represented more of a genuine choice; technically, the other options also existed

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> granted full approval; (2) Discriminate against an individual who has not received [such] a vaccine . . . , including by requiring the individual to engage in or refrain from engaging in activities or precautions that differ from the activities or precautions of an individual who has received such a vaccine.

OHIO REV. CODE § 3792.04(B) (2023); *see also* D.C. CODE § 38-502.01(d)(3) (2023) (repealed 2024) (requiring certification of immunization for K-12 students, including with "a vaccine against COVID-19 for which the [FDA] has granted full approval as opposed to emergency use authorization"); *cf.* ARK. CODE ANN. § 20-7-143(g) (2022) (expired 2023) (prohibiting all Covid-19 immunization mandates until two years after the FDA approves the vaccine, though without further elaboration).

83. *See* Daniel R. Feikin et al., *Duration of Effectiveness of Vaccines Against SARS-CoV-2 Infection and COVID-19 Disease: Results of a Systematic Review and Meta-Regression*, 399 LANCET 924, 936 (2022); J. Daniel Kelly et al., *Incidence of Severe COVID-19 Illness Following Vaccination and Booster with BNT162b2, mRNA-1273, and Ad26.COV2.S Vaccines*, 328 JAMA 1427, 1436 (2022). Then again, the Janssen Biotech (Johnson & Johnson) vaccine never secured full FDA approval; in the face of lingering questions about both its safety and efficacy, the company got this EUA revoked. *See* FDA, JANSSEN COVID-19 VACCINE (June 1, 2023), https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/janssen-covid-19-vaccine [perma.cc/C8SQ-XLHG]; *see also* Benjamin Rader et al., *Persistent Drop in Confidence Following US Recommended Pause of Ad26.COV2.S Vaccine Administration*, 41 VACCINE 5, 7 (2023).

84. *See* Heidi Ledford et al., *COVID Vaccines: What Scientists Now Want to Know*, 588 NATURE 205, 205-06 (2020) (noting a series of questions about the data submitted in support of the EUAs); Ellen Gabler & Abby Goodnough, *States Vow Extra Scrutiny of Coronavirus Vaccine*, HOUS. CHRON., Nov. 17, 2020, at A8 ("[A]bout a half-dozen states and the District of Columbia have planned an extra layer of scrutiny: committees that would vet any vaccine reviewed by the FDA, . . . in part a response to the Trump administration's handling of the pandemic and concerns that political considerations would influence vaccine approvals."); *see also* Alex Wigglesworth & Tracy Wilkinson, *COVID-19 Vaccine Clears a Key Hurdle; A Scientific Review Team Representing Four Western States Gives Its Endorsement*, L.A. TIMES, Dec. 14, 2020, at B1 (reporting that an expert group convened by California, Nevada, Oregon, and Washington endorsed Pfizer's vaccine two days after the FDA granted it an EUA). Indeed, some people persist in expressing their doubts, most notably of late the surgeon general of the Sunshine State (and my nominal cross-campus colleague) Joe Ladapo. *See* Dan Diamond et al., *Fla. Surgeon General Seeks to Stop Use of mRNA Covid Vaccines*, WASH. POST, Jan. 4, 2024, at A2 (characterizing his latest objections as "roundly debunked" and irresponsible); Apoorva Mandavilli, *Could the Covid-19 Vaccines Have Caused Some People Harm?*, N.Y. TIMES, May 5, 2024, at A1 (same, though also reporting some concerns that federal officials harbored undue skepticism about the possibility of rare side effects).

85. *See* Yaniv Heled et al., *Regulatory Reactivity: FDA and the Response to COVID-19*, 76 FOOD & DRUG L.J. 318, 324-29 (2021) (elaborating on objections to the EUAs for remdesivir, hydroxychloroquine, and convalescent plasma); Iwry, *supra* note 13, at 360-62 (same); Perryman, *supra* note 13, at 360-66 (same).

only pursuant to EUAs, but their authorizations did not include as a condition any disclosure about enjoying an option to decline.

III. CRITIQUING ITS VARIED INTERPRETATIONS

During the pandemic, both the executive and judicial branches attempted to make sense of the legislative command expressed in the EUA choice clause. Although the federal agencies tasked with its implementation offered no real guidance on this score apart from dictating the provision of the required statements,[86] other agencies have expressed some views about what Congress meant.[87] The actions taken by still other federal agencies suggest, however, hesitation about immunization mandates before the receipt of full FDA approval. Meanwhile, lawsuits challenging a variety of non-federal Covid-19 vaccination requirements gave courts around the country an opportunity to weigh in on the matter. Although objections premised on the EUA choice clause routinely failed, the cursory explanations offered by the judges resolving these various cases hardly settle the question. In particular, courts have largely neglected to appreciate the extent to which the statutory disclosure provision operates to preempt non-federal requirements.

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86. The FDA's guidance document offered little further elaboration on the disclosure requirement. *See* FDA's 2017 EUA Guidance, *supra* note 11, at 24-25; *id.* at 24 (explaining that "informed consent as generally required under FDA regulations [21 C.F.R. pt. 50] is not required for administration or use of an EUA product" (footnote omitted)). Although not appearing in the revised version, the FDA's original guidance included the following (stronger) statement interpreting the EUA choice clause: "Recipients must have an opportunity to accept or refuse the EUA product . . . ." FDA, GUIDANCE EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS, 2007 WL 2319112, at *15 (July 1, 2007) [hereinafter FDA's 2007 EUA Guidance]. A still newer guidance document that focused on Covid vaccines simply cross-referenced the 2017 EUA guidance for further details about the contents of the "Fact Sheets" prepared for recipients. *See* FDA, EMERGENCY USE AUTHORIZATION FOR VACCINES TO PREVENT COVID-19: GUIDANCE FOR INDUSTRY 6 (Oct. 2020), https://web.archive.org/web/20201223081724/https://www.fda.gov/media/142749/download [perma.cc/G8YC-WCP6]; *see also* Development and Licensure of Vaccines to Prevent COVID-19, 88 Fed. Reg. 72,489, 72,491 (Oct. 20, 2023) (withdrawing this guidance). When it granted the EUA for the anthrax vaccine in 2005, the FDA communicated its clear understanding that recipients would enjoy a genuine right of refusal. *See supra* note 57 and accompanying text.

87. Akin to the various FDA guidance documents discussed above, which formally have no binding force, *see supra* note 12, or the occasional medical journal articles penned by agency officials, *see supra* notes 41 & 63, many of these pronouncements amount to what I have previously dismissed as mere "interpretive detritus." Lars Noah, *BDSM in Administrative Procedure: Using Agency Guidance for Bondage and Discipline*, at 3 (Jan. 25, 2020), *archived at* https://perma.cc/UMJ4-P856 ("If agency officials testify before Congress, pen an op-ed in the *Washington Post*, write a commentary in a leading medical journal or law review, or even go on a tweet storm expressing their views, then regulated entities no doubt would pay some attention . . . ."). Call it an unsatisfying exercise in trying to read the proverbial tea leaves.

A. Flimsy Guidance from the Executive Branch

It did not take long for various federal agencies to opine about the lawfulness of Covid-19 immunization requirements. Amanda Cohn, the chief medical officer for the CDC's National Center for Immunization and Respiratory Diseases, offered the earliest official views on this precise question while serving in her capacity as the executive secretary of the agency's Advisory Committee on Immunization Practices (ACIP). During a meeting of that expert group held months before the FDA authorized a vaccine for emergency use, she "reminded everyone 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."[88] Dr. Cohn reiterated that stance during a subsequent meeting of an FDA advisory committee.[89] Although she had not communicated this position to the general public, committee members later asked to vote on authorizing emergency use of the Covid-19 vaccines may well have relied on her assurances about complete voluntariness.

Less than a week after the FDA issued its first EUA for a vaccine, the Equal Employment Opportunity Commission (EEOC) posted some informal guidance for employers.[90] Then, almost three months before the FDA fully approved the Pfizer vaccine, the EEOC revised this document to make clear that "federal [equal employment opportunity] laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated against COVID-19."[91] Although it focused on the Americans with Disabilities

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88. ACIP, SUMMARY REPORT 56 (Aug. 26, 2020), https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf [perma.cc/F9TE-XCMQ]. A posted video of that meeting confirms the accuracy of the quoted summary of her remarks. *See* https://www.cdc.gov/vaccines/videos/low-res/acipaug2020/Covid-19Supply-NextSteps_3_LowRes.mp4 [https://www.youtube.com/watch?v=p0zCEiGohJs&t=13s] (starting at counter #1:14:37).

89. *See* FDA, TRANSCRIPT OF THE 161ST VACCINES & RELATED BIOLOGICAL PRODS. ADVISORY COMM. (VRBPAC) MTG. 156 (Oct. 22, 2020), https://www.fda.gov/media/143982/download [perma.cc/U238-M36B]; *see also* Reiss & DiPaolo, *supra* note 28, at 51 n.238 (referencing an email from Dr. Cohn that confirmed her views on this issue).

90. *See* Vimal Patel, *Vaccine Can Be Required, U.S. Says*, N.Y. TIMES, Dec. 20, 2020, at A21. Technically, this fairly detailed online post reads more like a series of answers formulated by the agency to frequently asked questions (FAQs) than a somewhat more authoritative guidance document sometimes produced by the EEOC and other agencies, which itself would carry far less weight than a duly promulgated rule. *See* Noah, *supra* note 12, at 91-93, 110, 122; *see also id.* at 138 ("[G]uidance documents represent only the tip of the iceberg, with the FDA making use of any number of even less formal tools and techniques in order to accomplish its ends.").

91. EEOC, WHAT YOU SHOULD KNOW ABOUT COVID-19 AND THE ADA, THE REHABILITATION ACT, AND OTHER EEO LAWS § K.1 (May 28, 2021), *archived at* perma.cc/2E33-LW5D [hereinafter EEOC's Covid-19 FAQs]; *see also id.* § K ("This section was originally issued on Dec. 16, 2020 . . . . The EEOC has received many inquiries from employers and employees about the type of authorization granted by the . . . [FDA] for the administration of three COVID-19 vaccines."); Bridges v. Hous. Methodist Hosp., 543 F. Supp. 3d 525, 527 (S.D. Tex. 2021) ("This is not binding, but it is advice about the position one is likely to meet at the Commission."),

Act (ADA) rather than the EUA statute,[92] the agency suggested a subtle distinction between employers that require proof of vaccination and those that actually administered vaccines on site to their employees.[93]

Contemporaneously with the EEOC's revised FAQs, the CDC posted a similar document, explaining with little elaboration (and contrary to the views previously expressed by one of its high-level officials) that, "whether a state, local government, or employer, for example, may require or mandate COVID-19 vaccination is a matter of state or other applicable law."[94] The informal

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aff'd, 2022 WL 2116213, at *2 (5th Cir. 2022) (per curiam); Lucien J. Dhooge, *Pushing the Needle: Vaccination Mandates in the Age of COVID*, 59 SAN DIEGO L. REV. 481, 496-500, 504-12 (2022) (discussing the revised guidelines); Lauren Hirsch, *Office Vaccine Mandates: E.E.O.C. Clarifies the Rules*, N.Y. TIMES, June 2, 2021, at B4. For the latest version of the EEOC's FAQs, which includes some updates and further alterations, see https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws [perma.cc/77B9-UR4K] (last updated May 15, 2023).

92. *See* EEOC's Covid-19 FAQs, *supra* note 91, §§ K-L. It also addressed the Rehabilitation Act, the Genetic Information Non-Discrimination Act (GINA), and Title VII of the Civil Rights Act, while clearly stating that "[i]t is beyond the EEOC's jurisdiction to discuss the legal implications of EUA or the FDA approach." *Id.* § K. This caveat did not stop a pair of commentators from reading the EEOC's FAQs as implicitly finding no problem under that statute. *See* I. Glenn Cohen & Dorit Rubinstein Reiss, *Can Colleges and Universities Require Student COVID-19 Vaccination?*, HARV. L. REV. BLOG (Mar. 15, 2021), https://blog.harvardlawreview.org/can-colleges-and-universities-require-student-covid-19-vaccination/ [perma.cc/S2ZK-ZC9E]; *see also* Gostin et al., *supra* note 2, at 532 (offering a similar take on the EEOC's announcement as allowing employer vaccination mandates); Mark A. Rothstein et al., Editorial, *Employer-Mandated Vaccination for COVID-19*, 111 AM. J. PUB. HEALTH 1061, 1062 (2021) (same); Dale B. Thompson et al., *What Should Ethical and Strategic Employers Do About COVID-19 Vaccines?*, 56 U.S.F. L. REV. 219, 225, 229, 247-49 (2021) (alluding to the EUA choice clause and the lack of full FDA approval in barely perceptible ways, while reading the EEOC's FAQs as a green light for the adoption of employer mandates). *But see* Dhooge, *supra* note 91, at 500-01 (overreading this caveat as an indication that the EEOC thought employer mandates would have to await full FDA approval because of the EUA choice clause).

93. *See* EEOC's Covid-19 FAQs, *supra* note 91, § K.7; *see also id.* §§ K.16-.17 (worrying as well about undue influence exerted by an employer in nominally voluntary programs as potentially affecting this constraint under the ADA); *cf. id.* §§ K.20-.21 (explaining that GINA would allow no rewards or penalties for an employee to have a family member get vaccinated by the employer).

> [We would allow employers to encourage on-site immunizations] if any incentive (which includes both rewards and penalties) is not so substantial as to be coercive. Because vaccinations require employees to answer pre-vaccination disability-related screening questions, a very large incentive could make employees feel pressured to disclose protected medical information. . . . [T]his incentive limitation does not apply if an employer offers an incentive to employees to voluntarily . . . [get a] vaccination on their own from a third-party provider that is not their employer or an agent of their employer.

Id. § K.17.

94. CDC, WORKPLACE VACCINATION PROGRAM (last updated Mar. 25, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/essentialworker/workplace-vaccination-program.html [perma.cc/696U-PLBN] ("If an employer requires employees to provide proof that they have received a COVID-19 vaccination from a pharmacy or their own healthcare provider, the employer cannot mandate that the employee provide any medical information as part of the proof.").

advice emanating from both the EEOC and CDC, however, hardly seemed to assuage the concerns of most employers about requiring immunizations at that particular point in time.[95]

As the Biden administration began contemplating various immunization requirements, the Office of Legal Counsel (OLC) of the U.S. Department of Justice (DOJ) examined the question, which culminated in the issuance of a formal opinion in early July.[96] Responding to an inquiry from the White House counsel's office rather than from HHS or the FDA, OLC concluded that the EUA choice clause "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."[97] The opinion entirely rejected the view that the statute sought to ensure choice,[98] thereby apparently allowing entities subject to the conditions imposed under an EUA to order immunizations so long as they dutifully inform

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95. *See* Dan Diamond, *Most Employers Shy Away from Mandating Coronavirus Vaccines*, WASH. POST, May 23, 2021, at A1 (explaining as one reason for this hesitancy "the untested legal issues involving vaccines cleared under the [FDA]'s emergency authority"); *see also* Michael Corkery et al., *Covid Forces Bosses to Act*, N.Y. TIMES, Aug. 4, 2021, at B1 (reporting only limited movement toward immunization mandates by large private employers a couple of months later and a couple of weeks before the first full approval by the FDA); *id.* ("Many companies, already facing staffing shortages, are worried that requiring vaccines could give employees another reason to quit.").

96. *See* OLC, 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, 45 Op. O.L.C. __, slip op. (July 6, 2021), https://www.justice.gov/d9/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf [perma.cc/PY8V-5VLM]. On that same day, in a tweet favoring Covid vaccine mandates, the previous U.S. Surgeon General (2017-21) noted that the "lack of FDA licensure leave schools, colleges, businesses in a legal quandary." Jerome Adams (@JeromeAdamsMD), TWITTER (July 6, 2021, 11:30 AM), https://twitter.com/JeromeAdamsMD/status/1412433868511137798?s=20 [perma.cc/8RQQ-EMLT]; *see also* David Leonhardt, *Why, After Months of Shots, Are None Approved?*, N.Y. TIMES, July 22, 2021, at A12 (quoting this tweet, and adding that many people found the distinction between EUA and full approval puzzling in the context of official recommendations in favor of vaccination). In contrast, Professor Gostin, who initially had expressed similar doubts, *see supra* note 2, evidently changed his tune on the strength of the OLC opinion and in the face of disappointing voluntary uptake. *See* Lawrence O. Gostin, *Vaccine Mandates Are Lawful, Effective and Based on Rock-Solid Science*, SCI. AM. (Aug. 5, 2021), https://www.scientificamerican.com/article/vaccine-mandates-are-lawful-effective-and-based-on-rock-solid-science/ [perma.cc/4UKC-EP9T].

97. OLC, *supra* note 96, at 1; *id.* at 18; *cf. id.* ("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 [while under an EUA] if they effectively lack such an option because of a military order—[therefore,] DOD should seek a presidential waiver before it imposes a vaccination requirement.").

98. *See id.* at 7 ("By its terms, the provision directs only that potential vaccine recipients be 'informed' of certain information . . . ."); *id.* at 2 (concluding that the provision "specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements"); *id.* at 7 (same); *id.* at 15-16 (Section 1107a "likewise describes the 'option to accept or refuse' condition in purely informational terms. The language refers to the President's authority to waive a requirement to provide certain information, not to waive any right or affirmative 'option' to refuse administration of the product itself.").

prospective recipients of their freedom to walk away without a shot (and suffer the consequences).[99]

Even if the statute does not cover parties one or two steps removed from the federal agencies charged with implementing the EUA provision,[100] could these same agencies simply disregard the congressional directive that they demand disclosures to recipients about the freedom to decline?[101] OLC obliquely addressed this question in discussing the old EUA granted for the anthrax vaccine. As explained previously, the FDA had directed the DOD to remind soldiers that they could decline.[102] OLC's opinion dismissed this discussion as reflecting nothing other than the continuing effect of an injunction previously issued by the district court,[103] quoting a *Federal Register* notice issued exactly six months after the FDA first granted the EUA and elaborated on the statutory choice clause.[104] It also conflated INDs and EUAs as well as the affiliated but

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99. *See id.* at 8-9 (recognizing that some of the "parties administering the products . . . , such as universities, might also impose vaccination requirements," but making nothing of that possibility); *id.* at 13 n.14 ("[N]othing 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).").

100. *See id.* at 2 (observing that "these policies typically are conditions on employment, education, receipt of services, and the like rather than more direct legal requirements"). Three months before OLC published its opinion, the Congressional Research Service (CRS) issued a report that saw no problem with public mandates either—though it accepted reading the EUA choice clause as a consent requirement, CRS viewed it as inapplicable to anything less than forcible inoculation at the state's direction. *See* WEN W. SHEN, CRS-R46745, STATE AND FEDERAL AUTHORITY TO MANDATE COVID-19 VACCINATION 4-5 (Apr. 2, 2021), https://crsreports.congress.gov/product/pdf/R/R46745/2 [perma.cc/4CU4-7GTS] (arguing primarily that mandates only "impose secondary consequences—often in the form of exclusion from certain desirable activities, such as schools or employment—in the event of refusal"). In separately discussing possible federal mandates, however, CRS did not revisit the potential impact of the EUA choice clause. A substantially revised version of the report that appeared more than a year later gave the question about state mandates even less attention because it had largely become moot. *See id.* at 42-43 (revised May 17, 2022), https://crsreports.congress.gov/product/pdf/R/R46745 [perma.cc/9ATC-WXAU]; *see also id.* at 43 ("[C]ourts generally have concluded that the provision does not prohibit entities from requiring individuals, duly informed by their medical providers, to be vaccinated.").

101. *Cf.* Noah, *supra* note 33, at 354 ("[E]thically these [alternatives of noncoverage and conditional coverage] may not come to exactly the same thing insofar as the pressure exerted on beneficiaries flows less directly from CMS.").

102. *See supra* note 57 and accompanying text.

103. *See* OLC, *supra* note 96, at 14-15.

104. *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, 70 Fed. Reg. 44,657, 44,660 (Aug. 3, 2005) ("The Court's injunction means you have the right to refuse to take the vaccine without fear of retaliation."). In context, this in no way suggests that the district court's order, which predated the EUA, had dictated the FDA's previously issued and now reiterated gloss on the meaning of the EUA choice clause. Indeed, that injunction only barred the DOD from mandating use of the anthrax vaccine while subject to an IND and in the absence of a presidential waiver. *See* Doe v. Rumsfeld, 341 F. Supp. 2d 1, 19

distinctive presidential waiver provisions.

By virtue of its decisionmaking process and structural focus, OLC may give insufficient attention to the rights of private individuals.[105] Nonetheless, insofar as an opinion issued by OLC represents an official interpretation of the statute and purports to bind other Executive branch officials,[106] the FDA would seem safe in treating the disclosure requirement as nothing more than an empty gesture. In the event of a judicial challenge, however, what deference would courts owe to an OLC interpretation as it did not have delegated authority to implement this particular statute?[107] Would that calculus change if the FDA—having no apparent option in the matter—promulgated a rule adopting as its own

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(D.D.C. 2004). The subsequent authorization for emergency use served as a temporary and only partial end run around the court's order. *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, 70 Fed. Reg. 5452, 5254 (Feb. 2, 2005) ("But for the Court's order, FDA would not consider the use of AVA for inhalation anthrax to be an unapproved use."); *see also* Legaretta v. Macias, 603 F. Supp. 3d 1050, 1061 (D.N.M. 2022) ("[T]he plaintiffs in *Rumsfeld* did not base their claims on an asserted violation of § 360bbb, as do Plaintiffs here, or indeed even mention that provision in their challenge to the AVA. Rather, their claim involved wholly different provisions, namely 10 U.S.C. § 1107 . . . ."). The additional language appearing in the second *Federal Register* notice that OLC relied upon has a simple explanation: On April 6, 2005, three months after the FDA issued the original EUA, the district court granted the government's emergency motion to modify the injunction in order to confirm that it would allow for the administration of AVA under an EUA, though it insisted that this only happen "on a *voluntary* basis." *See* Doe v. Rumsfeld, No. Civ.A.03-707, 2005 WL 1124589, at *1 (D.D.C. Apr. 6, 2005).

105. *See* Trevor W. Morrison, *Stare Decisis in the Office of Legal Counsel*, 110 COLUM. L. REV. 1448, 1521 (2010) ("[T]he issue tends to come to OLC in rather one-sided fashion. The requesting agency will likely submit a formal statement of its views, but nongovernmental interests might not get a full airing. This is worrisome, especially in matters pitting executive power against individual rights." (footnote omitted)); *id.* at 1521-22 ("The fact that OLC lacks a mechanism for hearing directly from individual rights claimants does not make it inevitable that OLC will not take those (or other relevant) interests into account. . . . [Still,] individual rights are likely to be given short shrift."); *see also id.* at 1523 (suggesting mechanisms for greater attention to "civil liberties"); *cf.* Noah, *supra* note 33, at 330 (suggesting a loose parallel between the NIH's dubious advice on a particular question of biomedical research ethics and OLC's infamous torture memos).

106. *See* Morrison, *supra* note 105, at 1493 (explaining that "its advice is treated as binding within the Executive Branch," which "mean[s] that OLC's legal advice is itself a source of law"); *see also id.* at 1451-70 (offering extensive background on its functions); *cf.* Daphna Renan, *The Law Presidents Make*, 103 VA. L. REV. 805, 809 (2017) (asserting that "OLC's opinion-writing institution is withering"); *id.* at 869 (cautioning that "OLC's sometimes aggressive findings of legality in a wide range of difficult and fundamentally ambiguous legal questions (an approach that permeates OLC's opinions practice) further erodes its reputation").

107. *See* Sonia Mittal, *OLC's Day in Court: Judicial Deference to the Office of Legal Counsel*, 9 HARV. L. & POL'Y REV. 211, 239 (2015) (concluding that "the Supreme Court has [rightly] not accorded OLC substantial deference"). A few lower courts cited OLC's opinion in the course of rejecting objections to early Covid-19 vaccination mandates. *See, e.g.*, *Legaretta*, 603 F. Supp. 3d at 1060; Rhoades v. Savannah River Nuclear Sols., LLC, 574 F. Supp. 3d 322, 345 (D.S.C. 2021); Johnson v. Brown, 567 F. Supp. 3d 1230, 1244, 1256 (D. Or. 2021).

OLC's views about what the EUA choice clause meant?[108]

As it happens, the White House did not take OLC's opinion as a green light to adopt federal immunization requirements.[109] Instead, the FDA's decision less than two months later to grant full approval for adult use of the mRNA vaccine from Pfizer and BioNTech (branded Comirnaty®) made a far bigger difference.[110] Notably, given the EUA statute's origins in disputes involving military service members, the Defense Department started its campaign one day after the FDA's decision,[111] thereby avoiding previously announced plans to otherwise secure a presidential waiver.[112] A couple of weeks later, President

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108. *See* Mittal, *supra* note 107, at 226-27, 238 (posing such a question); Morrison, *supra* note 105, at 1462 n.52 (same); *cf.* OLC, *supra* note 96, at 13 (claiming that the "FDA agrees with our interpretation of section 564"). Then again, strong deference to agency interpretations hardly exists any longer. *See* Lars Noah, *"Major Questions" Malarkey: An Arbitrary and Capricious New Doctrine for Vetoing Controversial Agency Rules*, 97 ST. JOHN'S L. REV. __, __ & n.76 (forthcoming Aug. 2024).

109. Technically, one Cabinet-level department did so in late July for its health care workers. *See* Michael D. Shear et al., *Biden Rekindles Vaccination Push with New Orders*, N.Y. TIMES, July 30, 2021, at A1 ("The Department of Veterans Affairs became the first federal agency to require many of its employees to get a shot."); *see also id.* (adding that the President had ordered federal employees—both civilian and military—to either get vaccinated or else face regular testing, masking, social distancing and other restrictions, though these measures "fall short of a mandate").

110. *See* Sharon LaFraniere & Noah Weiland, *Mandates on Way as Pfizer Vaccine Gets Full U.S. Nod*, N.Y. TIMES, Aug. 24, 2021, at A1. Just over five months after licensing Comirnaty, and as the surge caused by the Omicron variant began to subside, the FDA granted full approval for adult use of Moderna's mRNA vaccine (branded as the decidedly edgier-sounding SpikeVax®). *See* Peter Loftus et al., *Moderna Shot Gets Full FDA Approval*, WALL ST. J., Feb. 1, 2022, at A3. During this interim period between approvals, some individuals facing immunization requirements objected that shortages of Pfizer's vaccine effectively forced them to accept not-yet-approved substitutes, including older stocks of the Pfizer vaccine that technically remained subject to the EUA. *See, e.g.*, Doe #1-#14 v. Austin, 572 F. Supp. 3d 1224, 1229-34 (N.D. Fla. 2021); *Johnson*, 567 F. Supp. 3d at 1247, 1252. Furthermore, it would take longer for the FDA to convert EUAs to BLA approvals in three sets of progressively younger age groups, and booster shots for all age groups also initially relied on EUAs. For a timeline of these and other regulatory milestones, see https://www.hhs.gov/coronavirus/covid-19-vaccines/index.html [perma.cc/MX3K-8WLH].

111. *See* Daniel E. Slotnik, *U.S. Military Mandates Vaccinations Against Covid*, N.Y. TIMES, Aug. 26, 2021, at A16 ("[O]nly vaccines that have been federally approved will be used."); Aidin Vaziri & Catherine Ho, *Pfizer Nod Could Spur More Shots*, S.F. CHRON., Aug. 24, 2021, at A1 ("The Pentagon immediately announced it will press ahead with plans to require 1.4 million active-duty military service members to get the vaccine."); *see also* Doster v. Kendall, 54 F.4th 398 (6th Cir. 2022) (affirming a preliminary injunction against the Air Force's immunization mandate), *vacated as moot*, 144 S. Ct. 481 (2023); Shawn D. McKelvy et al., *Shots Fired, Shots Refused: Scientific, Ethical, and Legal Challenges Surrounding the U.S. Military's COVID-19 Vaccine Mandate*, 55 ST. MARY'S L.J. 405, 467, 474 (2024) (counting more than 8,000 service members discharged for refusing to get vaccinated). Before long, Congress directed the military to phase out this vaccination requirement. *See id.* at 466-67; Lolita C. Baldor, *New Law Ends Contentious Covid-19 Vaccine Mandate for US Troops*, CHI. TRIB., Dec. 25, 2022, at 1.

112. *See* Nancy A. Youssef, *Vaccine Mandated for All Military*, WALL ST. J., Aug. 10, 2021, at A1 ("If the FDA doesn't approve the vaccines against Covid-19 by mid-September, [Defense Secretary] Austin plans to ask the president for a waiver, the Pentagon said, which the

Biden issued a pair of Executive Orders, one that directed a special task force to delineate Covid-19 safeguards appropriate for employees of certain federal contractors,[113] and another one to mandate the immunization of civilian federal workers.[114]

On the same day that he issued these orders, the President directed a pair of federal regulatory agencies to do likewise for far larger swaths of employees.[115] Less than two months later, the Occupational Safety and Health Administration (OSHA) issued an emergency temporary standard (ETS), which required large employers to demand vaccination or testing,[116] and the Centers for Medicare and Medicaid Services (CMS) promulgated an interim final rule, which ordered the vaccination of health care personnel.[117] Indeed, the latter agency noted that

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administration has said it would authorize."); *see also* Children's Health Def. v. FDA, 573 F. Supp. 3d 1234, 1242-45 (E.D. Tenn. 2021) (rejecting for lack of standing military service members' objections to the agency's licensing decisions related to the Pfizer vaccine), *aff'd*, 2022 WL 2704554, at *3-5 (6th Cir. 2022); *id.* at 1243 n.4 ("Plaintiffs have not sufficiently alleged that the FDA's decisions to license the Comirnaty vaccine or give EUA status to Pfizer-BioNTech's vaccine was the motivating factor in the military's decision to impose vaccine mandates."); *id.* at 1244 (finding a lack of redressability because unwinding the approval would leave the original EUAs in place and still allow the DOD to impose a mandate by mid-September with a presidential waiver); *id.* at 1238 (referencing the Secretary of Defense's announced plans to do so).

113. *See* Ensuring Adequate COVID Safety Protocols for Federal Contractors, Exec. Order No. 14,042, § 2 (Sept. 9, 2021), 86 Fed. Reg. 50,985, 50,985-86 (Sept. 14, 2021). A couple of weeks later, this culminated in an immunization mandate. *See* Determination of the Promotion of Economy and Efficiency in Federal Contracting Pursuant to Executive Order No. 14042, 86 Fed. Reg. 53,691, 53,692 (Sept. 28, 2021) (announcing that the Office of Management and Budget endorsed the "Safer Federal Workforce Task Force Guidance for Federal Contractors and Subcontractors on COVID-19 Workplace Safety"). States secured preliminary injunctions against its enforcement. *See* Georgia v. Biden, 574 F. Supp. 3d 1337, 1357 (S.D. Ga. 2021), *aff'd in part*, 46 F.4th 1283, 1308 (11th Cir. 2022) (vacating only its nationwide scope); Kentucky v. Biden, 571 F. Supp. 3d 715, 735 (E.D. Ky. 2021), *stay denied*, 23 F.4th 585, 612 (6th Cir. 2022).

114. *See* Requiring Coronavirus Disease 2019 Vaccination for Federal Employees, Exec. Order No. 14,043, § 2 (Sept. 9, 2021), 86 Fed. Reg. 50,989, 50,990 (Sept. 14, 2021); *see also* Annie Linskey et al., *Biden Announces Broad New Vaccine Mandates*, WASH. POST, Sept. 10, 2021, at A1 (reporting that federal workers previously could opt instead for periodic testing). An advocacy group objected that this order exceeded the President's authority and secured a preliminary injunction. *See* Feds for Med. Freedom v. Biden, 63 F.4th 366 (5th Cir.) (en banc), *vacated as moot*, 144 S. Ct. 480 (2023); *cf.* Payne v. Biden, 62 F.4th 598, 607 (D.C. Cir.) (declining to entertain such objections), *vacated as moot*, 144 S. Ct. 480 (2023).

115. *See* Katie Rogers & Sheryl Gay Stolberg, *Biden Issues Sweeping Mandates for Shots*, N.Y. TIMES, Sept. 10, 2021, at A1.

116. *See* COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402, 61,551-55 (Nov. 5, 2021), *withdrawn*, 87 Fed. Reg. 3928 (Jan. 26, 2022); *see also* Nat'l Fed'n of Indep. Bus. v. Dept' of Labor, 595 U.S. 109, 120-21 (2022) (per curiam) (granting a petition for an emergency stay of the agency's ETS); Emma Goldberg, *OSHA Withdraws Its Workplace Vaccine-or-Test Requirement; Comes After Supreme Court Blocked the Rule*, BOS. GLOBE, Jan. 26, 2022, at A4.

117. *See* Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,616-27 (Nov. 5, 2021) (codified in scattered parts of 42 C.F.R.); *see also* Biden v. Missouri, 595 U.S. 87, 97-98 (2022) (per curiam) (granting an emergency stay of preliminary injunctions issued by a pair of district courts in challenges to the

"workers whose hesitancy was related to EUA status now have a fully licensed COVID-19 vaccine option."[118] Other non-federal actors similarly had awaited the FDA's approval decision before adopting immunization requirements.[119]

B. Mostly Dicta from the Judicial Branch

A number of courts subsequently confronted these same sorts of questions without, however, answering them convincingly. In rejecting motions for preliminary relief as not likely to succeed on the merits, many of these judges offered only a cursory analysis of the issue, especially insofar as it represented just one among a grab bag of grounds offered by the various plaintiffs for objecting to Covid vaccination mandates.[120] Several of these courts dismissed

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CMS rule); David A. Lieb & Kavish Harjai, *Nursing Homes Push to End Federal Vaccine Rule; Some Say Covid-19 Shot Mandate for Workers Should End as Crisis Is Winding Down*, L.A. TIMES, Feb. 26, 2023, at A20 ("[T]he vaccination requirement affecting an estimated 10 million healthcare workers is the last remaining major mandate from President Biden's sweeping attempt to boost national vaccination rates. Similar requirements for large employers, military members and federal contractors all have been struck down, repealed or partially blocked.").

118. 86 Fed. Reg. at 61,584. In contrast, when OSHA issued an ETS a few months earlier covering just health care employees, it drew attention to the fact that the FDA had granted EUAs for three vaccines, which prompted it to only encourage rather than require their use at the time. *See* Occupational Exposure to COVID-19; Emergency Temporary Standard, 86 Fed. Reg. 32,376, 32,379, 32,396-97, 32,423-24, 32,459-60, 32,597-99 (June 21, 2021). When issuing its vaccination-or-testing ETS applicable to large employers less than five months later, OSHA's preamble only referenced EUAs for devices, primarily diagnostics. *See, e.g.*, 86 Fed. Reg. at 61,450 (pointing out that, "by October 1, 2021, the number of [such] EUAs issued had grown to 324"); *see also id.* at 61,520 ("[T]he FDA has issued EUAs for certain PPE products, including respiratory protective devices such as respirators.").

119. *See, e.g.*, Emily Anthes, *Pfizer Seeks Full Approval for Virus Vaccine in US; Application to FDA Is Key Step Toward Wider Use of Shot*, CHI. TRIB., May 9, 2021, at 25 ("Many companies have been hesitant to require the vaccines, especially while they have only emergency authorization, which is designed to be temporary."); Catherine Ho, *FDA Approval of Vaccine Could Mean More Takers*, S.F. CHRON., July 13, 2021, at A1 ("Approval would clear the way for workplaces and schools to mandate shots, since some major employers and universities say they will require vaccinations only after FDA approval."); *see also* Nina Agrawal et al., *UC, CSU Aim to Require Vaccine by Fall; University Systems Look to Set National Model in Mandating COVID-19 Shots for In-Person Learning*, L.A. TIMES, Apr. 23, 2021, at A1 ("[T]he UC and Cal State systems have not yet taken that step because of questions over the legality of requiring vaccines before they have been formally approved by the FDA."); *Government Vaccine Requirements Affect 12 Million Workers*, N.Y. TIMES, Dec. 23, 2021, at A12 ("At least 8 million people employed by state and city governments must get vaccinated.").

120. A few cases even raised questions about EUAs for masks and tests. *See, e.g.*, Aviles v. Blasio, No. 20 Civ. 9829, 2021 WL 796033, at *24 & n.13 (S.D.N.Y. Mar. 2, 2021) (declining to preliminarily enjoin the New York City school district's condition for returning to in-person classes that parents consent to random Covid-19 testing of their children, rejecting an objection based on the EUA choice clause), *vacated as moot sub nom.* Lisa v. Blasio, 2022 WL 1216298 (2d Cir. Apr. 21, 2022); Villareal v. Rocky Knoll Health Ctr., No. 21-CV-729, 2021 WL 5359018, at *2-3 (E.D. Wis. Nov. 17, 2021) (dismissing a wrongful discharge claim against a nursing home that had required testing employees for Covid-19 every two weeks, rejecting the argument that the EUA choice clause, which the defendant technically had satisfied by informing a nurse of her

the objections as moot: in some cases, after the FDA granted full approval,[121] and, in other cases, after the named defendants dropped their mandates.[122]

Other courts concluded that the statute had no application to particular defendants or indirect methods of limiting the freedom to decline administration of a countermeasure subject to an EUA. On this basis, judges dismissed such claims lodged against private employers, at least those that did not themselves administer the vaccines to workers.[123] Public employer mandates similarly escaped judicial condemnation, whether imposed by entities at the federal,[124] state,[125] or local level.[126]

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option to refuse, reflected a strong public policy so that she could not get fired for then making such a choice).

121. *See, e.g.*, Norris v. Stanley, 558 F. Supp. 3d 556, 559-60 (W.D. Mich. 2021) (denying the plaintiff's motion for a temporary restraining order, concluding that FDA approval of Pfizer's vaccine likely rendered a public university employee's EUA statutory claim moot).

122. *See, e.g.*, Coker v. Austin, No. 3:21-cv-1211-AW-HTC, 2022 WL 19333274, at *1-2, 6 (N.D. Fla. Nov. 7, 2022) (discussing military service members' EUA consent claims), *after further proceedings*, 688 F. Supp. 3d 1116, 1122-25 (N.D. Fla. 2023) (explaining that the DOD had rescinded its mandate as directed by Congress); Hoerig v. Bowling Green State Univ., 224 N.E.3d 567, 570-71 (Ohio Ct. App. 2023) (affirming the dismissal of claims asserted by students because the defendant had voluntarily discontinued its masking and vaccination-or-testing mandates).

123. *See, e.g.*, Johnson v. Tyson Foods, Inc., 607 F. Supp. 3d 790, 806-07 (W.D. Tenn. 2022) (dismissing an objection under the EUA choice clause in part because "there is no allegation that Defendants actually administered the vaccine"); Finkbeiner v. Geisinger Clinic, 623 F. Supp. 3d 458, 464 n.24 (M.D. Pa. 2022) ("Courts have been uniform that the [EUA] statute has no bearing in cases involving employer mandates."); *see also id.* at 465-70 (dismissing various claims of an employee against a private health care institution that granted her a religious exemption to its Covid-19 vaccination requirement conditioned on twice-a-week testing, which she had refused to do as well).

124. *See, e.g.*, Rhoades v. Savannah River Nuclear Sols., LLC, 574 F. Supp. 3d 322, 331, 344-47 (D.S.C. 2021) (declining to preliminarily enjoin a White House order that certain federal contractors demand proof of vaccination by their employees), *app. dismissed*, 2022 WL 17691567 (4th Cir. 2022); *see also* Church v. Biden, 573 F. Supp. 3d 118, 134-35 & n.22, 140, 148 (D.D.C. 2021) (declining to preliminarily enjoin a White House order that federal employees get vaccinated, finding the EUA choice clause and other objections unripe because the plaintiffs had already requested and would likely secure religious exemptions); *supra* note 111 (referencing some of the litigation over the DOD's immunization requirements).

125. *See, e.g.*, Boone v. Ill. Dep't of Corrections, No. 21-cv-3229-JES-JEH, 2022 WL 17083394, at *6-7 (C.D. Ill. Nov. 18, 2022) (dismissing claims by public employees against one state's vaccination-or-testing mandate), *rev'd on other grds.*, 71 F.4th 622, 624, 627 (7th Cir. 2023); Johnson v. Brown, 567 F. Supp. 3d 1230, 1244, 1255-57, 1267 (D. Or. 2021) (declining to issue a temporary restraining order against the governor's order that certain state employees get vaccinated six weeks (or possibly more) after full approval by the FDA).

126. *See, e.g.*, Legaretta v. Macias, 603 F. Supp. 3d 1050, 1058-61, 1073 (D.N.M. 2022) (dismissing these and other objections to a county order that first responders get inoculated more than six months before the FDA fully approved any of the vaccines); *id.* at 1060 (adding that the "Defendants are not 'directly administering the vaccine'" to their employees); Burcham v. City of Los Angeles, 562 F. Supp. 3d 694, 707-08 (C.D. Cal. 2022) (dismissing various challenges to a police department's vaccination-or-testing requirement, including a claim that the EUA choice clause served as a predicate for the employees' due process objections, because the FDA had

Because the earliest mandates targeted health care workers, the likelihood that hospitals and pharmacies would run their immunization programs in house made this question somewhat trickier, though you could hardly tell from the way that the courts assessed these cases.[127] Some institutions of higher education also supplied Covid-19 vaccinations on site, for employees as well as students.[128] The same thing happened in certain custodial settings, with the medical staff at some nursing homes (and prisons) inoculating residents (and inmates).[129]

Conversely, the EUA choice clause seemingly would have no direct application to entities that simply acted to exclude persons—whether employees, students, or customers—without proof of vaccination.[130] If,

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already approved Pfizer's vaccine and the statute only governed the duty of medical providers); Pelekai v. Hawai'i, No. 21-cv-00343-DKW-RT, 2021 WL 4944804, at *4-6 & n.9 (D. Haw. Oct. 22, 2021) (dismissing as moot challenges brought by municipal employees to a vaccination-or-testing requirement).

127. *See, e.g.*, Bridges v. Hous. Methodist Hosp., 543 F. Supp. 3d 525, 527-28 (S.D. Tex. 2021) (rejecting the argument that the EUA choice clause applied to a Covid-19 vaccination mandate adopted by a private employer or that requiring health care workers to receive vaccines not yet fully approved by the FDA amounted to nonconsensual human experimentation), *aff'd*, 2022 WL 2116213, at *2 (5th Cir. 2022) (per curiam). Principal-agent questions involving health care products and professionals can become complicated, including for duties to secure informed consent from research subjects. *See* Noah, *supra* note 73, at 902-06.

128. *See, e.g.*, Lauren Lumpkin, *Universities Plan a Push to Vaccinate Students*, WASH. POST, Mar. 27, 2021, at A2. I recall (voluntarily) getting my first couple of jabs—and several PCR tests—on my work site, during regular business hours, administered by co-workers from the other (medical professions) side of our sprawling campus in Gainesville. After offering a remarkably cramped reading of the EUA choice clause, a pair of commentators recommended that "universities can facilitate access to vaccines by having on-site vaccination clinics." Reiss & DiPaolo, *supra* note 28, at 59; *see also id.* at 63 n.271 ("Rutgers, for example, is offering a vaccine clinic on its campus as part of its mandate, but a university could also allow students to be vaccinated in its health services, if it has them, without a clinic."). As I have tried to explain, that could also increase an institution's legal jeopardy.

129. *See, e.g.*, Leana S. Wen, Opinion, *What Government Can Do About Dismal Nursing Home Vaccination Rates*, WASH. POST, Dec. 28, 2023, at A17. CMS rules require that long-term care facilities establish infection prevention and control programs, which must include offering influenza and pneumococcal immunizations, but in each case demand that these providers ensure that their residents have "the opportunity to refuse." 42 C.F.R. § 483.80(d)(1)(iii) & (2)(iii). Three months before the FDA fully approved the Pfizer vaccine, CMS amended this rule to provide likewise for Covid-19 immunizations. *See* Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff, 86 Fed. Reg. 26,306, 26,335 (May 13, 2021) (codified at 42 C.F.R. § 483.80(d)(3)(v)); *id.* at 26,311-12 (discussing their EUA status without, however, making any reference to the choice clause in the statute).

130. *See, e.g.*, Klaassen v. Trustees of Indiana Univ., 549 F. Supp. 3d 836, 870 (N.D. Ind.) ("[T]he informed consent requirement under the EUA statute only applies to medical providers. The university isn't directly administering the vaccine to its students; instead, it is requiring students to obtain the vaccine from a medical provider and to attest that they have been vaccinated . . . ."), *aff'd*, 7 F.4th 592 (7th Cir. 2021), *vacated as moot*, 24 F.4th 638 (7th Cir. 2022). As the district court in that case elaborated:

> The students will be informed of the risks and benefits of the vaccine and of the option

however, state or local law obligated businesses to condition access on evidence of prior immunization, then one might ask whether the federal statute operated to preempt those laws. Even so, courts hardly seemed more receptive to preemption arguments framed in this way.[131]

A number of lower courts have dismissed objections premised on the EUA choice clause simply because the FDCA does not provide a private right of action.[132] Although drawn from U.S. Supreme Court dictum from decades

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> to accept or refuse the vaccine by their medical providers. . . . The university isn't forcing the students to undergo injections. The university is presenting the students with a difficult choice—get the vaccine or else apply for an exemption or deferral, transfer to a different school, or forego school for the semester or altogether. But this hard choice doesn't amount to coercion. The students taking the vaccine are choosing it among other options, and before the shot reaches their arms, they are made aware of the risks and the option to refuse.

Id. at 870-71; *see also* Children's Health Def., Inc. v. Rutgers, State Univ. of N.J., No. 21-15333, 2022 WL 4377515, at *10 (D.N.J. Sept. 22, 2022) (same). Although the appellate court did not reference the EUA choice clause, it endorsed this broader analysis, which prompted me to ask (among other pointed questions about the court's rationale): "Are there no limits (other than market pressures) on what a public university might demand of students in exchange for the privilege of attendance—for instance, how about conditioning admission on undergraduates promising to volunteer to enroll as subjects in at least one clinical trial run by the medical school?" NOAH, *supra* note 5, at 236-37. *But see* Reiss & DiPaolo, *supra* note 28, at 51 (calling a statutory prohibition against compulsory immunization "a far cry from saying that no one can condition a benefit on a person's acceptance of the vaccine").

131. *See, e.g.*, Valdez v. Grisham, 559 F. Supp. 3d 1161, 1171-72 (D.N.M. 2021) (declining to preliminarily enjoin a state order on these grounds because one Covid-19 vaccine received full FDA approval for ages 16 and up less than a week after issuance of the mandate, the state did not administer the vaccines, and persons could decline when offered by a health provider though then unable to remain employed in their current position or access the state fairgrounds), *aff'd on other grds.*, 2022 WL 2129071, at *1 n.2 (10th Cir. June 14, 2022), *after further proceedings*, 676 F. Supp. 3d 1021, 1031 (D.N.M. 2022) (dismissing these objections); Dixon v. De Blasio, 566 F. Supp. 3d 171, 189-90 (E.D.N.Y. 2021) (finding no preemption of municipal orders that certain businesses and other entities exclude unvaccinated individuals because these did not force anyone to get vaccinated), *vacated as moot and remanded*, 2022 WL 961191 (2d Cir. 2022). Strangely, one commentator viewed the EUA choice clause as barring employee mandates without, however, also suggesting that it would stand in the way of state requirements. *Compare* Dhooge, *supra* note 91, at 500-01 (arguing that the statute made employer mandates dependent upon full approval by the FDA), *with id.* at 514-15, 524-28 (favoring state mandates); *id.* at 527 (noting that states could impose greater penalties than employers for noncompliance with a vaccine mandate); *see also id.* at 519 (arguing that the already strong constitutional case for public mandates only became more compelling after full approval by the FDA). So long as EUAs governed vaccines, that position strikes me as precisely backwards because the potential preemptive effect of the clause would more plausibly displace public rather than private immunization mandates, putting to one side the still clearer conflict with federal law for both public and private entities that chose to administer Covid-19 vaccines on site.

132. *See, e.g.*, Bowlin v. Bd. of Dirs. Judah Christian Sch., 695 F. Supp. 3d 1003, 1009-10 (C.D. Ill. 2023) (school employees subject to vaccination-or-testing requirements); Goodrich v. Good Samaritan Reg'l Health Ctr., No. 22-132, 2022 WL 1623648, at *2 (S.D. Ill. May 23, 2022) (employee discharged for refusing testing after he received religious exemption from private employer's vaccination requirement); Anderson v. United Airlines, Inc., No. 23 C 989, 2023 WL 5721594, at *2 (N.D. Ill. Sept. 5, 2023) (employees of a private company that required proof of

ago,[133] the federal appellate courts have consistently so held.[134] Nonetheless, private litigation alleging that a regulated party violated some FDA requirement generally remains available.[135] For the most part, however, the recent challenges to Covid-19 vaccination (and related) requirements do not represent efforts to recover damages from the named defendants in these cases; instead, the plaintiffs seek injunctive or declaratory relief against public or private actors on the grounds that their edicts have run afoul of federal law.

One federal district court offered a more detailed analysis of this question, though it arose from a challenge to a masking requirement adopted by a school board.[136] Rather than rest on its recognition that the FDA's EUA for face masks had declined to impose any "informed consent" condition,[137] the court explained that the FDCA expressly provided that only the United States could enforce the

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vaccination); *see also id.* at *1 (misunderstanding the first full FDA approval of Pfizer's vaccine on Aug. 23, 2021, as having only granted it an EUA); Jackson v. Methodist Health Servs. Corp., No. 22-cv-1307, 2023 WL 2486599, at *5 (C.D. Ill. Feb. 10, 2023) (dismissing the claim of a health care worker discharged for her refusal to undergo weekly testing after she was granted a religious exemption from the state's vaccination mandate, adding that no private right of action existed in any event).

133. *See* Merrell Dow Pharms. Inc. v. Thompson, 478 U.S. 804, 817 (1986) ("Congress has determined that there should be no private, federal cause of action for the [FDCA] violation . . . ."); *id.* at 810 (assuming without deciding "that there is no federal cause of action for FDCA violations" for purposes of determining whether federal question jurisdiction existed); *id.* at 818, 825 n.4 (Brennan, J., dissenting) (underscoring this caveat); *see also* Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341, 348-53 (2001) (refusing to consider fraud-on-the-FDA claims in tort litigation); *id.* at 349 n.4, 352 (citing 21 U.S.C. § 337(a) as demonstrating that the federal government exercises exclusive authority to enforce the statute).

134. *See, e.g.*, Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc., 48 F.4th 1040, 1048-50 (9th Cir. 2022); Morris v. PLIVA, Inc., 713 F.3d 774, 778 (5th Cir. 2013); *see also* Deborah F. Buckman, Annotation, *Remedies Available for Violations of Federal Food, Drug, and Cosmetic Act (FDCA)*, 25 A.L.R. FED. 2d 431, § 11 (2008 & Supp. 2023).

135. *See, e.g.*, Stanton *ex rel.* Brooks v. Astra Pharm. Prods., Inc., 718 F.2d 553, 563-65, 569-71 (3d Cir. 1983); Sharp v. Artifex, Ltd., 110 F. Supp. 2d 388, 393-94 (W.D. Pa. 1999); Allen v. Delchamps, Inc., 624 So. 2d 1065, 1067-68 (Ala. 1993); *see also* Gwendolyn McKee, *Injury Without Relief: The Increasing Reluctance of Courts to Allow Negligence Per Se Claims Based on Violations of FDA Regulations*, 83 UMKC L. REV. 161, 169-72, 203-06 (2014) (explaining the error made by those courts that adopt the contrary view); Lars Noah, *The Whole "Truthiness,"* 162 U. PA. L. REV. ONLINE 261, 265 (2014) ("Although courts have declined to recognize any private right of action for violations of the FDCA, infractions may provide the basis for seeking penalties under collateral statutes or common law."). Indeed, in response to a preemption defense asserted by a regulated party, only such "parallel" claims of noncompliance would survive. *See, e.g.*, Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 487 n.4 (2013); *In re* Reglan Litig., 142 A.3d 725, 740 (N.J. 2016) ("A number of federal and state courts . . . have found that federal law does not preempt state-law claims arising from the failure of generic drug manufacturers to update labeling to conform to that of the brand name."); *see also* J. David Prince, *The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 WM. MITCHELL L. REV. 1034, 1066-81 (2013).

136. *See* Lloyd v. Sch. Bd. of Palm Beach Cnty., 570 F. Supp. 3d 1165, 1173-78 (S.D. Fla. 2021).

137. *See id.* at 1174; *see also supra* note 17 (discussing the EUA for face masks).

terms of the statute.[138] In dismissing the lawsuit, it held that the plaintiffs could not use the express right of action of 42 U.S.C. § 1983 or the Declaratory Judgment Act to give force to the Constitution's Supremacy Clause in their effort to establish that the EUA choice clause preempted a local requirement insofar as it had prevented students from declining the use of a covered countermeasure.[139] Indeed, the court found essentially no judicial support for the plaintiffs' effort.[140]

This strikes me as far too facile. Granted, the use of federal preemption as a sword rather than as a shield may differ from the norm, whether raised defensively in tort litigation or in an enforcement action brought under state statute.[141] Nonetheless, courts regularly entertain preemption arguments asserted by plaintiffs contending that a state or local law cannot stand in the face of a conflicting federal law.[142] Perhaps the FDCA's express limitation of enforcement authority deviates from the norm among other potentially preemptive federal statutes, but the offensive use of the Supremacy Clause by private parties subject to FDA regulation hardly breaks new ground.[143]

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138. *See Lloyd*, 570 F. Supp. 3d at 1175-77 (citing 21 U.S.C. § 337(a) repeatedly). Thus, if a sponsor or provider violated a condition of authorization for an EUA, then only the United States could seek to impose sanctions or secure other relief available under the FDCA, something that these plaintiffs had not sought to do.

139. *See id.* at 1175-77. Although § 1983 allows recourse for the infringement of federal statutory rights as well, the Supreme Court seemingly (and somewhat circularly) has recognized civil rights claims on that basis only when the statutory privilege itself enjoys protection through an express private right of action. *See* Gonzaga Univ. v. Doe, 536 U.S. 273, 282-86 (2002); *cf.* Health & Hosp. Corp. of Marion Cnty. v. Talevski, 599 U.S. 166, 183-86 (2023) (suggesting a more flexible test). Would it have differed if a public school or other state actor tried to sanction violators and these parties then defended against their prosecution on the same grounds?

140. *See Lloyd*, 570 F. Supp. 3d at 1176-77. It even distinguished the Supreme Court's rejection of a preemption defense to tort claims involving prescription drugs by pointing out that express preemption exists for medical devices. *See id.* at 1177. Putting aside the fact that face masks would fall outside of the scope of this provision as largely unregulated devices, this rationale seemingly allows a different analysis for non-device countermeasures such as vaccines.

141. *See, e.g.*, Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1, 9-11, 15 (Cal. 2004) (holding that FDA labeling requirements for smoking cessation products preempted effort to enforce state disclosure law); Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2158-60 (2000).

142. In no sense would the plaintiffs enjoy a damages remedy in such a case. *Cf.* Golden State Transit Corp. v. City of Los Angeles, 493 U.S. 103, 107 (1989) (agreeing that the Supremacy Clause, "of its own force, does not create rights enforceable under § 1983"); *id.* at 113 (Kennedy, J., dissenting) (concurring in the view that the district court "had jurisdiction to enjoin the city's pre-empted action under other federal statutes"). State action that conflicts with federal law does not violate the U.S. Constitution; instead, the Supremacy Clause operates as little more than a tie-breaker. *See* Armstrong v. Exceptional Child Ctr., Inc., 575 U.S. 320, 324-25 (2015) (explaining that it "instructs courts what to do when state and federal law clash"); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 260-64 (2000); Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 951-52 (1996) (explaining preemption as a "choice-of-law principle").

143. *See, e.g.*, Lars Noah, *State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Bear?*, 124 DICK. L. REV. 633, 641-45 (2020) (discussing successful preemption

Even if courts had confronted the preemption question on the merits, it hardly admits of an easy answer. An uncodified savings clause applicable to many of the older provisions governing drug approval,[144] including the IND consent requirements, would not come into play, but neither it seems would any express preemption clause, even with regard to devices subject to EUAs.[145] In connection with prescription drugs, typically only implied preemption might operate and this analysis raises a variety of complexities. In particular, serious questions exist about the continued viability of preemption based on nothing more than posing an obstacle to congressional ends.[146] Nonetheless, the Supreme Court has broadened its approach to implied preemption premised on an impossibility of dual compliance so that it comes close to the now disfavored alternative premised on the frustration of federal purposes.[147]

Here again, however, the lower courts resolving EUA choice clause objections have let us down. The one case that confronted the preemption argument most directly rejected it with little more than the statement that technically the provision did not apply to a public university that had mandated vaccination of its staff less than a month before the FDA first fully approved

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challenges asserted by one drug manufacturer to state restrictions on the use of its product). These may, of course, fail on the merits, but the courts in such cases do not dismiss the challenges as nonjusticiable. *See, e.g.*, Hillsborough Cnty. v. Automated Med. Labs., Inc., 471 U.S. 707, 710-12, 723 (1985) (local ordinances that imposed additional screening requirements for blood plasma donors); Taylor v. Polhill, 964 F.3d 975, 984-85 (11th Cir. 2020) (state hearing aid dispensing requirements); This That & The Other Gift & Tobacco, Inc. v. Cobb Cnty., 285 F.3d 1319, 1322-23 (11th Cir. 2002) (state obscenity statute that barred advertising of sexual devices); *see also* Comm. of Dental Amalgam Mfrs. & Distribs. v. Stratton, 92 F.3d 807, 813-14 (9th Cir. 1996) (reversing a declaratory judgment in favor of the industry's preemption challenge to the application of a state disclosure law); GenBioPro, Inc. v. Sorsaia, 2023 WL 5490179, at *7-10 (S.D. W. Va. Aug. 24, 2023) (dismissing claims by the generic manufacturer of the abortion drug mifepristone that FDA approval preempted state restrictions).

144. *See* Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 8-9.

145. *See* Noah, *supra* note 81, at 913 (explaining that the U.S. Supreme Court has allowed express preemption as a defense to design defect claims only for "devices that have undergone full premarket review and approval").

146. *See* Lars Noah, *Preempting Red State Restrictions on the Use of FDA-Approved Drugs in Gender-Affirming Care?*, 2024 UTAH L. REV. 833, 843 & n.42, 846 n.60. The provision authorizing EUAs would not, however, confront an ambiguous savings clause applicable to much older amendments governing new drug approval. *See id.* at 842 & n.36; *see also id.* at 841 n.32 ("[A]n announcement from the agency that it welcomed sponsors to apply for such approval could help to buttress an obstacle preemption argument").

147. *See id.* at 844-47 (explaining how the Court has recognized implied preemption of state action that visits a penalty on conduct subject to federal regulation—namely, the sale of an FDA-approved drug—even though such a prospect technically did not present an impossibility of dual compliance). Members of the Court have disparaged obstacle preemption for inviting reference to legislative history materials of questionable value or the still looser exercise of trying to infer some weighty federal purpose, but that concern would have less relevance here insofar as Congress had codified (in an affiliated provision) its goal when first enacting the EUA choice clause. *See supra* note 32 (discussing 10 U.S.C. § 1107a).

Pfizer's vaccine.[148] In short, so long as the federal provision and state action can co-exist, the Supremacy Clause has no work to do.[149] Indeed, both the district and appellate courts in this case took the point as so self-evident that neither one of them cited any of the Supreme Court's ample recent guidance about the far more complex operation of implied preemption.[150]

Still more strikingly, absolutely no one has picked up on the FDA's extended discussion of how the Supremacy Clause should impact the use of medical countermeasures subject to EUAs. The agency's guidance document explained in relevant part as follows:

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

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148. *See* Norris v. Stanley, 2022 WL 247507, at *5 (W.D. Mich. Jan. 21, 2022) (rejecting objections of employees discharged for violating public university's vaccination requirement, holding that the EUA choice clause did not preempt it), *aff'd*, 73 F.4th 431, 438 (6th Cir. 2023). Apart from a now inactive link to the defendant's policy, *see id.* at *1 n.1, the courts did not explain whether these immunizations would have happened on site. *Cf. supra* note 128 and accompanying text (explaining that some universities had done so initially and how this might impact the analysis).

149. It would not have any work to do, of course, in the case of objections to federal vaccination mandates, though similar questions would arise about the consistency of actions by the Executive branch with the constraints imposed by the legislation. *See* 5 U.S.C. § 706(2)(C) (directing a reviewing court to "hold unlawful and set aside agency action" if "short of statutory right").

150. The handful of other courts that briefly touched on the preemption question hardly did any better. *See* Legaretta v. Macias, 603 F. Supp. 3d 1050, 1058-61 (D.N.M. 2022); Dixon v. De Blasio, 566 F. Supp. 3d 171, 189-90 (E.D.N.Y. 2021), *vacated as moot and remanded*, 2022 WL 961191 (2d Cir. 2022); Johnson v. Brown, 567 F. Supp. 3d 1230, 1255-57 (D. Or. 2021), *after further proceedings*, 614 F. Supp. 3d 776, 783 (D. Or. 2022) (dismissing complaint); *see also* Reiss & DiPaolo, *supra* note 28, at 55-56 (demonstrating a similar failure to appreciate the nuances of implied federal preemption). As those commentators put it: "Finding in the act a global prohibition for universities across the nation in particular to do something they have long been allowed to do is a big step." *Id.* at 56. But, of course, universities (and all manner of other entities) have never before been allowed to require (or even permit) the use of a therapeutic product lacking FDA approval! Clinical trials of investigational products conducted at universities pursuant to INDs have always required genuine consent from enrolled subjects. *Cf.* Mink v. Univ. of Chi., 460 F. Supp. 713, 718-19 & n.6 (N.D. Ill. 1978) (allowing battery claims to proceed against a manufacturer of diethylstilbesterol for sponsoring a clinical trial at a teaching hospital that administered the drug to hundreds of its patients without their knowledge), *aff'd mem. after further proceedings*, 727 F.2d 1112 (7th Cir. 1984).

> but are not limited to, laws governing the administration of investigational medical products, such as informed consent laws . . . . In an emergency, it is critical that the conditions that are part of the EUA . . . —those that FDA has determined to be necessary or appropriate to protect the public health—be strictly followed, and that no additional conditions be imposed.[151]

Although this passage did not explicitly reference state or local immunization mandates, and the FDA cannot in any event dictate how courts assess implied preemption arguments made by private litigants,[152] it offers ammunition for any judges inclined to find fault with state action that might conflict with the purposes reflected in the EUA choice clause.

The argument rests, however, on stronger grounds than suggested by this passage from the agency's nonbinding guidance document. In 2005, Congress enacted a sweeping preemption clause related to the use of pandemic countermeasures.[153] Although part of the PREP Act's tort immunity provision,[154] this text plainly reached beyond liability claims asserted under state law. Indeed, the Office of Legal Counsel issued an opinion that recognized as much.[155] Nonetheless, when it opined less than six months later about the permissibility of mandates for vaccines that remained subject to EUAs, OLC entirely neglected to mention the possibility that express federal preemption might stand in the way of the administration's goal of encouraging their adoption.[156]

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151. FDA's 2017 EUA Guidance, *supra* note 11, at 40-41 (internal quotation marks omitted). A somewhat truncated version of this analysis had appeared a decade earlier in the agency's original guidance document. *See* FDA's 2007 EUA Guidance, *supra* note 86, at 19-20. One year earlier still, when it promulgated an interim final rule to authorize the waiver of informed consent requirements applicable to the use of investigational IVDs designed to identify CBRN agents during a declared emergency, the FDA codified an express preemption provision. *See* Medical Devices; Exception from General Requirements for Informed Consent, 71 Fed. Reg. 32,827, 32,834 (June 7, 2006) (codified as amended at 21 C.F.R. § 50.23(e)(6)); *id.* at 32,833 (discussing this aspect of the rule).

152. *See* Wyeth v. Levine, 555 U.S. 555, 575-81 (2009) (declining to defer to the FDA's similar implied preemption analysis tucked into the preamble to a final rule on the formatting of prescription drug labeling promulgated in 2006); *see also* LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 664 (5th ed. 2022) (discussing the "FDA's preamble stunt" as part of a broader strategy during the second Bush administration of having numerous federal agencies push for preemption).

153. *See* 42 U.S.C. § 247d-6d(b)(8) (extending this broad preemptive effect to any requirements made applicable to a countermeasure under the FDCA).

154. *See supra* note 24.

155. *See* OLC, PREEMPTION OF STATE AND LOCAL REQUIREMENTS UNDER A PREP ACT DECLARATION, 45 Op. O.L.C. __, slip op. at 4 (Jan. 19, 2021), https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf [perma.cc/X36M-LANP] ("We conclude that the Act expressly preempts state and local requirements to the extent that they would effectively prohibit qualifying pharmacists from ordering and administering COVID-19 tests and vaccines authorized by the Secretary's declaration.").

156. *See supra* notes 96-103 and accompanying text.

CONCLUSION

Aside from initial doubts expressed by a few commentators, it seems that nearly everyone to have considered this question, including agency officials and judges, has taken a position contrary to mine. Although each of these voices carries only limited weight, offers different rationales, and may spring from particular motivations, in the aggregate this seeming consensus poses a daunting challenge for anyone apt to disagree.[157] To my mind, the issue remains far from settled. The argument that Congress has codified a special right of refusal for medical countermeasures authorized only for emergency use strikes me as a good deal stronger than others have appreciated to date. Insofar as these cases have run their course in the judiciary without any particularly authoritative resolution, Congress or FDA should act to clarify matters before the next public health emergency strikes.[158]

157. That has not, however, deterred me before. *See, e.g.*, Lars Noah, *An Inventory of Mathematical Blunders in Applying the Loss-of-a-Chance Doctrine*, 24 REV. LITIG. 369 (2005) (cataloging the various mistakes that seemingly everyone has made when using a peculiar rule in medical malpractice litigation); *id.* at 378 ("conclud[ing] that the 'attributable risk' calculation, which is nowhere to be found in either the case law or the academic commentary, provides the most appropriate figure to select"); *id.* at 383 ("[T]he experience with loss-of-a-chance claims offers a case study in the hazards associated with judicial innumeracy."); *id.* at 404 (decrying "the frequency of errors appearing in the reported decisions and the scholarly commentary").

158. In contrast, a pair of other commentators expressed far greater confidence about cracking this particular nut, simply wanting to share their insights for future reference. *See* Reiss & DiPaolo, *supra* note 28, at 58 ("[W]e hope this Article will provide guidance not just for this pandemic, but for future pandemics, and potentially future EUA vaccines."); *id.* at 66 (same); *cf. id.* at 35 n.168 ("This Article is not written to provide medical advice, of course."). Wishful thinking does not make it so. *Cf.* Lars Noah, *Listening to Mifepristone*, 80 N.Y.U. ANN. SURV. AM. L. 33, 49 (2023) (cautioning against the close-mindedness of "results-oriented scholars"); *id.* at 37 (preferring to adopt a posture of "agnosticism about the endpoint"); *id.* at 61 (recognizing "the risk of unintentionally giving still more aid and comfort to the enemy" thereby).