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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

CALIFORNIA EDUCATORS FOR MEDICAL FREEDOM, ARTEMIO QUINTERO, MIGUEL SOTELO, JANET PHYLLIS BREGMAN, CEDRIC JOHNSON, MISANON (SONI) LLOYD, HEATHER POUNDSTONE, and THERESA D. SANFORD,

Plaintiffs,

v.

THE LOS ANGELES UNIFIED SCHOOL DISTRICT, AUSTIN BEUTNER, in his official capacity as Superintendent of the Los Angeles Unified School District, and LINDA DEL CUETO, in her official capacity as the Director of Human Resources for the Los Angeles Unified School District,

Defendants.

Case No.: 2:21-cv-02388-DSF-PVC

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Date: May 17, 2021
Time: 1:30 p.m.
Judge: Hon. Dale S. Fischer
Courtroom: 7D

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I. INTRODUCTION

This case, and the instant Motion, present a straightforward question of federal preemption: Can LAUSD, a public entity, require Plaintiffs to be vaccinated against COVID-19 (the "Mandate"), despite the fact that federal law and the rules and regulations of the Food and Drug Administration prohibit administering the available COVID Vaccines to any person without his or her consent? Given the clear meaning and purpose of 21 U.S.C. § 360bbb-3, and the terms of the FDA's Emergency Use Authorizations (the "EUAs"), the only viable answer is that LAUSD cannot mandate the administration of a vaccine that remains experimental. Plaintiffs are therefore substantially likely to prevail on the merits of their suit for declaratory relief.

Plaintiffs are also able to show a threat of irreparable harm for which they lack an adequate legal remedy. In essence, Plaintiffs are faced with having to choose between their careers and their right against the forced administration of experimental medicine. The loss of one's job, or an employment detriment such as being denied promotion or even being demoted, carries with it emotional damages and stress that cannot be remedied by the mere payment of back wages and pension contributions. The forced administration of experimental medicine is, of course, irreversible.

Granting an injunction will also clearly serve the public interest, as the failure to enjoin Defendants would usurp and frustrate the legislative purpose behind § 360bbb-3, as well as the directives of the FDA arising under that statute. Moreover, there is no evidence that LAUSD students cannot safely return to in-classroom learning without forcibly injecting Plaintiffs with a substance that is, by legal definition, experimental.

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II. STATEMENT OF FACTS

1. On January 30, 2020, the World Health Organization ("WHO") declared a "public health emergency of international concern over the global outbreak" of COVID 19.[1] Among other recommendations, the WHO called for accelerated development of "vaccines, therapeutics and diagnostics." *Id*.

2. The following day, then-U.S. Health and Human Services ("HHS") Secretary Alex Azar declared a national Public Health Emergency ("PHE"), retroactive to January 27, 2020, "to aid the nation's healthcare community in responding" to COVID-19.[2] By then, HHS was already collaborating with the pharmaceutical industry regarding the development of vaccines.

3. In May 2020, the national Administration announced Operation Warp Speed ("OWS") – a public/private partnership to develop and distribute a vaccine for COVID-19 by the end of 2020 or early 2021.[3]

4. The process for developing and obtaining approval for a new vaccine normally takes place in several phases, over a period of years.[4] The timeline set by OWS telescoped this years-long process into a matter of months.

5. Two potential vaccines emerged early on as likely candidates: one developed by Moderna (the "Moderna Vaccine"), the other by Pfizer (the "Pfizer

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[1] *See* https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)

[2] *See* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx

[3] *See* https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

[4] *See* https://www.cdc.gov/vaccines/basics/test-approve.html.

Vaccine"), with both announcing Phase III trial results in November 2020.[5]

6. In order for a new vaccine to be approved, the manufacturer must submit an application to the FDA pursuant to section 505(b) of the Food, Drug, and Cosmetics Act, encoded at 21 U.S.C. § 355(b) (the "FDCA"). None of the currently-available COVID Vaccines, including the Moderna and Pfizer Vaccines that have been acquired and are being administered to employees by LAUSD, has been approved by the FDA. Rather, after a highly compressed development and trial schedule, Pfizer and Moderna applied for Emergency Use Authorizations ("EUA"), pursuant to 21 U.S.C. § 360bbb-3, in November-December 2020.[6]

7. 21 U.S.C. § 360bbb-3 requires that:

> **individuals to whom the** product **is administered are informed—**
>
> **(I)** that the Secretary has authorized the emergency use of the product;
>
> **(II)** of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> **(III) of the option to accept or refuse administration of the** product, of the consequences, if any, of refusing administration of the product, and of the alternatives to

---

[5] *See* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against; https://abcnews.go.com/Health/moderna-announces-initial-phase-data-showing-covid-19/story?id=74227175.

[6] *See* https://www.cnbc.com/2020/11/20/covid-19-vaccine-pfizer-will-apply-for-fda-emergency-use-authorization.html; https://www.aha.org/news/headline/2020-11-30-moderna-apply-fda-emergency-use-authorization-covid-19-vaccine-candidate.

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> the product that are available and of their benefits and risks.[7]
>
> (emphasis added).

8. The federal Food and Drug Administration (the "FDA") granted an EUA for Pfizer's vaccine on December 11, 2020. A copy of the FDA's EUA Letter to Pfizer is attached as Exhibit "A". The FDA granted Moderna an EUA for its vaccine on December 18, 2020. A copy of the FDA's EUA Letter to Moderna is attached as Exhibit "B".

9. In early 2021, Johnson & Johnson subsidiary Janssen Biotech, Inc. submitted Phase III trial results for its adenovirus vector vaccine (the "Janssen Vaccine") and applied for an EUA.[8] The FDA granted an EUA to Janssen for its vaccine on February 27, 2021. A copy of the FDA's EUA Letter to Janssen is attached as Exhibit "C".

10. Collectively, the Pfizer, Moderna, and Janssen Vaccines will be referred to as the "COVID Vaccines".

11. Consistent with the requirements of 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III), each of the EUA Letters provides details regarding the reasoning for the EUAs, and dictating strict conditions for, among other things, administering the Vaccines.

12. Under "Conditions of Authorization," each of the EUA Letters directs that the manufacturers:

> and authorized distributor(s) will ensure that the authorized [] COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the

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[7] 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III).

[8] *See* https://www.jnj.com/johnson-johnson-announces-submission-of-application-to-the-u-s-fda-for-emergency-use-authorization-of-its-investigational-single-shot-janssen-covid-19-vaccine-candidate. Note that Janssen refers to its vaccine as "investigational" in the Johnson & Johnson press release. This is a critical point that applies to all of the COVID Vaccines.

> authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers *consistent with the terms of this letter*.

See, e.g., Ex. "C" at 5, ¶A (emphasis added).

13. Each EUA Letter is accompanied by a Fact Sheet for Health Care Providers and a Fact Sheet for Patients and Caregivers. The Fact Sheets to Providers mandate, among other things, that a provider must communicate, to the recipient or the caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to administering the vaccine, including information that "***the recipient or their caregiver has the option to accept or refuse***" the vaccine. *See* Pfizer Fact Sheet for Health Care Providers, attached as Exhibit "D" (emphasis added).

14. The Fact Sheets for Recipients and Caregivers likewise contain the following advice:

> **WHAT IF I DECIDE NOT TO GET THE [] COVID-19 VACCINE?**
>
> ***It is your choice to receive or not receive the [] COVID-19 Vaccine***. Should you decide not to receive it, it will not change your standard medical care.

See Moderna Fact Sheet for Recipients and Caregivers, attached as Exhibit "E" (emphasis added).

15. The FDA continues to refer to the Vaccines as "unapproved" or "investigational" products. *See, e.g.*, Ex. "D" at 8 (referring to Pfizer Vaccine as an "*unapproved* product") (emphasis added); Ex. "B" at 1 (noting that the Moderna Vaccine "is an *investigational* vaccine *not licensed* for any indication") (emphasis added).

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THE MANDATE

16. On or about March 16, 2020, LAUSD closed all of its schools to in-person instruction.[9] Since that time, LAUSD has struggled to come up with a plan for reopening in-classroom instruction; this, despite growing evidence that public schools in other large school districts have reopened to in-classroom instruction while maintaining infection rates that are far below those of their surrounding communities.[10]

17. LAUSD's internal policies, and particular statements made by Defendants, demonstrate that LAUSD's *de facto* policy is or will soon be to require that all employees be vaccinated against COVID-19.

18. For example, on January 20, 2021, Plaintiff Artemio Quintero received an email that had been sent to employees of the Operations Department by a representative of Teamsters Local 572, which provided an update on the status of reopening. *See* Decl. of Artemio Quintero, attached hereto as Exhibit "F". Among the points in that email was the following:

> • COVID Vaccinations: Superintendent Beutner has informed the Unions that a mandatory COVID vaccination program will be instituted by the District within the next month. **To be clear, the District is making vaccinations mandatory for all employees**. There are some legal exceptions to this requirement, but they are very limited, and they may have a significant impact on your ability to

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9 *See* https://losangeles.cbslocal.com/2020/03/24/list-socal-schools-cancel-in-person-instruction-due-to-coronavirus/.

10 *See* https://edition.cnn.com/2021/01/11/us/miami-dade-schools-open-coronavirus-wellness/index.html.

> work and earn a living. We will "meet and confer" with the District on their vaccination program. We have heard from some of you who have concerns about getting vaccinated; rest assured that we will address all your concerns when we meet with the District. Stay tuned for additional information on this important issue.

Ex. "F" at ¶4 and Exhibit "1" thereto (emphasis added).

19. On or about February 11, 2021, Mr. Quintero received a follow-up email regarding the results of the "Meet and Confer" between Teamsters Local 572 and the District regarding the District's vaccination program. Ex. "F" at ¶5 and Exhibit "2" thereto. That email informed employees of Operations Department that, in response to a question as to whether vaccinations will be mandatory, LAUSD representatives answered: "***All District employees will be required to be vaccinated. No exceptions have been made. . . .***" *Id*. (emphasis in original).

20. On February 23, 2021, Mr. Quintero attended a meeting between executives of LAUSD and persons from the negotiating team representing the skilled trades under the District's Unit E contract. Ex. "F" at ¶7. Among the LAUSD executives present at that meeting was Defendant Linda Del Cueto, the Director of Human Resources for LAUSD. *Id*.

21. At that February 23 meeting, Ms. Del Cueto stated that LAUSD was about to make vaccination mandatory. She stated that the policy was still being written, but that once it was written, vaccination would be mandatory for all employees. *Id*. at ¶8.

22. When asked how she could justify making the vaccines mandatory when they were still experimental, Ms. Del Cueto stated that the unvaccinated were much more of a threat than the vaccines, themselves, and that her department relied on guidance from the federal EEOC. *Id*. at ¶9.

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23. When asked whether it would be possible to put unvaccinated personnel on alternate shifts, Ms. Del Cueto said that one could only remain unvaccinated if one either obtained a medical exemption or worked remotely. *Id*. at ¶10. She stated that otherwise any failure to get vaccinated would trigger a disciplinary act, and that the goal was to have all employees vaccinated by April 2021. *Id*.

24. Subsequent to that meeting, LAUSD began a campaign of harassing employees with emails instructing them to schedule an appointment to be vaccinated. *Id*. at ¶13. When they ignored the initial emails, they received follow up emails noting that they had failed to schedule a vaccination appointment and instructing them again to click on a link to schedule one. *Id*. at 13-15 and Exhibit "3" thereto.

25. These coercive emails are consistent with a March 4, 2021 interoffice memorandum from Ms. Del Cueto to the Local District Superintendents, Executive Cabinet and Administrators of Operations bearing the subject line: "HUMAN RESOURCES COVID-19 EMPLOYEE VACCINATION INFORMATION AND RESOURCES" (the "Cueto Memorandum"). *See* Exhibit "G", attached hereto.

26. Nowhere in the Cueto Memorandum is there any indication that vaccination is optional. Rather, the Cueto Memorandum states that "District employees may *either* participate in the District's COVID-19 vaccination program *or* provide vaccination documentation in the form of an official Vaccination Record certified by a medical professional." *Id*. at 1 (emphasis added).

27. Attached to the Cueto Memorandum was a document entitled "VACCINATION GUIDANCE FOR EMPLOYEES." *Id*. at 3. This GUIDANCE contained a series of commands, including:

- You *will schedule* your appointment at https://covidvaccine.lausd.net and *will receive* a confirmation email with a QR code which *you must show* at the time of check-in.

- You *must bring* official identification or school ID to your appointment.
- You *will be allowed* a three-hour window for your vaccination. . . .
- *Notify* your supervisor at least one day ahead of your vaccination appointment.
- You *will provide proof of vaccination* via the DailyPass for time reporting purposes.

Id. (emphasis added).

28. In a blatantly cynical attempt to forestall a justiciable issue in this case, on March 18, 2021 – *the day after Plaintiffs filed the instant lawsuit* – Ms. Del Cueto issued an "UPDATED" version of her Memorandum (the "UPDATED Memorandum"). *See* Exhibit "H", attached hereto. Among the minor changes to the UPDATED Memorandum is the introduction of the phrase, "While vaccinations are not mandatory *at this time*. . . ." Ex. "H" at 1. In addition, the UPDATED Memorandum has been revised to give employees the option of getting vaccinated or tested. *Id*. at Attachment 1 – Return to In Person Instruction Vaccination and Testing Guidance for Employees. As will be explained below, this UPDATED Memorandum changes nothing.

III. PROCEDURAL HISTORY

Plaintiffs filed this lawsuit on March 17, 2021, seeking declaratory and injunctive relief based on (I) federal preemption under 21 U.S.C. § 360bbb-3 and the FDA's guidance thereunder; (II) Plaintiffs' substantive due process right to be free from medical experimentation; and (III) violation of California's Protection of Human Subjects in Medical Experimentation Act. Defendant LAUSD has acknowledged service of the Complaint.

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IV. ARGUMENT AND CITATIONS OF AUTHORITY

A plaintiff seeking a preliminary injunction "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Am. Trucking Associations, Inc. v. City of Los Angeles*, 559 F.3d 1046, 1052 (9th Cir. 2009) (quoting *Winter v. Nat. Resources Defense Council*, 555 U.S. 7, 20 (2008)). The Ninth Circuit reviews a grant or denial of a preliminary injunction for an abuse of discretion. *Id*. (citing *Lands Council v. Martin*, 479 F.3d 636, 639 (9th Cir. 2007)). However, it reviews a "district court's decision regarding preemption and its interpretation and construction of a federal statute de novo." *Id*. (citation omitted).

Plaintiffs are likely to prevail on the merits of their lawsuit. First, the Mandate is patently contrary to federal law as well as the guidance and dictates of the FDA regarding the EUAs. At best for Defendants, the Mandate frustrates the obvious intent of Congress to make experimental medical products available to the public during an emergency while preserving the right of a patient to decline administration of the product. To hold otherwise would be to say that Congress intended to shortcut the process for approving new drugs.

More broadly, Plaintiffs have a substantive due process right to be free from compulsory medical experimentation. As a legal matter, the COVID Vaccines remain experimental, as they have not been approved and are still regarded as "investigational" products.

As well, Plaintiffs are likely to suffer irreparable harm in the absence of an injunction, the balance of equities tip in their favor, and an injunction will serve the public interest. Accordingly, Plaintiffs' motion should be granted.

A. Plaintiffs' Complaint Presents a Justiciable Controversy.

The Court will no doubt want to first address the impact of LAUSD's UPDATED

Memorandum, Ex. "H", on whether Plaintiffs' allegations are ripe for adjudication. On its face, the UPDATED Memorandum reflects a tacit admission by Defendants that the Mandate is legally unsupportable, which is why it was purportedly issued the day after Plaintiffs filed their Complaint.[11] It is patently contrary to the original Cueto Memorandum, Ex. "G", in that it adds the option of regular testing. It is also patently contrary to remarks made by Ms. Cueto, herself, in the presence of Plaintiff Quintero and many others, in that it refers to vaccination as not being mandatory "at this time." SOF ¶¶20-23, 28.

But this U-turn by Defendants is not enough to moot the controversy. "It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) (citing *City of Mesquite v. Aladdin's Castle*, 455 U.S. 283, 289 (1982)) (internal quotation marks omitted). "If it did, the courts would be compelled to leave the defendant free to return to his old ways." *Id*. (citation and internal punctuation omitted). "The heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to start up again lies with the party asserting mootness." *Id*. (citation and internal punctuation omitted). This "test for mootness in cases like this is a stringent one." *United States v. Concentrated Phosphate Export Ass'n*, 393 U.S. 199, 203 (1968).

Defendants cannot possibly meet this high burden. The UPDATED Memorandum says that "vaccinations are not mandatory *at this time*. . . ." SOF ¶28 & Ex. "H" (emphasis added). The UPDATED Memorandum also does not say when or under what conditions the vaccination requirement will be reinstituted, but it plainly indicates that such a reinstitution is imminent.

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[11] For the sake of discussion, Plaintiffs accept that the UPDATED Memorandum was distributed on March 18, 2021, but do not know whether it was in fact distributed on that date.

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Thus, the UPDATED Memorandum cannot moot Plaintiffs' claims. On the contrary, it plainly highlights the very reason for the voluntary cessation doctrine – that Defendants should not be let off the hook, "free to return to [their] old ways." *City of Mesquite*, 455 U.S. at 289, n. 10 (citation omitted).

B. Plaintiffs Are Likely to Succeed on The Merits.

1. The Mandate is preempted by federal law.

> The Supremacy Clause provides that the laws and treaties of the United States "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Accordingly, it has long been settled that State laws that conflict with federal law are "without effect."

Mutual Pharm. Co., Inc. v. Bartlett, 570 U.S. 472, 479-80 (2013) (citations omitted).

"[T]he purpose of Congress is the ultimate touchstone in every preemption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted). Relevant to the analysis is "the structure and purpose of the statute as a whole, as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and is surrounding regulatory scheme to affect business, consumers, and the law." *Id*. at 486 (internal citations and quotation marks omitted).

Here, § 505 of the federal Food, Drug & Cosmetic Act (the "FDCA") clearly provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug." 21 U.S.C. § 355(a). None of the currently-available COVID Vaccines has been approved pursuant to this section of the FDCA.

Rather, each of the currently-available COVID Vaccines has been authorized for

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emergency use pursuant to 21 U.S.C. § 360bbb-3.[12] SOF ¶¶6-15. Section 360bbb-3 vests the Secretary of Health and Human Services with the ability to "authorize the introduction into interstate commerce, during the effective period of a declaration [of emergency], of a drug, device, or biological product intended for use in an actual or potential emergency. . . ." 21 U.S.C. § 360bbb-3(a)(1). The statute provides for the authorization of both unapproved products and unapproved uses of an approved product. *See* 21 U.S.C. § 360bbb-3(a)(2). Because they have not been previous approved for any use, the COVID Vaccines fall under the former category.

Section 360bbb-3 mandates the following conditions for authorization of an unapproved product:

> . . . [T]he Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), ***shall***, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> **. . . (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***. . . .

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

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[12] The current iteration of Section 360bbb-3 was initially passed as part of the Project Bioshield Act of 2004, 108 P.L. 276,118 Stat. 835, when concerns about countermeasures to bioweapons and other weapons of mass destruction was at a high.

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The FDA continues to refer to the Vaccines as "unapproved" or "investigational" products. SOF ¶15. In other words, as a legal matter and as a matter of FDA policy and guidance, the Vaccines remain experimental. Also, consistent with its mandate under section 360bbb-3, the FDA's EUA Letters and its Fact Sheets for Health Care Providers, Caregivers and Recipients all note that the Recipient or his Caregiver must be notified of the Recipient's right to refuse administration of the vaccine. SOF ¶¶12-14.

Because it would require Plaintiffs to be vaccinated with an unapproved product against their will, the Mandate is patently contrary to both the statute's requirements and to the FDA's guidance. It is therefore plainly contrary to the "structure and purpose" of the statute. *Lohr*, 518 U.S. at 486.

Defendants might argue that the FDCA does not expressly, completely preempt the field of regulation of medical products. *See, e.g., Wyeth v. Levine*, 555 U.S. 555 (2009). But that would be beside the point, as cases such as *Wyeth* concern the question of whether preemption under the FDCA may be raised as a defense to a claim arising under state tort law. *See, generally, Wyeth, supra*; *Elliott v. Smith & Nephew*, Case No. 12-CV-0070, 2013 U.S. Dist. LEXIS 59072 (D. Idaho April 15, 2013) (discussing precedents). In those cases, courts look to whether it would be "impossible for a private party to comply with both federal and state requirements," *Mut. Pharm. Co.*, 570 U.S. at 480, or whether, "under the circumstances of a particular case, state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth*, 555 U.S. at 589 (Thomas, J., concurring) (citation and internal brackets omitted). *See also Arizona v. United States*, 567 U.S. 387, 399 (2012) (citations omitted); *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000); *Geier v. American Honda Motor Company, Inc.*, 529 U.S. 861, 873 (2000); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Here, the Mandate is clearly "an obstacle to the accomplishment and execution

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of the full purposes and objectives of" both sections 355 and 360bbb-3 of Title 21. Plainly read, the statutory scheme created by Congress was intended to allow *voluntary* access to experimental medical products in a public health emergency, while also reserving the right of the individual to refuse administration of the experimental product.

The FDA expressly supports this conclusion in its Guidance for Industry and Other Stakeholders regarding Emergency Use Authorizations:

> FDA believes that the terms and conditions of an EUA issued under section 564 [21 U.S.C. § 360bbb-3] preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564. . . .
>
> To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular medical product within the scope of the declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, and conflicts with the exercise of Federal authority under [§ 564].

See FDA, Emergency Use Authorization of Medical Products and Other Authorities: Guidance for Industry and Other Stake Holders (January 2017) at p. 40, available online at <https://www.fda.gov/media/97321/download> (legal citations and internal quotation marks omitted).

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While not all pronouncements of the FDA are necessarily entitled to *Chevron* deference, *Wyeth*, 555 U.S. at 575-77, agencies such as the FDA "do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* at 576-77. Here, the FDA's interpretation is entitled to at least some deference. As discussed above, the intent behind § 360bbb-3 is clear on its face, and that FDA's interpretation of its scope and intent, *vis a vis* federal-state preemption, is consistent with the statute's plain meaning. Allowing state actors to mandate administration of an investigative medical product that has been made available pursuant to an EUA would impose "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. at 399.

The decision of the D.C. District in *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) is particularly instructive. In that case, members of the U.S. military brought an action seeking injunctive relief against being forcibly inoculated against inhaled anthrax. *Id*. at 122. The plaintiffs contended that Anthrax Vaccine Adsorbed ("AVA") was "an experimental drug unlicensed for its present use" and that the military Anthrax Vaccine Immunization Program was therefore contrary to law. *Id*. at 123. The court found that, because the FDA had never approved the vaccine, it was an investigational drug and the court thus enjoined its administration to military servicemembers without their informed consent. *Id*. at 131-36.

The FDA subsequently issued an EUA pursuant to Section 360bbb-3, and the court amended the injunction to allow administration of the vaccine, but only "on a voluntary basis," pursuant to the EUA. *Doe v. Rumsfeld*, Civil Action No. 03-707, 2005 U.S. Dist. LEXIS 5573 (D.D.C. April 6, 2005) (emphasis in the order). Although *Doe* was based on a statutory prohibition on administering investigational drugs to U.S. servicemembers without their informed consent, 297 F. Supp. 2d at 125 (referencing 10

U.S.C. § 1107), the outcome here must be no different. Defendants' Mandate is plainly contrary to federal laws and regulations governing the authorization and administration of experimental drugs. Plaintiffs' request for a preliminary injunction must be granted.

2. Plaintiffs have a substantive due process right to be free from nonconsensual medical experimentation.

Among the substantive rights recognized as being protected by the Due Process Clause is the right to bodily integrity. *See Albright v. Oliver*, 510 U.S. 266, 272 (1994). This extends to a substantive due process right to deny medical treatment. *See Cruzan v. Dir., Mo. Dept. of Health*, 497 U.S. 261 (1990); *Washington v. Harper*, 494 U.S. 210, 221-22 (1990). In *Harper*, the Court recognized that "[t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." 494 U.S. at 229. *See also Riggins v. Nevada*, 504 U.S. 127, 135 (1992) (holding that the forced administration of antipsychotic medication to a criminal defendant during trial violated his 14th Amendment due process rights where the state had failed to demonstrate an overriding justification and a determination of medical appropriateness).

Section 360bbb-3, and the FDA rules and guidelines implementing the EUAs, recognize an even more fundamental due process right – that of a prohibition against forced medical experimentation. This right has its foundations in both domestic law and regulations, as well as in customary international law. *See Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009). As held by the court in *Abdullahi*, the internationally-recognized prohibition on nonconsensual human experimentation has its roots in the Nuremberg Code, and is so universally accepted as to constitute a *jus cogens* norm under international law. *See id*. at 177-79. A *jus cogens* norm is one "from which no derogation is permitted, irrespective of the consent or practice of a given State." *Id*. at

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179 (citing *Siderman de Blake v. Republic of Arg.*, 965 F.2d 699, 715 (9th Cir. 1992)).[13]

As noted by the *Abdullahi* court, this universal prohibition has been repeatedly ratified and recognized by numerous international conventions and declarations, as well as regulations of the FDA governing medical research. *See Abdullahi*, 562 F.3d at 180-83. In particular, "the fact that the prohibition on medical experimentation on humans without consent has been consciously embedded by Congress in our law and reaffirmed on numerous occasions by the FDA demonstrates that the United States government views the norm as the source of a binding legal obligation. . . ." *Id*. at 180-81.

In 1979, the Department of Health, Education and Welfare issued the Belmont Report, which addressed the issue of informed consent in the human experimentation setting.[14] The Report identified respect for self-determination by "autonomous persons" as the first of three "basic ethical principles" which "demands that subjects enter into the research voluntarily and with adequate information." *Id*. Ultimately, the principles of the Belmont Report, which itself was guided by the Nuremberg Code and the Declaration of Helsinki,[15] were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research. *See* 21 C.F.R. § 50.20. The Department of Health and Human Services has similarly adopted this standard in its

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[13] As recently as this past December, the High Court of Justice, Queen's Bench Division, Administrative Court in the United Kingdom concluded that minors lack the ability to give informed consent to the administration of puberty blockers to treat gender dysphoria because the procedure remains experimental. *See Bell v. The Tavistock and Portman NHS Foundation Trust*, Case No. CO/60/2020, [2020] EWHC 3274 (Admin) (Engl. & Wales) https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf.

[14] *See* https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html.

[15] *See* https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

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regulations governing grants for medical research. *See* 45 C.F.R. § 46.116.

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

Because the COVID Vaccines are experimental, there is no doubt that Plaintiffs are likely to prevail on the merits of their claims against Defendants. An injunction should therefore be granted.

C. Plaintiffs Will Suffer Irreparable Harm Unless an Injunction is Granted.

It is beyond dispute that the loss of one's livelihood may constitute irreparable harm. *See Nelson v. Nat'l Aeronautics and Space Admin.*, 530 F.3d 865, 882 (9th Cir. 2008), *petition for reh'g en banc denied*, 568 F.3d 1028 (9th Cir. 2009), *rev'd on other grounds*, 562 U.S. 314 (2011). Here, Plaintiffs have been threatened with disciplinary action if they refuse to be vaccinated against COVID-19. SOF ¶26. It therefore suffices to say that they have been threatened with irreparable harm, and a preliminary injunction should be granted.

D. The Balance of Equities Favors Plaintiffs.

As noted above, Plaintiffs have been threatened with disciplinary action, which could include the loss of their careers and pensions, unless they submit themselves to

medical experimentation. On the other hand, by issuing the UPDATED Memorandum, Defendants have tacitly conceded that their actions have been contrary to law, and there is no indication that LAUSD schools will be unable to reopen absent enforcement of the Mandate.

E. An Injunction Will Serve the Public Interest.

Consistent with the above discussion, the relief sought by Plaintiffs would vindicate the statutory framework of the FDCA as well as regulations and guidance from the FDA governing the approval and emergency authorization of medical products such as vaccines. By requiring Defendants to comply with this legal framework, an injunction will clearly serve the public interest.

V. CONCLUSION

Based on the foregoing points and authorities, Plaintiffs respectfully request that the Court grant their Motion and enjoin Defendants from requiring them to be vaccinated against COVID-19 so long as the available COVID Vaccines remain experimental.

Dated: April 15, 2021

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