IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

JEANNA NORRIS, KRAIG EHM, and D'ANN ROHRER, *Plaintiffs*,	)	
v.	)	
SAMUEL L. STANLEY, JR., in his official capacity as President of Michigan State University; DIANNE BYRUM, in her official capacity as Chair of the Board of Trustees, DAN KELLY, in his official capacity as Vice Chair of the Board of Trustees; and RENEE JEFFERSON, PAT O'KEEFE, BRIANNA T. SCOTT, KELLY TEBAY, and REMA VASSAR, in their official capacities as Members of the Board of Trustees of Michigan State University, and JOHN and JANE DOES 1-10,	)	**CLASS ACTION COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** JURY TRIAL DEMANDED
Defendants.	)	

Plaintiffs and those similarly situated, by and through their attorneys at the New Civil Liberties Alliance ("NCLA"), hereby complain and allege the following:

INTRODUCTORY STATEMENT

a. By the spring of 2020, the novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, had spread across the globe. Since then, and because of the federal government's "Operation Warp Speed," three separate coronavirus vaccines have been developed and approved more swiftly than any other vaccines in our nation's history. The Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for the Pfizer-

BioNTech COVID-19 Vaccine ("BioNTech Vaccine") on December 11, 2020.[1] Just one week later, FDA issued a second EUA for the Moderna COVID-19 Vaccine ("Moderna Vaccine").[2] FDA issued its most recent EUA for the Johnson & Johnson COVID-19 Vaccine ("Janssen Vaccine") on February 27, 2021 (the only EUA for a single-shot vaccine).[3]

b. FDA fully approved the Pfizer Comirnaty Vaccine ("Comirnaty Vaccine") on August 23, 2021. Though both are affiliated with Pfizer, the BioNTech Vaccine and the Comirnaty Vaccines are legally distinguishable. Upon information and belief, they are also factually distinguishable.

c. The EUA statute, 21 U.S.C. § 360bbb-3, explicitly states that anyone to whom an EUA product is administered must be informed of the option to accept or to refuse it, as well as alternatives to receiving the product and the risks and benefits of receiving it.

d. Michigan State University ("MSU") announced "COVID directives" for the Fall 2021 semester by email and on its website on July 30, and then provided an expanded version via its website on August 5, 2021. The directives include a "Mandatory COVID-19 Vaccine" ("the Directive").

e. According to the Directive, all faculty, staff, and students must either be fully vaccinated or have received one of a two-dose series by August 31, 2021, unless they obtain a religious or medical exemption, both of which are limited in nature and application. The Directive specifically excludes natural immunity as a basis for a medical exemption. Even employees who work remotely are subject to the Directive.

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[1] *Pfizer-BioNTech Vaccine FAQ*, FDA, bit.ly/3i4Yb4e (last visited August 26, 2021).

[2] *Moderna, About Our Vaccine*, bit.ly/2Vl4lUF (last visited August 26, 2021).

[3] *EUA for Third COVID-19 Vaccine*, FDA, bit.ly/3xc4ebk (last visited August 26, 2021).

f. MSU's Directive recognizes all vaccines currently approved by the World Health Organization ("WHO"), including the Janssen Vaccine and others which the FDA has not approved, such as the Sinovac and Sinopharm Vaccines.

g. Those who do not comply with the Directive face potential disciplinary action, including termination of employment, as demonstrated by Plaintiff Ehm's recent termination.

h. Plaintiffs have already contracted and fully recovered from COVID-19. As a result, they have naturally acquired immunity, confirmed unequivocally by recent SARS-CoV-2 antibody tests. Immunologist Dr. Hooman Noorchashm has advised them that it is *medically unnecessary* to undergo a vaccination procedure at this point (which fact also renders the procedure and any attendant risks medically unethical).

i. Yet, if Plaintiffs follow Dr. Noorchashm's advice and elect not to take the vaccine, they face adverse disciplinary consequences. Indeed, Plaintiffs Ehm and Rohrer are undergoing disciplinary proceedings due to remaining unvaccinated, culminating in Ehm's termination just yesterday. In short, the Directive is unmistakably coercive and cannot reasonably be considered anything other than an unlawful mandate. Furthermore, it represents an unconstitutional condition being applied to Plaintiffs' constitutional and statutory rights to bodily integrity and informed consent, respectively.

j. Plaintiffs bring this action on behalf of a class of similarly situated individuals – employees of MSU who have naturally acquired immunity to COVID-19 and for whom the Directive represents a violation of their constitutional rights to bodily autonomy and to decline medical treatment.

k. Given their naturally acquired immunity, MSU cannot establish a compelling governmental interest in overriding the personal autonomy and constitutional rights of Plaintiffs

and those who are similarly situated by forcing them either to be vaccinated or to suffer adverse professional consequences.

l. Naturally acquired immunity is at least as robust and durable as that attained through the most effective vaccines, and it is significantly more protective than some of the inferior vaccines that MSU accepts. Studies further indicate that naturally acquired immunity is significantly longer lasting than that acquired through the best vaccines. As a result, MSU's Directive is designed to nullify informed consent and infringes upon Plaintiffs' rights, and the rights of those who are similarly situated, under the Ninth and Fourteenth Amendments to the United States Constitution.

m. For similar reasons, the Directive constitutes an unconstitutional condition, because it is poorly calibrated to protect the public health, yet it imposes disproportionate risks on some of its targets. That renders the Directive an unlawful condition insufficiently germane to its purported purpose. Furthermore, the disciplinary action that MSU is using to leverage ostensibly voluntary compliance with its Directive is not proportional to MSU's purported public health aims.

n. Even beyond its constitutional defects, MSU's unlawful Directive is irreconcilable with and frustrates the objectives of the statute governing administration of medical products authorized for emergency use only. Pursuant to the Supremacy Clause of the United States Constitution, federal law overrides conflicting state law and action by agents of the State of Michigan. Accordingly, the Directive is preempted by the EUA statute and must be enjoined.

o. In a highly publicized opinion recently made public, the U.S. Department of Justice's Office of Legal Counsel ("OLC") argues that public and private entities can lawfully

mandate that their employees receive one of the EUA vaccines.[4] The opinion is silent on preemption, however, and thus cannot be read to prevent the EUA statute from having its ordinary preemptive effect. This is especially true in light of the fact that Congress never assigned any role to OLC to administer the EUA statute. The OLC Opinion, as explained in detail in Count III below, is also deeply flawed on multiple additional legal grounds.

p. Regardless of whether Pfizer recently received full FDA approval for the Comirnaty Vaccine, the remaining vaccines "approved" for use by MSU have not. As Pfizer itself acknowledges, the Comirnaty Vaccine is not widely available in the United States. And despite its attempts to create equivalence between its BioNTech and Comirnaty Vaccines, the two are legally distinguishable (and, on information and belief, are factually distinguishable as well). And, as the federal government has acknowledged, many individuals cannot be guaranteed access to a specific COVID-19 vaccine. Thus, even after the Comirnaty Vaccine's approval, the Directive still essentially forces individuals, including Plaintiffs and those who are similarly situated, to take an EUA vaccine.

q. In sum, the Directive violates *both* the constitutional *and* federal statutory rights of Plaintiffs and those who are similarly situated because it undermines their bodily integrity and autonomy and conditions their employment on their willingness to take a medically unnecessary vaccine. Forcing Plaintiffs and others to take this vaccine will provide no discernible, let alone compelling, benefit either to Plaintiffs or to the MSU community. Although obtaining the vaccine could elevate Plaintiffs' antibody levels, their levels are already high enough to be equivalent to most vaccinated people, so any augmented benefit is negligible and does not translate into a clinical

[4] Evan Perez & Tierney Sneed, *Federal Law Doesn't Prohibit COVID-19 Vaccine Requirements, Justice Department Says*, CNN (July 26, 2021), *available at* https://cnn.it/3iWxH42, last visited (August 26, 2021).

benefit. The unconstitutional conditions doctrine exists precisely to prevent government actors from clothing unconstitutional objectives and policies in the garb of supposed voluntarism when those actors fully intend and expect that the pressure they are exerting will lead to the targets of such disguised regulation succumbing to the government's will. Plaintiffs invoke this Court's Article III and inherent powers to insulate them from this pressure and to vindicate their constitutional and statutory rights.

PARTIES

1. Plaintiff Jeanna Norris (37 years old) is a supervisory Administrative Associate and Fiscal Officer at MSU. She resides in Portland, Michigan, which is located in the Western District of Michigan, Southern Division.

2. Plaintiff Kraig Ehm (57 years old) is a video producer for MSU and resides in Laingsburg, Michigan, which is located in the Eastern District of Michigan.

3. Plaintiff D'Ann Rohrer (51 years old) is an Extension Educator at MSU and resides in Ludington, Michigan, which is located in the Western District of Michigan.

4. Defendant Samuel L. Stanley is President of MSU, a public research institution located in East Lansing, Michigan. He is sued in his official capacity.

5. Defendant Dianne Byrum is Chair of the Board of Trustees at MSU.[5] She is sued in her official capacity.

6. Defendant Dan Kelly is Vice Chair of the Board of Trustees. He is sued in his official capacity.

[5] The Board of Trustees "have general supervision over the university and its funds." "Board of Trustees," *Michigan State University*, *available at* https://trustees.msu.edu (last visited Aug. 27, 2021).

7. Defendants Renee Jefferson, Pat O'Keefe, Brianna T. Scott, Kelly Tebay and Rema Vassar are Members of the Board of Trustees. They are sued in their official capacities.

8. John and Jane Does 1-10 are as-yet-unidentified MSU officials involved in setting the policy embodied in the Directive.

9. MSU, for whom the Defendants are agents, is principally located in the Western District of Michigan.

STATUTORY AND NONSTATUTORY JURISDICTION AND VENUE

10. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3)-(4) (equitable relief), and 42 U.S.C. §§ 1983 and 1988, as well as under nonstatutory equitable jurisdiction. That is because the claims here arise under the Constitution and statutes of the United States and because Plaintiffs seek prospective redress against state actors in their official capacity to end the deprivation, under state law, of their rights, privileges, and immunities secured by federal law.

11. Venue for this action properly lies in this District pursuant to 28 U.S.C. § 1391. Plaintiff Norris resides in this judicial district, a substantial part of the events, actions, or omissions giving rise to the claim occurred in this judicial district, and MSU is located in this judicial district.

12. The Western District of Michigan is comprised of both a Southern and a Northern Division. MSU is located in the Southern Division. *See* Civ. L. R. 3.2.

13. This Court's equitable powers permit it to issue nonstatutory injunctions to protect Plaintiff against wayward state actors engaged in unlawful conduct. *See Trump v. Vance*, 140 S. Ct. 2412, 2428-29 (2020) ("*Ex parte Young*, 209 U.S. 123, 155–156 (1908) (holding that federal

courts may enjoin state officials to conform their conduct to federal law).").[6] The only limitation is that a defendant subject to such an injunction must possess a connection to the establishment and enforcement of MSU's vaccine mandate. Defendants in this action have the requisite connection. *See, e.g., Russell v. Lundergan-Grimes*, 784 F.3d 1037 (6th Cir. 2015) (finding that, in action brought by business owners alleging that electioneering statute violated their First Amendment rights, Attorney General could be sued under *Ex parte Young*, since he fielded and investigated complaints of impermissible electioneering and threatened criminal sanctions). *See generally Free Enter. Fund v. PCAOB*, 561 U.S. 477, 491 n.2 (2010) (collecting cases in the vein of *Bell v. Hood*, 327 U.S. 678, 684 (1946) ("[I]t is established practice for this Court to sustain the *jurisdiction* of federal courts to issue injunctions to protect rights safeguarded by the Constitution") (emphasis added)); *Schuette v. Coalition to Defend Affirmative Action, Integration, and Immigrant Rights*, 572 U.S. 291 (2014) (Board of Trustees was initially named defendant in Equal Protection claim against Michigan State University).

14. In addition, this Court may issue declaratory relief pursuant to 28 U.S.C. § 2201. "Further necessary or proper relief based on a declaratory judgment may [also] be granted …," including via injunction. *See Powell v. McCormack*, 395 U.S. 486, 499 (1969) ("A declaratory judgment can then be used as a predicate to further relief, including an injunction. 28 U.S.C. § 2202 ….").

[6] *See* Erwin Chemerinsky, FEDERAL JURISDICTION, 8th ed. (2021) (*Ex parte Young* "has been heralded as 'one of the three most important decisions the Supreme Court of the United States has ever handed down.'"), *quoting Allied Artists Pictures Corp. v. Rhodes*, 473 F. Supp. 560, 564 (E.D. Ohio 1979) (citations omitted).

STATEMENT OF FACTS

I. BACKGROUND PERTAINING TO THE CORONAVIRUS PANDEMIC AND COVID-19 VACCINES

15. The novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, is a contagious virus spread mainly from person-to-person, including through the air.

16. It is well settled that the coronavirus presents a significant risk primarily to individuals aged 70 or older and those with comorbidities such as obesity and diabetes. Bhattacharya and Kulldorff Joint Decl. ¶¶ 10-14 ("Joint Decl.") (Attachment A). *See* Smiriti Mallapaty, *The Coronavirus Is Most Deadly If You Are Older and Male*, NATURE (Aug. 28, 2020) (individuals under 50 face a negligible threat of a severe medical outcome from a coronavirus infection, akin to the types of risk that most people take in everyday life, such as driving a car).

17. In fact, a meta-analysis published by the WHO concluded that the survival rate for COVID-19 patients under 70 years of age was 99.95%. Joint Decl. ¶ 12.

18. CDC estimates that the survival rate for young adults between 20 and 49 is 99.95%, and for people ages 50-64 is 99.4%. Joint Decl. ¶ 12.

19. A seroprevalence study of COVID-19 in Geneva, Switzerland, reached a similar conclusion, estimating a survival rate of approximately 99.4% for patients between 50 and 64 years old, and 99.95% for patients between 20 and 49. Joint Decl. ¶ 13.

20. This past winter, FDA approved three vaccines pursuant to the federal EUA statute, 21 U.S.C. § 360bbb-3.

a. FDA issued an EUA for the BioNTech Vaccine on December 11, 2020.

b. Just one week later, FDA issued an EUA for the Moderna Vaccine.

c. FDA issued its most recent EUA, for the Janssen Vaccine, on February 27, 2021.

d. The Comirnaty Vaccine received full FDA approval on August 23, 2021.

21. In a letter to Pfizer, FDA states that "the Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) have the same formulation. The products are legally distinct with certain differences that do not impact safety or effectiveness." (emphasis added). FDA, "Letter to Pfizer, Inc." (October 29, 2021), *available at* https://www.fda.gov/media/150386/download (last visited Nov. 4, 2021).

a. The Comirnaty Vaccine is *not* widely available due to limited supply, as Pfizer also notes that "there is not sufficient approved vaccine [the Comirnaty] available for distribution to this population in its entirety at the time of the reissuance of this EUA." *See id.* at p. 9 fn. 7. *See also* FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), *available at* https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Oct. 29, 2021).

b. Indeed, the Task Force Guidance governing the federal mandate warns that meeting the deadlines rests exclusively on the shoulders of the employees, availability problems being no excuse at that point: "Depending on employees' locations, they may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot." *See* United States Government, "Safer Federal WorkForce," *available at* https://www.saferfederalworkforce.gov/faq/vaccinations/ (last visited Nov. 3, 2021).

c. Information regarding the differences between the BioNTech Vaccine and the Comirnaty Vaccine is not readily available. Generally speaking certain drugs that the public believes are identical, generic versions of brand name drugs for instance, do not

need to be formulaically identical in actuality. FDA, "Generic Drugs: questions & Answers," *available at* https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q5 (last visited Nov. 4, 2021). Despite Pfizers' proclamations to the contrary, an analysis of the ingredients in the two indicates they are not, in fact, identical.

22. The EUA status of the vaccines that are available at present in the United States means that FDA has not yet fully approved them but permits their conditional use nonetheless due to exigent circumstances.

23. The standard for EUA review and approval is lower than that required for full FDA approval.

24. Typically, vaccine development includes six stages: (1) exploratory; (2) preclinical (animal testing); (3) clinical (human trials); (4) regulatory review and approval; (5) manufacturing; and (6) quality control. *See* CDC, *Vaccine Testing and the Approval Process* (May 1, 2014), *available at* https://bit.ly/3rGkG2s (last visited August 26, 2021).

25. The third phase typically takes place over years, because it can take that long for a new vaccine's side effects to manifest, and must be followed by a period of regulatory review and approval, during which data and outcomes are peer-reviewed and evaluated by FDA. *Id.*

26. Finally, to achieve full approval, the manufacturer must demonstrate that it can produce the vaccine under conditions that assure adequate quality control.

27. FDA must then determine, based on "substantial evidence," that the medical product is effective and that the benefits outweigh its risks when used according to the product's approved labeling. *See* CDC, "Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19" (Oct. 22, 2020), *available at* bit.ly/3x4vN6s (last visited August 26, 2021).

28. In contrast to this rigorous, six-step approval process that includes long-term data review, FDA grants EUAs in emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic." FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), *available at* bit.ly/3x8wImn (last visited August 26, 2021).

29. EUAs allow FDA to make a product available to the public based on the best available data, without waiting for all the evidence needed for FDA approval or clearance. *See id.*

30. The EUA statute lays out the: "Appropriate conditions designed to ensure that individuals to whom the product is administered are informed." This means they must be told:

> that the Secretary has authorized the emergency use of the product;
> 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
> of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

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

31. Studies of immunizations outside of clinical-trial settings began in December 2020, following the first EUA for a COVID vaccine.

32. None of the precise EUA vaccines approved for use in the United States has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. Indeed, trials conducted so far have *specifically excluded* survivors of previous COVID-19 infections. Noorchashm Decl. ¶ 28 (Attachment B).

33. Recent research indicates that vaccination presents a heightened risk of adverse side effects—including serious ones—to those who have previously contracted and recovered from COVID-19. Noorchashm Decl. ¶¶ 21-26; Joint Decl. ¶ 28; Decl. of Jayanta Bhattacharya ¶30 (Attachment C).

34. The heightened risk of adverse effects results from "preexisting immunity to SARS-Cov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals." Angeli, *et al*., *SARS-CoV-2 Vaccines: Lights and Shadows*, 88 EUR. J. INTERNAL MED. 1, 8 (2021).

II. PRIOR INFECTION LEADS TO NATURALLY-ACQUIRED IMMUNITY TO COVID-19 AT LEAST AS ROBUST AS VACCINE-ACQUIRED IMMUNITY

35. Naturally acquired immunity developed after recovery from COVID-19 provides broad protection against severe disease from subsequent SARS-CoV-2 infection. Joint Decl. ¶¶ 15-24.

36. Multiple extensive, peer-reviewed studies comparing naturally acquired and vaccine-acquired immunity have concluded overwhelmingly that the former provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (BioNTech and Moderna). Joint Decl. ¶¶ 18-23.

37. These studies confirm the efficacy of natural immunity against reinfection with COVID-19 and show that almost all reinfections are less severe than first-time infections and almost never require hospitalization. Joint Decl. ¶ 18-24.

38. A study from Israel released several months ago found that vaccinated individuals had 13.1 times greater risk of testing positive, 27 times greater risk of symptomatic disease, and around 8.1 times greater risk of hospitalization than unvaccinated individuals with naturally acquired immunity. Joint Decl. ¶ 20.

39. The authors concluded that the "study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 [BioNTech's research name] two-dose vaccine-induced immunity." Joint Decl. ¶ 20.

40. Recent Israeli data found that those who had received the BioNTech Vaccine were 6.72 times *more likely* to suffer a subsequent infection than those with natural immunity. David Rosenberg, *Natural Infection vs Vaccination: Which Gives More Protection*? ISRAELNATIONALNEWS.COM (Jul. 13, 2021), *available at* https://www.israelnationalnews.com/News/News.aspx/309762 (last visited Aug. 26, 2021).

41. Israeli data also indicates that the protection BioNTech grants against infection is short-lived compared to natural immunity and degrades significantly faster. In fact, as of July 2021, vaccine recipients from January 2021 exhibited only 16% effectiveness against infection and 16% protection against symptomatic infection, increasing linearly until reaching a level of 75% for those vaccinated in April. *See* Nathan Jeffay, *Israeli, UK Data Offer Mixed Signals on Vaccine's Potency Against Delta Strain*, THE TIMES OF ISRAEL (July 22, 2021), *available at* bit.ly/3xg3uCg (last visited Aug. 26, 2021).

42. Those who received a second dose of the BioNTech Vaccine between January and April of this year were determined to have 39% protection against infection and 41% protection against symptomatic infection. The large number of breakthrough infections likely was the result of waning vaccine protection in the face of the Delta variant's spread. *See* Carl Zimmer, *Israeli Data Suggests Possible Waning in Effectiveness of Pfizer Vaccine*, THE NEW YORK TIMES (July 23, 2021); Kristen Monaco, *Pfizer Vax Efficacy Dips at 6 Months*, MEDPAGE TODAY (July 29, 2021), *available at* https://bit.ly/2VheBxw (last visited Aug. 26, 2021).

43. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T

cells, 17 years after infection during the 2003 epidemic.[7] A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.[8] Bhattacharya Decl. ¶ 18.

44. A CDC/IDSA clinician call on July 17, 2021, summarized the current state of the knowledge regarding the comparative efficacy of natural and vaccine immunity. The presentation reviewed three studies that directly compared the efficacy of prior infection versus mRNA vaccine treatment and concluded "the protective effect of prior infection was similar to 2 doses of a COVID-19 vaccine."

45. Given that there is currently *more* data on the durability of naturally acquired immunity than there is for vaccine immunity, researchers rely on the expected durability of naturally acquired immunity to predict that of vaccine immunity. Joint Decl. ¶ 23.

46. Indeed, naturally and vaccine-acquired immunity utilize the same basic immunological mechanism—stimulating the immune system to generate an antibody response. Joint Decl. ¶ 16.

47. The level of antibodies in the blood of those who have natural immunity was initially the benchmark in clinical trials for determining the efficacy of vaccines. Joint Decl. ¶ 16.

48. Studies have demonstrated prolonged immunity with respect to memory T and B cells, bone marrow plasma cells, spike-specific neutralizing antibodies, and IgG+ memory B cells following a COVID-19 infection. Joint Decl. ¶ 17.

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[7] Le Bert, N., Tan, A. T., Kunasegaran, K., Tham, C. Y. L., Hafezi, M., Chia, A., Chng, M. H. Y., Lin, M., Tan, N., Linster, M., Chia, W. N., Chen, M. I. C., Wang, L. F., Ooi, E. E., Kalimuddin, S., Tambyah, P. A., Low, J. G. H., Tan, Y. J. & Bertoletti, A. (2020). SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control. *Nature*, *584*, 457-462. doi: 10.1038/s41586-020-2550-z

[8] Yu, X., Tsibane, T., McGraw, P. A., House, F. S., Keefer, C. J., Hicar, M. D., Tumpey, T. M., Pappas, C., Perrone, L. A., Martinez, O., Stevens, J., Wilson, I. A., Aguilar, P. V., Altschuler, E. L., Basler, C. F., & Crowe Jr., J. E. (2008). Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors. *Nature*, *455*, 532-536. doi: 10.1038/nature07231

49. New variants of COVID-19 resulting from the virus's mutation do not escape the natural immunity developed by prior infection from the original strain of the virus. Joint Decl. ¶¶ 29-33.

50. In fact, vaccine immunity only targets the spike-protein of the original Wuhan variant, whereas natural immunity recognizes the full complement of SARS-CoV-2 proteins and thus provides protection against a greater array of variants. Noorchashm Decl. ¶ 17.

51. While the CDC and the media have touted a study from Kentucky as proof that those with naturally acquired immunity should get vaccinated, that conclusion is unwarranted. As Drs. Bhattacharya and Kulldorff explain, although individuals with naturally acquired immunity who received a vaccine showed somewhat increased antibody levels, "[t]his does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths." Joint Decl. ¶ 37; Bhattacharya Decl. ¶¶ 47-48. In other words, higher antibody levels do not necessarily translate into a clinical benefit.

52. Similarly, Dr. Noorchashm explains that this study did not actually assess the appropriate groups. Instead of comparing individuals who had naturally-acquired immunity only to those who were only vaccinated, the study compared those with naturally-acquired immunity only to those who had naturally-acquired immunity *and* received the vaccine. Furthermore, the study "did not address or attempt to quantify the magnitude of risk and adverse effects in its comparison groups." Noorchashm Decl. ¶¶ 29-31.

53. The Kentucky study is also problematic because it appears cherry-picked. In other words, the CDC gathered data on this subject from all 50 states, but seems to have chosen to draw attention only to the one state that yielded data that arguably supported its position. *See* Marty Makary, "Covid Confusion at the CDC," *The Wall Street Journal* (Sept. 13, 2021), *available at*

https://www.wsj.com/articles/covid-19-coronavirus-breakthrough-vaccine-natural-immunity-cdc-fauci-biden-failure-11631548306 (last visited Nov. 3, 2021).

54. The CDC has also claimed that another study, of several thousand patients hospitalized with "covid-like illness," demonstrates the superiority of vaccine-achieved immunity. "Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19 Like Illness," *CDC* (Oct. 29, 2021), *available at* https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e1.htm (last visited Nov. 3, 2021).

55. This study is highly problematic for many reasons experts have pointed out, chief among them that its design meant that it did not actually address the question of whether the covid recovered benefit from being vaccinated. *See* Martin Kulldorff, "A Review and Autopsy of Two COVID Immunity Studies," *Brownstone Institute* (Nov. 2, 2021), *available at* https://brownstone.org/articles/a-review-and-autopsy-of-two-covid-immunity-studies/ (last visited Nov. 3, 2021).

56. Rather, "the CDC study answers neither the direct question of whether vaccination or Covid recovery is better at decreasing the risk of subsequent Covid disease, nor whether the vaccine rollout successfully reached the frail. Instead, it asks which of these two has the greater effect size. It answers whether vaccination nor Covid recovery is more related to Covid hospitalization or if it is more related to other respiratory type hospitalizations." *Id.*

57. Kulldorff explains that the Israeli study discussed above, indicating that naturally acquired immunity provides significantly better protection against reinfection, produced far more reliable results due to its design. *Id.*

58. Indeed, shortly after publishing the results of the study, the CDC (much more quietly) conceded that "A systematic review and meta-analysis including data from three vaccine

efficacy trials and four observational studies from the US, Israel, and the United Kingdom, found no significant difference in the overall level of protection provided by infection as compared with protection provided by vaccination; this included studies from both prior to and during the period in which Delta was the predominant variant." "Science Brief: SARA-CoV-2 Infection-induced and Vaccine-induced Immunity," *CDC* (Oct. 29, 2021), *available at* https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html (last visited Nov. 3, 2021).

59. In short, contrary to the claims of the CDC and the media, this study did *not* establish a valid reason to vaccinate individuals with naturally-acquired immunity. *See* Joint Decl. ¶ 37; Noorchashm Decl. ¶¶ 29-31.

60. The Janssen Vaccine provides immunity protection of somewhere between 66% and 85%, far below that conferred by natural immunity. Joint Decl. ¶ 16; Noorchashm Decl. ¶ 15.

61. The Chinese Sinovac Vaccine has been approved by WHO (making it adequate to satisfy MSU's policy), which itself determined that this vaccine prevented *symptomatic* disease in just 51% of those who received it. *See WHO Validates Sinovac COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WHO.INT (June 1, 2021), *available at* bit.ly/3yitIW7 (last visited Aug. 26, 2021).

62. Other clinical studies have found that the Sinovac Vaccine offers even lower levels of protection against infection. For instance, a study of Brazilian healthcare workers determined a mere 50.39% efficacy in preventing infection. *See* Elizabeth de Faria et al., *Performance of Vaccination with Coronavac*[9] *in a Cohort of Healthcare Workers (HCW)—Preliminary Report*,

[9] Sinovac and Coronavac are the same. *See* WHO, *Who Validates Sinovac COVID-19 Vaccine For Emergency Use*, (June 1, 2021), *available at* https://www.who.int/news/item/01-06-2021-

MEDRXIV (Apr. 15, 2021), *available at* https://www.medrxiv.org/content/10.1101/2021.04.12.21255308v1 (last visited Aug. 26, 2021).

63. Real-world evidence also suggests that the Sinovac Vaccine provides only minimal protection against the Delta variant. *See* Alexander Smith, *China on 'High Alert' as Variant of Covid-19 Spreads to 5 Provinces*, NBCNEWS.COM (July 30, 2021), *available at* nbcnews.to/2VcK3NB (last visited Aug. 27, 2021); Chao Deng, *As Delta Variant Spreads, China Lacks Data on Its Covid-19 Vaccines*, WALL ST. J. (July 9, 2021), *available at* on.wsj.com/3rMjlXW (last visited Aug. 27, 2021); Matt D.T. Hitchings, et al., *Effectiveness of CoronaVac in the Setting of High SARS-Cov-2 P.1 Variant Transmission in Brazil: A Test-Negative Case-Control Study*, THE LANCET (July 25, 2021), *available at* bit.ly/3C6F41J (last visited Aug. 26, 2021).

64. The Sinopharm Vaccine also is from China and is WHO-approved. Although its reported level of efficacy against symptomatic infection has been reported as reasonably high (78%), real-world experience has generated severe doubts about the accuracy of that estimate. Because of the Sinopharm Vaccine's poor performance, several countries have stopped using it. *See* Yaroslav Trofimov & Summer Said, Bahrain, *Facing a Covid Surge, Starts Giving Pfizer Boosters to Recipients of Chinese Vaccine*, WALL ST. J. (June 2, 2021), *available at* on.wsj.com/3ljM0lX (last visited Aug. 26, 2021).

65. The COVISHIELD vaccine, manufactured by the Serum Institute of India and South Korea's SK Bioscience Co., Ltd., is also WHO-approved and thus recognized as adequate to satisfy MSU's Policy. The WHO itself reported a mere 70.42% efficacy against *symptomatic*

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who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations (last visited Aug. 26, 2021).

COVID-19 infection, which fell to 62.10% in individuals who received two standard doses. *See Recommendation on Emergency Use Listing on COVISHIELD Submitted by SIIPL*, WHO (Feb. 26, 2021), *available at* bit.ly/3rNjnPo (last visited Aug. 26, 2021); *Recommendation for an Emergency Use Listing of AZD1222 Submitted by AstraZeneca AB and Manufactured by SK Bioscience Co. Ltd.*, WHO (Feb. 23, 2021), *available at* bit.ly/3yiQD3s (last visited Aug. 26, 2021). These vaccines have not been approved by the FDA for use in the United States.

66. Early data also suggests that naturally acquired immunity may provide greater protection against both the Delta and Gamma variants than that achieved through vaccination. A recent analysis of an outbreak among a small group of mine workers in French Guiana found that 60% of fully vaccinated miners suffered breakthrough infections compared to *zero* among those with natural immunity. Nicolas Vignier, et al., *Breakthrough Infections of SARS-CoV-2 Gamma Variant in Fully Vaccinate Gold Miners, French Guiana, 2021*, 27(10) EMERG. INFECT. DIS. (Oct. 2021), *available at* https://wwwnc.cdc.gov/eid/article/27/10/21-1427_article (last visited Aug. 26, 2021).

67. In this vein, the CDC recently reported that "new scientific data" indicated that vaccinated people who experienced breakthrough infections carried similar viral loads to the unvaccinated (but not naturally immune), leading the CDC to infer that vaccinated people transmit the virus at concerning levels. *See CDC Reversal on Indoor Masking Prompts Experts to Ask, "Where's the Data?"*, WASHINGTON POST (July 28, 2021), *available at* wapo.st/2THpmIQ (last visited Aug. 26, 2021). For example, 74% of cases in a Cape Cod outbreak occurred in vaccinated individuals, again demonstrating that the vaccines are inferior to natural immunity when it comes to preventing infection. *See* Molly Walker, *CDC Alarmed: 74% of Cases in Cape Cod Cluster*

Were Among the Vaxxed, MEDPAGE TODAY (July 30, 2021), *available at* bit.ly/2V6X3UP (last visited Aug. 26, 2021).

68. As Drs. Bhattacharya and Kulldorff have explained, there is no legitimate public-health rationale for MSU to require proof of vaccination to participate in activities that do not involve care for high-risk individuals:

> Since the successful vaccination campaign already protects the vulnerable population, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to the vaccinated. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero and natural immunity, which provides benefits that are at least as strong[.] At the same time, the requirement for … proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice.

Joint Decl. ¶¶ 50-51.

III. COVID-19 VACCINES CAN CAUSE SIDE EFFECTS, INCLUDING SEVERE ADVERSE REACTIONS

69. Though the COVID-19 vaccines appear to be relatively safe at a population level, like all medical interventions, they carry a risk of side effects. Those side effects include common, temporary reactions such as pain and swelling at the vaccination site, fatigue, headache, muscle pain, fever, and nausea. More rarely, they can cause serious side effects that result in hospitalization or death. Joint Decl. ¶¶ 25-26.

70. The vaccines could cause other side effects that remain unknown at this time due to their relatively recent development. Joint Decl.¶¶ 26-27.

71. Put differently, as a matter of simple logic, one cannot be certain about the long-term effects of a vaccine that has not been in existence for the long term and thus cannot have been

studied over a span of years. For that reason, "[a]ctive investigation to check for safety problems is still ongoing." Joint Decl. ¶ 26.

IV. PLAINTIFFS HAVE ROBUST NATURALLY ACQUIRED IMMUNITY TO COVID-19

72. Jeanna Norris, age 37, is a supervisory Administrative Associate and Fiscal Officer at MSU. She has been employed at MSU for eight years. Jeanna Norris Declaration ("Norris Decl.") ¶ 1 (Attachment D).

73. Her duties and responsibilities entail approving expenditures, ensuring compliance with financial policy, developing financial reports and budgets, and approving personnel actions. Norris Decl. ¶ 2.

74. Since March of 2020, Ms. Norris has been working remotely. MSU currently has no timetable for her to return to work in person. Norris Decl. ¶ 4.

75. Ms. Norris is the stepmother of her husband's five children, who range in age from 14 to 22. She is the primary breadwinner for the family. Norris Decl. ¶ 3.

76. On November 19, 2020, Ms. Norris became ill with a severe headache and dry cough. The following day she developed body aches and pains that reminded her of the flu. Norris Decl. ¶ 5.

77. Ms. Norris received a positive COVID-19 Rapid test on November 21, 2020 at Ouch Urgent Care in Clinton County, Michigan. Norris Decl. ¶ 6.

78. After approximately four days, Ms. Norris's symptoms began to abate and her health condition improved, but her sense of taste and smell disappeared for a full month. Norris Decl. ¶ 7.

79. Ms. Norris received a positive COVID-19 antibody test on August 17, 2021 at Sparrow Health System, and a second positive COVID-19 antibody test on August 21, 2021 at LabCorp. Norris Decl. ¶ 8; Noorchashm Decl. ¶ 7(f); Joint Decl. 44.

80. The test results confirmed that she contracted and recovered from the SARS-CoV-2 virus. Her recent semi-quantitative antibodies screening test established that her level of immune protection remains high. Noorchashm Decl. ¶ 13. Indeed, her "spike antibody level is highly likely to be above the minimum necessary to provide adequate protection against re-infection from the SARS-CoV-2 virus." Noorchashm Decl. ¶ 7(g).

81. Having consulted with Plaintiff and reviewed her lab results, Dr. Noorchashm concluded that undergoing a full vaccination course would be medically unnecessary, create a risk of harm to her, and provide insignificant or no benefit either to her or the MSU community. Noorchashm Decl. ¶ 12.

82. Plaintiff Kraig Ehm is a video producer for MSU, where he has been employed for 21 years. Oct. 20, 2021 Declaration of Kraig Ehm ("Ehm Decl.") ¶ 2 (Attachment E).

83. He was diagnosed with COVID-19 in April of 2021, and antibody tests from August 21 and October 8, 2021 confirm that he has naturally acquired immunity to the virus. Ehm Decl. ¶ 3; Bhattacharya Decl. ¶ 25.

84. Plaintiff Ehm underwent disciplinary proceedings because he has declined to receive a COVID-19 vaccine. Ehm Decl. ¶ 6. He was terminated on November 3, 2021.

85. Plaintiff D'Ann Rohrer is an Extension Educator at MSU, where she has worked for over 6 years. Declaration of D'Ann Rohrer ("Rohrer Decl.") ¶ 1 (Attachment F).

86. She was diagnosed with COVID-19 in August of 2021, and a serological test from October 4, 2021 confirmed that she has naturally acquired immunity to the virus. Rohrer Decl. ¶ 4; Bhattacharya Decl. ¶ 25.

87. She has been placed on unpaid leave because she has declined to receive a vaccine.

88. Plaintiffs have real, substantial, and legitimate concerns about taking a COVID-19 vaccine in light of their natural immunity and the potential for short- and long-term side effects and potential adverse reactions from the vaccines themselves. Norris Decl. ¶ 15-17; Rohrer Decl. ¶¶ 9, 10; Ehm Decl. ¶ 9.

89. Dr. Noorchashm explains that substantial scientific literature demonstrates that, while the COVID-19 vaccines carry the possibility of side effects, as do all medical procedures, the risk of harm is greater to those who have recovered from the disease. Noorchashm Decl. ¶¶12 -28.

90. Accordingly, mandating that Plaintiffs receive a COVID-19 vaccine violates the rules governing medical ethics. Noorchashm Decl. ¶¶ 8-35.

91. There are other MSU employees who are similarly situated, e.g., they previously contracted COVID-19, they have naturally acquired immunity, and they have real, substantial, and legitimate concerns about taking the COVID-19 vaccine in light of their naturally acquired immunity and the potential for short- and long-term side effects and potential adverse reactions from the vaccines themselves.

92. MSU's Directive applies equally to employees working on or off campus and thus Plaintiffs Norris's, Ehm's, and Rohrer's ability to function as class representatives is not diminished as to class members working on or off campus. many of whom may, from time to time, also work from home. *See also infra* at ¶¶ 92-99.

V. BACKGROUND AND MSU'S IMPOSITION OF A BLANKET VACCINE REQUIREMENT AS PART OF ITS REOPENING POLICY

93. MSU is a public research university located in East Lansing, Michigan, in Ingham County, in the Western District of Michigan.

94. MSU announced its "COVID Directives" for the Fall 2021 semester via email and on its website on July 30, 2021 and, and provided a more detailed version on its website on August 5, 2021, which includes FAQ. (Attachments G-I). MSU's Directives include a vaccine mandate.

95. The Directive requires all faculty, staff, and students to be fully vaccinated or to obtain an approved exemption for the Fall 2021 semester. (Attachments G-I).

96. By August 31, 2021, all faculty, staff, and students must have completed a full COVID-19 vaccination course or received at least one dose of a two-dose series. Employees and students also are required to report their vaccine status using an online form. (Attachments G-I).

97. Those who have not completed a full vaccine course (but only a partial one) by August 31, 2021 are subject to various restrictions pursuant to the "Early Detection Policy," including testing and quarantining requirements. (Attachment H).

98. MSU accepts all FDA-authorized as well as all WHO-approved vaccines. (Attachments G-I).

99. In order to obtain a medical exemption, an individual must demonstrate:

a. A documented anaphylactic allergic reaction or other severe adverse reaction to any COVID-19 vaccine;

b. A documented allergy to a component of a COVID-19 vaccine;

c. Another documented medical condition that constitutes a disability under the Americans with Disabilities Act; or

d. A limited-term inability to receive a vaccine such as pregnancy or breastfeeding. (Attachment H).

100. In its "FAQs" Section pertaining to the Directive, MSU states that the rationale for its policy is that, *inter alia*, "new studies demonstrate[] both unvaccinated and vaccinated individuals can transmit the disease to those who cannot currently be vaccinated, including children less than 12 years old and immunocompromised individuals" and "new data reveal[s] the Delta variant can create breakthrough infections in vaccinated individuals." (Attachment I).

101. Employees who do not comply with the vaccine requirements are subject to disciplinary action, including termination from the university. (Attachment I).

102. One of the questions posed in the FAQ section is "I have had COVID-19 in the past and have laboratory evidence of antibodies. Do I need to be vaccinated?" The answer is "Even those who have contracted COVID-19 previously are required to receive a vaccine, which provides additional protection." (Attachment I). Hence, there is no doubt that MSU does not recognize natural immunity as a basis for getting a medical exemption.

103. In response to the question, "[w]hy should I get a vaccine if the delta variant breaks through the current vaccines," the webpage states that: "[t]he current vaccines remain highly effective in preventing hospitalizations, severe disease and death from the delta variant of COVID-19." (Attachment I).

104. Even employees who have arranged to work remotely during the Fall semester must either be vaccinated or obtain a religious or medical exemption. (Attachment I).

105. Plaintiffs were forced to file their lawsuit and motions for a temporary restraining order ("TRO") and preliminary injunction on a tight timeline because MSU did not announce the Directive until a mere month before the August 31, 2021 deadline it set for employees to receive

the vaccine. (Attachments H-J). Indeed, the email version contained insufficient data from which remote workers, including Plaintiff Norris, and others similarly situated could conclude whether or not they were subject to the mandate. Thus, they were only provided with the final version three weeks before the deadline to receive the vaccine.

106. Potential litigation by those not wishing to be vaccinated was a prospect that was or should have been reasonably foreseeable to the Defendants and other agents of MSU.

VI. PLAINTIFF HAS EXPERIENCED, AND WILL CONTINUE TO EXPERIENCE, CONCRETE AND PARTICULARIZED HARM AS A DIRECT CONSEQUENCE OF MSU'S VACCINE POLICY

107. Plaintiffs either must receive a COVID-19 vaccine or face disciplinary action, including loss of employment. Plaintiff Rohrer is in the midst of such disciplinary proceedings, and Plaintiff Ehm has been terminated. Accordingly, Plaintiffs' personal autonomy is being infringed, and their constitutional rights violated.

108. By threatening adverse professional and personal consequences, MSU's Directive not only directly and palpably harms Plaintiffs' bodily autonomy and dignity, but it forces them to endure the stress and anxiety of choosing between their employment and their health.

109. Should they give in and get the vaccine due to financial pressure or other concerns that accompany loss of a job, they will also suffer irreparable harm. As an Illinois court recently determined:

> But what of the December 31, 2021 vaccination requirement? "Obey now, grieve later" is not possible. If every union member complied and was vaccinated by December 31 (or otherwise exempt), they would have no grievance to pursue and there would be no remedy an arbitrator could award. An award of back pay or reinstatement cannot undo a vaccine. Nothing can. If that aspect of the City's policywas found to violate the collective bargaining agreements, the arbitral process couldnot restore the parties to their original positions. An award in favor of the police unions would be an "empty victory." "Obey now, grieve later" would be transformed into "obey now and forever" -without a meaningful opportunity to arbitrate. That constitutes irreparable injury.

Fraternal Order of Police Chicago Lodge No. 7, et. al v. City of Chicago, Case No. 2021 CH 5276, at 3 (Circuit Court of Cook County, Ill.) (Nov. 1, 2021) (internal citations omitted), *available at* bit.ly/3mHqCaK (last visited Nov. 3, 2021).

110. The risk-avoidance benefits that the Directive provides, compared to the restrictions and intrusive options offered to Plaintiffs, are disproportionate. Similarly, given that naturally acquired immunity confers equal or greater protection than that provided by the vaccines (especially with respect to some of the WHO-approved vaccines that MSU considers adequate to fulfill the Directive's requirements), the Directive is arbitrary and irrational. There is no indication that the Directive is tailored to account for its impact on those who have acquired natural immunity. In fact, official MSU explanations of the Directive specifically refuse to recognize those with natural immunity as posing different issues and requiring different treatment as compared to unvaccinated individuals who lack natural immunity.

CLASS ACTION ALLEGATIONS

111. ***Class Definition.*** Plaintiff brings this action on behalf of herself and all others similarly situated ("the Class"), pursuant to Federal Rule of Civil Procedure 23. The Class is defined as follows:

> (i) All MSU employees employed by the University (ii) on or after August 31, 2021 (the deadline for those employees to become vaccinated against COVID-19), including employees newly hired, whether or not they work on campus, at home, or both (iii) who have naturally acquired immunity demonstrable by antibody testing and where (iv) application of the Directive will invade their rights of bodily integrity, coerce or significantly burden their choices, or deny their rights of informed consent.

112. For purposes of this Complaint, references to Plaintiffs, because this suit is being brought as a class action, should be construed as applying to class members even where not explicitly so stated.

113. ***Numerosity.*** The exact size of the class is unknown. However, by the end of March 2020, 23% of New Yorkers had COVID-19 antibodies and by February of 2021, 45% of Los Angeles residents did. *See* Marty Makary, *The Power of Natural Immunity*, THE WALL STREET JOURNAL (June 8, 2015), *available at* https://www.wsj.com/articles/the-power-of-natural-immunity-11623171303 (last visited August 26, 20210). MSU has around 7,365 staff members and 5,703 faculty, meaning that the size of the class is likely large. Hence, the numerosity requirement in Fed. R. Civ. P. 23(a)(1) is met here.

114. ***Commonality.*** There are multiple questions of law and fact common to the class, including but not limited to:

a. Whether MSU's Directive constitutes an unconstitutional infringement on Plaintiffs' rights to bodily autonomy and to decline medical treatment under the Ninth, and Fourteenth Amendments to the United States Constitution;

b. Whether MSU's Directive creates an unconstitutional condition on the exercise of Plaintiffs' constitutionally protected rights; and

c. Whether MSU's Directive violates Plaintiffs' federal statutory rights under the Emergency Use Authorization (EUA) statute.

As a result, the commonality requirement of Fed. R. Civ. P. 23(a)(2) is met here.

115. ***Typicality.*** Plaintiffs' claims are typical of the Class, as she has naturally acquired immunity to COVID-19, as verified by two recent antibodies tests, she is an employee of MSU, and she objects to the Directive on the grounds that it violates her constitutional and statutory rights as described above. As a result, the typicality requirement of Fed. R. Civ. P. 23(a)(3) is met here.

116. ***Adequacy of Representation.*** Plaintiffs will fairly and adequately protect the interests of the members of the Class. Plaintiffs' interests are aligned with, and not antagonistic to, those of the other members of the Class. Additionally, Plaintiffs are seeking identical declaratory and injunctive relief that would benefit all putative class members. Plaintiffs have also retained counsel competent and experienced in the prosecution of class-action litigation to represent herself and the Class. As a result, the adequacy-of-representation requirement of Fed. R. Civ. P. 23(a)(4) is met here.

117. ***Fed. R. Civ. P. 23(b)(2) Class Type.*** Certification for injunctive and declaratory relief is appropriate under Rule 23(b)(2) because Defendants have both acted (principally by mandating that MSU employees receive the vaccines) and refused to act (via their refusal to recognize natural immunity) on grounds that generally apply to the whole class. This also makes temporary, preliminary, and permanent injunctive relief appropriate "respecting the class as a whole." Fed. R. Civ. P. 23(b)(2).

118. ***Class Action Superiority & Efficiency.*** Additionally, though it is not necessary to plead as part of a Rule 23(b)(2) class action, class-wide treatment of the common issues presented by this suit against MSU in a single forum represents a superior means of determining Defendants' liability to each Class Member than potentially hundreds or thousands of individual lawsuits. As a result, class-wide adjudication of Defendants' liability followed by the grant of undifferentiated declaratory and injunctive relief is the most efficient means of adjudication.

CLAIMS FOR RELIEF

COUNT I: VIOLATION OF THE RIGHT TO REFUSE UNWANTED AND MEDICALLY UNNECESSARY CARE

119. Plaintiffs reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

120. MSU's Directive requires Plaintiffs to take a vaccine without their consent—and against the expert medical advice of an immunologist—thereby depriving them of their ability to refuse unwanted medical care.

121. The Supreme Court has recognized that the Ninth and Fourteenth Amendments protect an individual's right to privacy. A "forcible injection … into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" *Washington v. Harper*, 494 U.S. 210, 229 (1990). The common law baseline is also a relevant touchstone out of which grew the relevant constitutional law. *See, e.g., Cruzan v. Dir., Mo. Dep't of Public Health*, 497 U.S. 261, 278 (1990) ("'At common law, even the touching of one person by another without consent and without legal justification was a battery'"). *See* W. Keeton, D. Dobbs, R. Keeton, & D. Owen, PROSSER AND KEETON ON LAW OF TORTS § 9, pp. 39-42 (5th ed. 1984).); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129-130, 105 N.E. 92, 93 (1914) (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.").

122. Subsequent Supreme Court decisions have made explicit that the Constitution protects a person's right to "refus[e] unwanted medical care." *Cruzan*, 497 U.S. at 278; *King v. Rubenstein*, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same).

123. This right is "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment." *Washington v. Glucksberg,* 521 U.S. 702, 722 n.17 (1997).

124. The Court has explained that the right to refuse medical care derives from the "well-established, traditional rights to bodily integrity and freedom from unwanted touching." *Vacco v. Quill*, 521 U.S. 793, 807 (1997).

125. To the extent that some courts, including this one, have held otherwise in denying preliminary injunctions for COVID-19 vaccine mandates, it is worth noting that none have made it to Courts of Appeals, let alone the Supreme Court. *See, e.g., Norris v. Stanley*, 1:21 cv 756 (W.D. Mich. Oct. 8, 2021); *Kheriaty v. Regents*, No. 8:21-cv-01367 (C.D. Cal. Sept. 29, 2021).

126. Furthermore, *Jacobson* typically is relied upon for the proposition that rational basis level analysis only applies – generally leading to findings in favor of the Government -- this is the wrong standard, because *Jacobson* differed in crucial respects. First of all, as the Court itself stated, one of the reasons it applied a low level of scrutiny was that the law at issue was the product of legislative action. *See Jacobson*, 197 U.S. at 37.

127. Second, the Court considered the deadliness of smallpox to be pertinent to the inquiry (and presumably its holding), as it was "an epidemic threatening the safety of all." *Id.* at 28. Though COVID-19 is of course a serious disease, it does not present a significant risk to the vast majority of individuals. That is even more true now that those who wish to do so can get immunized.

128. Third, naturally-acquired immunity was not an issue in *Jacobson*: there was no contention that Jacobson had survived smallpox and consequently had immunity to it. Finally, *Jacobson* was determined during an era in which schools often were segregated and states could

ban interracial marriage. It served as one of the justifications for the decision in *Buck v. Bell*, allowing the forced sterilization of mentally ill women. Clearly, our concepts of bodily autonomy have changed since *Jacobson*, making blind reliance upon it misguided.

129. Coercing employees to receive a vaccine (whether approved under an EUA or fully by the FDA) for a virus that presents a near-zero risk of illness or death to them and which they are exceedingly unlikely to pass on to others because those employees already possess natural immunities to the virus, violates the liberty and privacy interests that the Ninth and Fourteenth Amendments protect.

130. "Government actions that burden the exercise of those fundamental rights or liberty interests [life, liberty, property] are subject to strict scrutiny, and will be upheld only when they are narrowly tailored to a compelling governmental interest." *Does v. Munoz*, 507 F.3d 961, 964 (2007).

131. Defendants cannot show that they have a compelling interest in coercing Plaintiffs or others similarly situated into taking a COVID-19 vaccine, because MSU has no compelling interest in treating employees with natural immunity any differently from employees who obtained immunity from a vaccine.

132. Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. Noorchashm Decl. ¶¶ 14-17; Joint Decl. at ¶¶ 15-24; Nabin K. Shrestha, et al., *Necessity of COVID-19 Vaccination In Previously Infected Individuals*, MEDRXIV (June 5th, 2021), *available at* https://bit.ly/2TFBGcA (last visited Aug. 26, 2021); *see also* Yair Goldberg, et al., *Protection of Previous SARS-Cov-2 Infection Is Similar to That of BNT162b2 Vaccine Protection: A Three-Month Nationwide Experience from Israel*, MEDRXIV (Apr. 20, 2021), *available at*

https://bit.ly/3zMV2fb (last visited Aug. 26, 2021); Michael Smerconish, *Should Covid Survivors and the Vaccinated Be Treated the Same?*: CNN Interview with Jay Bhattacharya, Professor of Medicine at Stanford University (June 12, 2021), *available at* https://cnn.it/2WDurDn (last visited Aug. 26, 2021); Marty Makary, *The Power of Natural Immunity*, WALL STREET JOURNAL (June 8, 2021), *available at* https://on.wsj.com/3yeu1Rx (last visited Aug. 26, 2021).

133. In recognition of the highly protective character of natural immunity, the European Union has recognized "a record of previous infection" as a substitute for any vaccine passport requirements. Noorchashm Decl. ¶ 38. Even France's controversial new restrictive mandate on the ability to participate in daily life focuses on a person's immunity rather than their vaccine status—treating natural immunity and vaccine immunity equally. *See, e.g.*, Clea Callcutt, *France Forced to Soften Rules After Coronavirus Green Pass Backlash*, POLITICO (July 20, 2021), *available at* https://politi.co/3f9AZzS (last visited Aug. 26, 2021).

134. Similarly, the United States requires everyone, including its citizens, to provide proof of a negative COVID-19 test before returning to the country from abroad. Yet, documentation of recovery suffices as a substitute, although proof of vaccination does not. *See Requirement of Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States*, CDC (July 6, 2021), *available at* https://bit.ly/3yfcJDM (last visited Aug. 26, 2021).

135. Recent data from Israel suggests that individuals who receive the BioNTech Vaccine can pass the virus onto others a mere few months after receiving it, casting doubt on any claim that the vaccine prevents spread of the virus, or at least any claim that it does so to a greater extent than natural immunity.

136. The blithe statement on MSU's FAQ page to the effect that vaccinating a naturally immune individual provides "additional protection"—without citation to *any* scientific data—does not establish the validity of a vaccine mandate. As Drs. Bhattacharya, Kulldorff, and Noorchashm attest, the study from Kentucky that the CDC has touted as substantiating MSU's proposition has been both wrongly interpreted and incorrectly portrayed by the media. *See* Joint Decl. ¶ 37; Noorchashm Decl. ¶¶ 29-31; Bhattacharya Decl. ¶¶ 47-48. Furthermore, the study "did not address or attempt to quantify the magnitude of risk and adverse effects in its comparison groups," Noorchashm Decl. ¶¶ 29-31, as it did not compare vaccinated individuals to COVID-recovered individuals.

137. Moreover, the study did not establish that vaccinating the naturally immune confers a discernable benefit. Although vaccinating naturally immune individuals may raise their antibody levels, that does not necessarily translated into a clinical benefit either for themselves or for third parties. "[t]his does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths." Joint Decl. ¶ 37. In other words, there is no evidence that vaccinating naturally immune individuals makes them safer either in terms of their personal health or potential for infecting others.

138. Assuming *arguendo* that vaccinating the naturally immune provides some marginal benefit, that is not a justification for a mandate that overrides individuals' rights to make choices about their own medical care, particularly one that accepts as sufficient to fulfill its requirements several inferior vaccines such as the Sinovac and Sinopharm. *See infra* at ¶ 143.

139. This is particularly so given that vaccines can cause injury, and that the risk is even greater to those who are COVID-recovered. Put otherwise, the risk-benefit analysis at that point

ought to be left to the individual and his or her doctor. Noorchashm Decl. ¶¶ 21-26; Joint Decl. ¶ 28; Decl. of Jayanta Bhattacharya ¶30.

140. The CDC has also claimed that another study, of several thousand patients hospitalized with "covid-like illness," demonstrates the superiority of vaccine-achieved immunity. "Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19 Like Illness," *CDC* (Oct. 29, 2021), *available at* https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e1.htm (last visited Nov. 3, 2021). This study is highly problematic for many reasons experts have pointed out, chief among them that its design meant that it did not actually address the question of whether the COVID-19 recovered benefit from being vaccinated. *See* Martin Kulldorff, "A Review and Autopsy of Two COVID Immunity Studies," *Brownstone Institute* (Nov. 2, 2021), *available at* https://brownstone.org/articles/a-review-and-autopsy-of-two-covid-immunity-studies/ (last visited Nov. 3, 2021). Rather, "the CDC study answers neither the direct question of whether vaccination or Covid recovery is better at decreasing the risk of subsequent Covid disease, nor whether the vaccine rollout successfully reached the frail. Instead, it asks which of these two has the greater effect size. It answers whether vaccination nor Covid recovery is more related to Covid hospitalization or if it is more related to other respiratory type hospitalizations." *Id.*

141. Indeed, shortly after publishing the results of the study, the CDC (much more quietly) conceded that: "A systematic review and meta-analysis including data from three vaccine efficacy trials and four observational studies from the US, Israel, and the United Kingdom, found no significant difference in the overall level of protection provided by infection as compared with protection provided by vaccination; this included studies from both prior to and during the period in which Delta was the predominant variant." "Science Brief: SARA-CoV-2 Infection-induced and Vaccine-induced Immunity," *CDC* (Oct. 29, 2021), *available at*

https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html (last visited Nov. 3, 2021). In short, contrary to (some of) the claims made by the CDC and the media, these studies do *not* establish a valid reason to mandate vaccination of individuals with naturally acquired immunity. *See* Joint Decl. ¶ 37; Noorchashm Decl. ¶¶ 29-31.

142. The State of Michigan's public policy, as established by the state legislature, has also traditionally reflected that it lacks any interest in vaccinating persons for a disease to which they carry antibodies. For instance, the law mandating vaccination of school children *explicitly exempts* from the requirements those who can demonstrate existing immunity through serological testing that measures protective antibodies. MICH. ADMIN. CODE r. 325.176 (2021).

143. MSU simply has no compelling interest in departing from the State's typical public policy in this case. There is no question that Plaintiffs possess natural immunity, given their recent antibodies screening tests and as confirmed by Drs. Noorchashm and Bhattacharya. Joint Decl. ¶ 44; Noorchashm Decl. ¶¶ 7(f), (g), 13; Bhattacharya Decl. ¶ 25.

144. In addition to MSU's lack of a valid governmental interest in requiring that already immune employees get vaccinated, Defendants cannot show that the Directive is narrowly tailored to a compelling governmental interest.

145. Any interest that MSU may have in promoting immunity on campus does not extend to those employees who already have natural immunity—particularly those who can demonstrate such immunity through antibody screenings. Naturally immune MSU employees are already as safe to themselves and to other people on campus as vaccinated individuals are, so there is no justification to force vaccinations on them. Doing so does not make anyone else safer, but it does subject naturally immune employees to a disproportionate risk of adverse side effects.

146. Hence, MSU is trying to exert control over individuals' personal health decisions, rather than attempting to promote a legitimate public health aim.

147. Indeed, MSU's Directive—likely inadvertently—acknowledges that it lacks a valid public health basis for its vaccine policy. In explicating the reasoning underlying the Directive on its "FAQ" page, MSU states that the vaccines are "highly effective in preventing hospitalizations, severe disease and death from the delta variant of COVID-19." (Attachment G). Of course, all of these effects are exclusively individual benefits and not public health benefits.

148. In other words, MSU does not even pretend that the mandate is truly about protecting others, since natural immunity also prevents hospitalizations, severe disease and death. Thus, the Directive infringes on Plaintiffs' bodily autonomy with no public health justification.

149. Another ground MSU provides for its Directive is that "new studies demonstrate[] both unvaccinated and vaccinated individuals can transmit the disease to those who cannot currently be vaccinated, including children less than 12 years old and immunocompromised individuals" and that "new data reveal[s] the Delta variant can create breakthrough infections in vaccinated individuals." (Attachment G).

150. However, if vaccinated people can also transmit the disease, as MSU concedes, that only further undercuts any public health rationale for a vaccine mandate. It certainly drives home the arbitrary, nonsensical nature of MSU's position that robust, naturally acquired immunity should not be recognized, while more limited immunity acquired through vaccination should be.

151. Nor does MSU provide any sound reasoning for the claim that its Directive will protect those who cannot be vaccinated.

a. *First*, college campuses are rarely frequented by individuals under 12 years of age. And vaccinations are now available to children 5-11.

b. *Second*, MSU has not provided any information about or otherwise provided any assurance that it has analyzed the number of immunocompromised people living and working on campus, rendering this justification flimsy.

c. *Finally*, as MSU acknowledges, vaccinated individuals can also spread COVID-19. It is thus unclear just how a vaccine mandate will protect immunocompromised individuals. Presumably, anyone who cannot receive the vaccine and is at risk from severe illness already takes measures to protect him or herself, most likely by working or attending school remotely.

152. In sum, MSU's justifications for its Directive are not only speculative, but logically incoherent.

153. Another reason the Directive lacks any constitutional validity is that many of the vaccines that MSU accepts, such as the Janssen, Sinovac, and Sinopharm vaccines are much less effective in preventing infection, compared to natural immunity. That renders Plaintiffs significantly less likely to contract or spread the virus than their colleagues who have been immunized with these inferior vaccines. Yet they are subject to termination while their similarly situated colleagues, who have received these subpar vaccines, are not.

154. By failing to tailor its Directive to only those employees who lack immunity, MSU forces employees like Plaintiffs (and those similarly situated), who have naturally acquired immunity, to choose between their health, their personal autonomy and their careers.

155. Plaintiffs have suffered and will continue to suffer damage from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiffs for the deprivation of her constitutional rights. They will suffer irreparable harm unless this Court enjoins Defendants from enforcing their Directive against employees with natural

immunity. Plaintiffs will also suffer irreparable harm if coerced to in fact take the vaccine, because there is no way to undo the effects of a vaccine once it has been administered. Any adverse side effects could be permanent at that point.

156. Plaintiffs are entitled to a judgment declaring that the Directive violates their constitutional rights to refuse medical treatment and an injunction restraining Defendants' enforcement of the Directive.

COUNT II: VIOLATION OF THE UNCONSTITUTIONAL CONDITIONS DOCTRINE AND THE FOURTEENTH AMENDMENT'S RIGHT TO DUE PROCESS

157. Plaintiffs reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

158. The Due Process Clause of the Fourteenth Amendment provides: "nor shall any state deprive any person of life, liberty, or property, without due process of law … ." U.S. Const., amend. XIV, sec. 1.

159. Unconstitutional conditions case law often references the existence of varying degrees of coercion. According to that body of law, MSU cannot impair Plaintiffs' rights to refuse medical care through subtle forms of coercion any more than it could through an explicit mandate. *See, e.g.*, *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013) ("[U]nconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them"); *Memorial Hosp. v. Maricopa Cty.*, 415 U.S. 250 (1974) (finding that state residency requirement impinged on the constitutionally guaranteed right to interstate travel, while lacking a compelling state interest, and thus was unconstitutional).

160. Plaintiffs possess a liberty interest in their bodily integrity, a property interest in their careers, and statutory interests in informed consent.

161. Unconstitutional conditions claims do not need to establish that a challenged government policy amounts to coercion. Instead, it is sufficient that the state policy burdens a constitutional right by imposing undue pressure on an otherwise voluntary choice with a nexus to the exercise of a constitutional right.

162. In other words, the presence of some remaining voluntarism after new conditions are imposed on the exercise of a constitutional right does not stand as a barrier to establishing a successful unconstitutional conditions claim.

163. MSU similarly possesses no compelling interest that could justify its defective Directive that will inevitably result in at least some unwarranted medical intrusions into the bodies of members of the MSU community.

164. In *Speiser v. Randall*, 357 U.S. 513 (1958), the Court invalidated a loyalty oath imposed as a condition for veterans to obtain a state property tax exemption, even though (a) California citizens were not required to own real property, of course; (b) California veterans could freely opt not to seek the exemption and simply pay the unadorned tax; (c) California was not even obligated to provide veterans with the exemption but rather the exemption was a mere privilege.

165. Here, the analogue of the criminal defendant rights of "transcending value" referenced in *Speiser* are the liberty rights of all persons to be free of unconsented-to bodily intrusions and medical interventions. This means that unconstitutional conditions doctrine and due process rights *combine* to invalidate the Directive. That result occurs because MSU has not and cannot show that the school's forcing Plaintiffs and those similarly situated to take the vaccine

reduces any risk that they will become infected with and spread the virus to MSU students and personnel.

166. The *Speiser* Court found the oath condition a violation of procedural due process, in part because the burden to establish qualification for the exemption was placed on applicants. *See id.* at 522. The question the Supreme Court saw itself deciding was "whether this allocation of the burden of proof, on an issue concerning freedom of speech, falls short of the requirements of due process." *Id.* at 523.

167. The Court addressed this question by stating the guiding principle that

> Where one party has at stake an interest of transcending value—as a criminal defendant his liberty—this margin of error is reduced as to him by the process of placing on the other party the burden of producing a sufficiency of proof in the first instance …. [But] Due process commands that no man shall lose his liberty unless the Government has borne the burden of producing the evidence and convincing the factfinder of his guilt.

Id. at 525-26.

168. This is especially true when a government actor couples an unconstitutional condition with a procedural system stacked against the right-holder, creating a procedural Due Process violation.

169. Similar to the California law in *Speiser* "creat[ing] the danger that … legitimate utterance will be penalized," 357 U.S. at 526, the process MSU has established in relation to taking COVID-19 vaccines poses dangers to Plaintiffs' health (and thus to their liberty interests) as well as threatening them with penalties if they do not comply.

170. Indeed, more so than in *Speiser*, the factual issues involved in this case are complex. "How can a claimant … possibly sustain the burden of proving the negative of these complex factual elements? In practical operation, therefore, this procedural device must necessarily

produce a result which the State could not command directly." *Id.* There is perhaps no better encapsulation than the preceding sentence by the Supreme Court of how unconstitutional conditions doctrine and Due Process can and do intersect and reinforce one another. *See also id.* at 529 ("The State clearly has no such compelling interest at stake as to justify a short-cut procedure which must inevitably result in suppressing protected speech.").

171. For these reasons, MSU cannot by means of its Directive effectively flip the burden of proof and require Plaintiffs and others similarly situated to prove that it is safe for them to perform their respective jobs while unvaccinated. And setting up such a process, which is what MSU's directive does, thereby represents a concurrent *procedural* due process of law violation *and* an unconstitutional condition burdening their liberty interests to be free of unwanted medical interventions.

172. *Speiser* also rests on the mismatch between the loyalty oath California required and the grant of a property tax exemption to veterans. "[T]he State is powerless to erase the service which the veteran has rendered his country; though he be denied a tax exemption, he remains a veteran." *Id.* at 528.

173. In this situation, there is an equally jarring logical incongruity. MSU's Directive is terse. It offers no justifications for why the penalties and other restrictions it establishes are appropriate and tailored to members of the University community who have acquired robust natural immunity. And the rationales it does offer are not logically coherent. Whatever MSU is trying to decree through its unconstitutional-conditions sleight of hand, Plaintiff remains a community member with natural immunity as a matter of pre-Directive fact (just as the *Speiser* veterans remained veterans as a matter of pre-tax-law fact), and the existence of such immunity fully serves the supposed purposes of the public-health protection that MSU says that it is pursuing.

174. The proportionality of the Directive is also deficient because it does not seek to assess the current antibody levels of its targets, something that it is now feasible for medical science to test.[10]

175. The Directive is not a mere initial presumption that vaccination is superior to natural immunity (a contention that would have to be borne out by the science in any event or else MSU had no business adopting its Directive) that Plaintiffs can try to overcome.

176. The Directive is, in essence, *a conclusive presumption* (and thus a procedural due process of law violation) that vaccination is required (even as to vaccines of far-lesser efficacy), unless the risks of the vaccine to a particular recipient warrant a special exception.

177. But Plaintiffs and others with natural immunity possess equal or higher degrees of protection than those who took one or more of the various inferior vaccines that MSU accepts and equivalent levels to those who took the mRNA vaccines approved by the FDA.

178. MSU has deemed all vaccines to be equally protective in the fictitious presumption it has established. There is no scientific basis for the suppositions that MSU has built into its Directive.

179. For the foregoing reasons, the *de facto* presumptions the Directive establishes become another part of MSU's procedural due process of law violations that run afoul of unconstitutional conditions doctrine. In short, by allocating burden of proof responsibility to those with natural immunity like Plaintiffs, coupled with MSU stacking the process deck with

[10] Such antibody testing was not possible more than a century ago when *Jacobson v. Massachusetts* was decided, as diagnostic antibody testing was not invented until the 1970's. 197 U.S. 11 (1905) (upholding a city regulation fining individuals $5 if they refused to take Smallpox vaccine). *See The History of ELISA from Creation to COVID-19 Research*, MOLECULAR DEVICES, *available at* https://www.moleculardevices.com/lab-notes/microplate-readers/the-history-of-elisa (last visited Aug. 1, 2021).

presumptions that Plaintiffs have shown are scientifically unwarranted, MSU contravenes the Due Process Clause. *See Perry v. Sinderman*, 408 U.S. 592, 597 (1972) (holding that the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests"); *Wieman v. Updegraff*, 344 U.S. 183, 192 (1952) ("We need not pause to consider whether an abstract right to public employment exists. It is sufficient to say that constitutional protection does extend to the public servant whose exclusion pursuant to a statute is patently arbitrary or discriminatory").

COUNT III: VIOLATION OF THE SUPREMACY CLAUSE

180. Plaintiffs reallege and incorporate by reference all the foregoing allegations as though fully set forth herein.

A. The EUA Statute Preempts MSU's Directive

181. Defendants' Directive requires Plaintiffs and others similarly situated to receive a vaccine in order to continue working for MSU without regard to their natural immunity or the advice of their doctors.

182. Plaintiffs and others must also divulge personal medical information by uploading it into an online form and are threatened with disciplinary action if they decline to comply with these arbitrary mandates.

183. The Directive thus coerces or, at the very least, unduly pressures, Plaintiffs and others like her into getting vaccines that FDA approved only for emergency use.

184. The United States Constitution and federal laws are the "Supreme Law of the Land" and supersede the constitutions and laws of any state. U.S. Const. art. VI, cl. 2.

185. "State law is pre-empted to the extent that it actually conflicts with federal law." *English v. General Elec. Co*., 496 U.S. 72, 79 (1990) (internal citations and quotation marks omitted).

186. Federal law need not contain an express statement of intent to preempt state law for a court to find any conflicting state action invalid under the Supremacy Clause. *See Geier v. American Honda*, 520 U.S. 861, 867-68 (2000).

187. Rather, federal law preempts any state law that creates "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399-400 (2012).

188. The EUA statute mandates informed and voluntary consent. *See John Doe No. 1 v. Rumsfeld*, No. Civ. A. 03-707(EGS), 2005 WL 1124589, *1 (D.D.C. Apr. 6, 2005) (allowing use of anthrax vaccine pursuant to EUA "on a *voluntary* basis"). *See also* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

189. It expressly states that recipients of products approved for use under it be informed of the "option to accept or refuse administration," and of the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." *Id.*

190. Since MSU's Directive (a state program) coerces Plaintiffs by making enjoyment of their constitutionally and statutorily protected consent rights contingent upon receiving an experimental vaccine, it cannot be reconciled with the letter or spirit of the EUA statute. *See* 21 U.S.C. § 360bbb-3.

191. The conflict between the Directive and the EUA statute is particularly stark given that the statute's informed consent language requires that recipients be given the "option to refuse"

the EUA product. That is at odds with the Directive effectively forcing Plaintiffs to sustain significant injury to their career if they do not want to take the vaccine.

192. Put differently, the Directive frustrates the objectives of the EUA process. *See Geier*, 520 U.S. at 873 (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

B. The OLC Opinion Cannot Save MSU's Directive from Preemption

193. As noted above, OLC made a memorandum available to the public on July 27, 2021 (dated July 6, 2021) opining that the EUA status of a medical product does not preclude vaccine mandates that might be imposed by either the public or private sectors. *See* "Memorandum Opinion for the Deputy Counsel to the President," *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* (July 6, 2021) (OLC Op.) at 7-13, *available at* https://www.justice.gov/olc/file/1415446/download (last visited Aug.1, 2021).

194. Of course, the separation of powers dictates that this Court is not bound by the OLC Opinion—an advisory opinion written *by* the Executive Branch *for* the Executive Branch. *See Citizens for Responsibility & Ethics in Wash. v. Office of Admin.*, 249 F.R.D. 1 (D.C. Cir. 2008) ("OLC opinions are not binding on the courts[; though] they are binding on the executive branch until withdrawn by the Attorney General or overruled by the courts[.]") (cleaned up).

195. Relatedly, the Justice Department until only recently took a very different approach. *See* Attorney General Memorandum, *Balancing Public Safety with the Preservation of Civil Rights* (Apr. 27, 2020), *available at* https://www.justice.gov/opa/page/file/1271456/download (last visited Aug. 26, 2021, 2021) ("If a state or local ordinance crosses the line from an appropriate exercise of authority to stop the spread of COVID-19 into an overbearing infringement of constitutional and statutory protections, the Department of Justice may have an obligation to

address that overreach in federal court."). *See also* Kevin Liptak, CNN, *Biden Jumps Into Vaccine Mandate Debate as VA Requires Health Workers to Get Vaccinated* (July 26, 2021) ("The [new OLC] opinion marks a reversal from the previous administration. Last year, Attorney General William Barr used the Justice Department's legal power to try to fight certain Covid restrictions, including joining some businesses that sought to overturn state mask mandates."), *available at* cnn.it/37bwAbl (last visited Aug. 26, 2021).

196. Moreover, the OLC Opinion is entirely silent on the issue of preemption. As such, it cannot be read even as offering a potentially persuasive legal view on whether the MSU Policy is preempted by the EUA statute or not. In light of what this Count pleads, the OLC opinion is a legal *non sequitur*.

197. The OLC Opinion is also premised on faulty reasoning. While recognizing that EUA products have "not yet been generally approved as safe and effective," and that recipients must be given "the option to accept or refuse administration of the product," the Opinion nevertheless maintains that the EUA vaccines can be mandated. OLC Op. at 3-4, 7.

198. According to OLC, the requirement that recipients be "informed" of their right to refuse the product does not mean that an administrator is precluded from mandating the vaccine. All that an administrator must do, in OLC's view, is tell the recipient they have the *option* to refuse the vaccine. *Id.* at 7-13.[11] That facile interpretation sidesteps the fact that the Directive's (or other similar policies') employment consequences effectively coerce or at least unconstitutionally

[11] The OLC opinion is as irrelevant to the constitutional questions in this case posed by Counts I and II as it is to the preemption questions in Count III. For it was no answer in *Speiser* to the due process and unconstitutional conditions problems created by California's property tax exemption and oath system for the courts to breathe a sigh of relief when the state's tax authorities could simply tell veterans applying for the tax exemption that they could just go away and forgo the tax exemption. The Constitution and the text of congressional statutes cannot be so easily dodged.

leverage the MSU community into taking the vaccine, reducing to nothingness both the constitutional and statutory rights of informed consent. This approach of stating the obvious but ignoring competing arguments is likely why the Opinion remained mum on the doctrine of preemption.

199. Recognizing the illogic of the Opinion and its inability to square its construction with the text of the EUA statute, OLC admits that its "reading … does not fully explain why Congress created a scheme in which potential users of the product would be informed that they have 'the option to accept or refuse' the product." *Id.* at 10. This understatement would be droll but for the serious rights at stake, especially given that the elephant in the room—which the OLC Opinion ignores—is the Supremacy Clause and the preemption doctrine that Clause powers. In truth, Congress called for potential vaccine recipients to be informed precisely so that they could decide whether to refuse to receive an EUA product. OLC's obtuse reading of the statute blinks reality.

200. In other words, nothing in the OLC Opinion addresses the fact that if it were taken as a blanket authorization for state and local governments to impose vaccine mandates, a vital portion of the EUA statute's text would be rendered superfluous. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") (cleaned up).

201. Yet, OLC turns around and claims that Congress would have explicitly stated if it intended to prohibit mandates for EUA products. *Id.* at 8-9. But Congress *did* say so. The plain language states that the recipient of an EUA vaccine must be informed "of the option to accept or refuse the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). Especially when read against the backdrop

of what the Constitution requires *and* against the common law rules from which the constitutional protections for informed consent arose, Congress's intent to protect informed consent is pellucid. And Congress "is understood to legislate against a background of common-law … principles," *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991).

202. The EUA statute's prohibition on mandating EUA products is reinforced by a corresponding provision that allows the President, in writing, to waive the option of those in the U.S. military to accept or refuse an EUA product if national security so requires. 10 U.S.C. § 1107a(a)(1). That provision would be redundant if consent could be circumvented merely by telling a vaccine recipient that he or she is free to refuse the vaccine but nonetheless must suffer various adverse employment consequences violating the unconstitutional conditions doctrine.

203. To circumvent the statutory text about the military waiver, OLC spins out a tortured argument under which the President's waiver would merely deprive military members of their rights to *know* that they can refuse the EUA product—rather than waiving their rights to actually refuse the product. OLC Op. at 14-15.

204. Unsurprisingly, OLC's strained reading runs counter to the Department of Defense's understanding of this statutory provision. As the OLC Opinion acknowledges, "DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section 1107a." *Id.* at 16 (citing DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008)).

205. OLC even acknowledges that its opinion is belied by the congressional conference report, which also contemplated that 10 U.S.C. § 1107a(a)(1) "would authorize the President to waive *the right of service members to refuse administration of a product* if the President

determines, in writing, that affording service members the right to refuse a product is not feasible[.]" *Id.* (quoting H.R. Rep. No. 108-354, at 782 (2003) (Conf. Rep.)).

206. Unlike OLC, this Court must not ignore the plain statutory prohibition on mandating EUA products. Though released to much fanfare in the media, the Court should discount the severely flawed OLC Opinion in its entirety, affording it no weight in this litigation.

C. The FDA's Approval of the Comirnaty Vaccine Does Not Save MSU's Directive from Preemption

207. The other defense that we anticipate MSU mounting is premised on the recent FDA approval of the Comirnaty Vaccine.

208. That the Comirnaty Vaccine has received full FDA approval does not foreclose the preemption argument presented in this Count, since this approval does not extend to the BioNTech Vaccine, which is actually available. Indeed, even Pfizer acknowledges that the two vaccines are "legally distinct." (Attachment C).

209. The two Pfizer vaccines are legally distinct and include differences. For example, the two vaccines have different number of ingredients: Comirnaty has eleven (11) ingredients while Pfizer-BioNTech has just ten (10) ingredients. FDA, Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) (Aug. 23, 2021), *available at* https://www.fda.gov/media/151733/download (last viewed Nov. 4, 2021).

210. The approval announcement posted on the FDA's website reads, "On August 23, 2021, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the PfizerBioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older."

211. While Pfizer's Comirnaty approval letter states that its two vaccines share the same formulation, the FDA concedes that "the products are legally distinct with certain differences . . ." *Id.* (emphasis added).

212. To date, no entity has revealed, nor have Plaintiffs been able to obtain, any evidence indicating what those "certain differences" may be. Despite this, the FDA asserts that the two formulations can be used interchangeably.

213. For example, in the FDA's fact sheet for recipients and caregivers, for example, it reads, "The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series." *Id.*

214. In a press release announcing Pfizer's collaboration with Brazil's Eurofarma to manufacture COVID-19 vaccine doses, Pfizer wrote, "COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech" and "PfizerBioNTech COVID-19 Vaccine has received EUA from FDA." The press release continued, stating, "This emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) . . ." *Pfizer, Pfizer and BioNTech Announce Collaboration with Brazil's Eurofarma to Manufacture COVID-19 Vaccine Doses for Latin America* (Aug. 26, 2021), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-brazils (last visited Nov. 3, 2021).

215. Then, in a September 6, 2021, press release announcing a submittal to a request by the European Medicines Agency (EMA) to update its Conditional Marketing Authorization (CMA) for a booster dose, BioNTech–Pfizer's co-partner in the production of the Pfizer-BioNTech

COVID-19 vaccine–clearly states, "The Pfizer-BioNTech COVID-19 vaccine has not been approved or licensed by [FDA]" but has been authorized under an EUA. Press Release, *Pfizer and BioNTech Submit a Variation to EMA with the Data in Support of a Booster Dose of COMIRNATY®, BIONTECH* (Sept. 6, 2021), *available at* https://investors.biontech.de/node/10581/pdf (last visited Nov. 3, 2021).

216. The claim that the two vaccines are interchangeable comes from a Guidance document, which does not carry force of law and is contradicted by Pfizer's own reissuance letter. *See Christensen v. Harris County*, 529 U.S. 576, 587-88 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference."); *Appalachian Power v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (guidance documents that agencies treat as *de facto* law are void because they did not run the notice-and-comment gauntlet) (setting aside an agency guidance document in its entirety); *see also Maple Drive Farms Ltd. v. Vilsack*, 781 F.3d 837, 857 (6th Cir. 2015) (instructing USDA to carefully consider on remand whether its approach to the term "prior-converted wetlands" ran afoul of *Appalachian Power*).

217. The FDA cannot convert a legally distinct product that is available (the BioNTech vaccine) into a fully approved vaccine (Comirnaty) that is not yet widely available. The FDA, via a mere guidance document, is improperly trying to establish equivalence between what are two legally distinct vaccines. That is improper as a general matter of administrative law. It is yet more improper since it is a maneuver conducted to override federal statutory rights to informed medical consent.

218. MSU cannot be permitted to rely on mere FDA-issued guidance documents, especially not where doing so would vitiate clear statutory rights.

219. Moreover, specifically referring to the Comirnaty Vaccine, Pfizer has admitted that there "is not sufficient approved vaccine available for distribution to this population in its entirety at the time of the reissuance of this EUA." (Attachment C).

220. Since the Comirnaty Vaccine, being the only FDA-approved vaccine, is not widely available, and certainly is not available to all members of the population, per the manufacturer's own admission, the EUA statute's sphere of preemption continues to apply to override MSU's Directive. Worse yet, no publicly released documents from MSU indicate that MSU has even considered the issue of federal preemption and whether the full approval granted to the unavailable Comirnaty Vaccine has any significance to the rights of Plaintiffs and the Class.The federal government, in issuing its own mandate, acknowledges that "Depending on employees' locations, they may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot." *Id.*

221. Thus, even if the Comirnaty and BioNTech are factually identical—which it should be the Government's burden to establish and which it has not done—MSU cannot show that MSU employees have access to the Comirnaty. Therefore, they may be forced to take only EUA-approved vaccines, contravening the informed consent provision of the EUA statute.

D. The Supremacy Clause, the Nuremburg Code, and Related Sources of Law

222. Just as Congress prohibited the federal government from mandating EUA products, the state governments cannot do so, for the Supremacy Clause dictates that the EUA statute must prevail over conflicting state law or policy.

223. Defendants' Directive is thus preempted by federal law. *See* U.S. Const. art. VI, cl. 2; *see also Kindred Nursing Ctrs. Ltd P'ship v. Clark*, 137 S. Ct. 1421 (2017) (holding that Federal Arbitration Act preempted incompatible state rule); *Hughes v. Talen Energy Marketing, LLC*, 136 S. Ct. 1288, 1297 (2016) ("federal law preempts contrary state law," so "where, under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" the state law cannot survive).

224. For similar reasons, the Directive violates the 1947 Nuremberg Code, a multilateral agreement between the United States, USSR, France, and the United Kingdom, governing human experimentation and inspired, of course, by events that took place during the Holocaust. The Nuremberg Code expressly states that "[t]he voluntary consent of the human subject is *absolutely essential*" and prohibits experimental treatments on anyone using "force, fraud, deceit, duress, overreaching, or other ulterior forms of constraint or coercion." United States Holocaust Museum, *Nuremburg Code*, https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code (last visited Aug. 26, 2021) (emphasis added).

225. Title 45 of the Code of Federal Regulations part 46 is to similar effect. As is the Helsinki Declaration and the International Covenant on Civil and Political Rights adopted by the United Nations, to which the United States is a party. *See* International Covenant on Civil and Political Rights, pt III, art. 7, *available at* https://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx (last visited Aug. 26, 2021); World Medical Association, *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, *available at* https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (last visited Aug. 26, 2021).

226. Defendants' Directive is invalid pursuant to Article VI, Cl. 2 of the United States Constitution, and must be enjoined and set aside.

ADDITIONAL LEGAL CLAIMS

227. Plaintiffs have suffered and will continue to suffer damage from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiffs or class members for the deprivation of their constitutional and statutory rights. They will suffer irreparable harm—both to their constitutional rights and to their physical well-being if coerced into taking the vaccine—unless this Court enjoins Defendants from enforcing their Directive.

228. 42 U.S.C. § 1983 provides a civil right of action for deprivations of constitutional protections taken under color of law.

229. Plaintiffs (and those similarly situated) are entitled to declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 because they are being deprived of "rights, privileges, or immunities secured by the Constitution and laws." Section 1983 thus supports both Plaintiffs' constitutional and statutory causes of action against MSU defendants because Section 1983 protects rights "secured by the Constitution *and* laws." 42 U.S.C. § 1983 (emphasis added).

230. Likewise, Plaintiffs are entitled to injunctive relief pursuant to *Ex parte Young*'s nonstatutory equitable right of action. *See Verizon Md., Inc. v. Public Serv. Comm'n of Md.*, 535 U.S. 635, 648 (2002) ("We conclude that 28 U.S.C. § 1331 provides a basis for jurisdiction over Verizon's claim that the Commission's order requiring reciprocal compensation for ISP-bound calls is pre-empted by federal law. We also conclude that the doctrine of *Ex parte Young* permits Verizon's suit to go forward against the state commissioners in their official capacities.").

231. In sum, Plaintiffs are entitled to a judgment declaring that the Directive violates the Supremacy Clause and an injunction restraining Defendants' enforcement of the Directive, since it is preempted by federal law.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that the Court find the Defendants have committed the violations alleged and described above, and issue in response the following:

A. A declaratory judgment that MSU's Directive infringes upon Plaintiffs' constitutionally protected rights to protect their bodily integrity and autonomy and to refuse unnecessary medical treatment.

B. A declaratory judgment that MSU's Directive represents an unconstitutional condition, especially in light of a set of explicit and implicit procedures that violate the Due Process Clause of the Fourteenth Amendment.

C. A declaratory judgment that MSU's Directive is preempted under the Supremacy Clause because the Policy, a state program, conflicts with the federal EUA Statute; AND

D. Temporary, preliminary and permanent injunctive relief restraining and enjoining Defendants, their agents, servants, employees, attorneys, and all persons in active concert or participation with them (*see* Fed. R. Civ. P. 65(d)(2)), and each of them, from enforcing coercive or otherwise pressuring policies or conditions similar to those in the Directive that act to compel or try to exert leverage on MSU employees with natural immunity to get a COVID-19 vaccine.

E. Plaintiffs seek nominal damages of $1.

JURY DEMAND

Plaintiffs herein demands a trial by jury of any triable issues in the present matter.

November 5, 2021

Respectfully submitted,

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