

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

JEANNA NORRIS, on behalf of herself)
and all others similarly situated,)

Plaintiffs,)

v.)

CIVIL ACTION NO. _____

SAMUEL STANLEY, JR., in his)
official capacity as President of)

(ORAL ARGUMENT REQUESTED)

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,)

Defendants.)

PLAINTIFES' BRIEF IN SUPPORT OF MOTION
FOR A PRELIMINARY INJUNCTION
(ORAL ARGUMENT REQUESTED)

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INTRODUCTION

Pursuant to Rule 65(a) of the Federal Rules of Civil Procedure, Plaintiff Jeanna Norris seeks preliminary injunctive relief in this matter on behalf of herself and similarly situated individuals,¹ against the Defendants identified above (collectively, “Defendants”), who are governing officials or managers of Michigan State University (“MSU” or “the University”), including the President and Chair of the Board of Trustees (“the Board”). They are sued in their official capacities for purely prospective injunctive and declaratory relief. Plaintiff, Jeanna Norris, also seeks a temporary restraining order (“TRO”) (or administrative stay) to prevent Defendants from implementing MSU’s vaccine mandate (“the Directive”) due to her natural immunity to COVID-19.

The Directive requires all employees to receive a COVID-19 vaccine (permitting *any* that has been approved by the World Health Organization [“WHO”]) unless they receive a religious or medical exemption. MSU expressly excludes natural immunity as a basis for a medical exemption. Those who do not comply with MSU’s Directive by August 31, 2021, are threatened with disciplinary action, including termination of employment.

Plaintiff possesses robust natural immunity following a COVID-19 infection, as confirmed in two recent antibody tests. In fact, the level of protection conferred by her natural immunity is *stronger* than that provided by many of the vaccines that MSU accepts, including the Sinovac, Sinopharm, and Janssen vaccines. Plaintiff’s doctor, immunologist Hooman Noorchashm, M.D., Ph.D., attests that vaccinating an individual who has recovered from COVID-19, especially with

¹ Plaintiff is prepared to quickly brief class-certification issues but is also confident that if this Court orders preliminary injunctive relief against MSU here, MSU will cease applying its unlawful Directive as a general matter while any such preliminary injunction is in force. Freezing the *status quo* while this litigation goes forth as to class certification and on the merits is entirely appropriate.

the antibodies levels she possesses, is not merely fruitless, but presents a risk of harm. Vaccinating her thus violates fundamental tenets of medical ethics, which prohibit unnecessary medical interventions.

1. Invasion of the Right of Medical Consent. MSU states on its website that it refuses to exempt Plaintiff from the vaccine requirement based on her naturally acquired immunity. Under the Ninth and/or Fourteenth Amendments to the United States Constitution, Plaintiff has a right to decline medical treatment absent a compelling state interest. No such interest can be shown here, since she is immune to a COVID-19 re-infection to an equal or greater extent than vaccinated personnel. Thus, the Directive constitutes an unlawful infringement upon her constitutional rights.

2. Unconstitutional Conditions. In addition to the Directive's flat incursions on bodily autonomy, the unconstitutional conditions doctrine prohibits state actors from burdening the Constitution's enumerated rights by withholding benefits from those who exercise them. Here, MSU's Directive requires Plaintiff to surrender her Ninth and Fourteenth Amendment rights, or face termination and other disciplinary action. It therefore constitutes an unlawful set of conditions. Relatedly, as most applicable unconstitutional conditions case law reveals, the system MSU has established to resolve applications for medical exemptions runs afoul of the Fourteenth Amendment's Due Process Clause.

3. Federal Preemption. Finally, the three COVID-19 vaccines available in the United States have been approved only under the Emergency Use Authorization ("EUA") statute.² This

² While the Pfizer Comirnaty Vaccine has been granted full FDA approval, it appears that particular vaccine is *not* widely available due to limited supply, and is legally distinct from the Pfizer BioNTech, which is the vaccine actually in circulation. See "FDA Approves First COVID-19 Vaccine," *US Food & Drug Administration* (Aug. 23, 2021), available at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited Aug. 25, 2021); FDA, *Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers)* (Pfizer) (Aug. 23, 2021) (Attachment C).

federal law requires the free and informed consent of individuals who receive products authorized for use under it. The coercive nature of the Directive conflicts with the objective and spirit of the statute, and accordingly is preempted by the Supremacy Clause of the United States Constitution.

Plaintiff is likely to prevail on the merits. Given that she is being forced to choose between her health (a core liberty interest) and damage to her career, including possible termination of her employment, and that her constitutional rights are being blatantly violated, if the Court does not issue a TRO and/or a preliminary injunction, Plaintiff will suffer irreparable harm, including infringement of her Ninth and/or Fourteenth Amendment rights to bodily autonomy, due process, and other statutory and privacy interests. At the same time, neither Defendants nor the public will be harmed in any way by issuance of a TRO and/or preliminary injunction, as Plaintiff possesses natural immunity to COVID-19, and thus is exceedingly unlikely to infect anyone. Moreover, the public has an interest in seeing Plaintiff's constitutional rights vindicated. Accordingly, this Court should issue a TRO and/or preliminary injunction to protect the *status quo* while this matter works its way through the legal process.

I. FACTS

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

The novel coronavirus, SARS-CoV-2, which can cause the disease COVID-19, is a contagious virus spread mainly through person-to-person contact.³ FDA approved three vaccines pursuant to the federal EUA statute, 21 U.S.C. § 360bbb-3, between December of 2020 and February of 2021: (1) the Pfizer BioNTech, (2) Moderna, and (3) Johnson & Johnson (Janssen)

³ More background is laid out in Complaint ¶¶ 12-16.

vaccines. The EUA statute states that individuals to whom the product is administered must be informed: (1) that the Secretary has authorized emergency use of the product; (2) of the significant known and potential benefits and risks of such use, and the extent to which such benefits and risks are unknown; and (3) 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. *See* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). Inherently, the EUA system confers on all individuals, in consultation with their respective doctors, the risk-benefit choice of deciding for themselves whether to accept or reject a given EUA medical treatment.

B. PRIOR INFECTION CONFERS NATURAL IMMUNITY TO COVID-19 AT LEAST AS ROBUST AS VACCINE IMMUNITY

As explained by Dr. Jayanta Bhattacharya of Stanford University (M.D., Ph.D.), and Dr. Martin Kulldorff (Ph.D.), of Harvard University, multiple, extensive, peer-reviewed studies comparing natural and vaccine immunity have concluded overwhelmingly that natural immunity provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna). (Joint Decl. ¶ 18). Natural and vaccine immunity utilize the same basic immunological mechanism—stimulating the immune system to generate an antibody response. (Joint Decl. ¶ 16). In fact, the level of antibodies in the blood of those who have naturally acquired immunity was initially the benchmark in clinical trials for determining the efficacy of vaccines. (Joint Decl. ¶ 16). And, as there is currently more data on the durability of natural immunity than there is for vaccine immunity, researchers rely on their findings with respect to naturally acquired immunity to predict the durability of vaccine-acquired immunity. (Joint Decl. ¶ 23).

As time passes, data demonstrating that naturally acquired immunity is more durable and longer lasting than vaccine immunity is accumulating. A study from Israel, released only days ago, found that vaccinated individuals had 13.1 times higher risk of testing positive, 27 times greater risk of symptomatic disease, and around 8.1 times higher risk of hospitalization than unvaccinated individuals with naturally acquired immunity. (Joint Decl. ¶ 20). 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 two-dose vaccine-induced immunity.” (Joint Decl. ¶ 20). See David Rosenberg, *Natural Infection vs. Vaccination: Which Gives More Protection?* ISRAELNATIONALNEWS.COM (July 13, 2021), available at <https://www.israelnationalnews.com/News/News.aspx/309762> (last visited Aug. 1, 2021) (those who received BioNTech Vaccine were 6.72 times more likely to suffer subsequent infection than those with natural immunity); 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. 4, 2021) (declining efficacy of Pfizer protection against infection).

Prolonged immunity also stems from 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). See Interview with Dr. Harvey Risch, Yale School of Medicine, *Ingraham Angle* (July 26, 2021), available at <https://bit.ly/3zOL6Sx> (last visited Aug. 27, 2021). In short, these studies confirm the efficacy of natural immunity against reinfection of COVID-19 and show that almost all reinfections are less severe than first-time infections and virtually never require hospitalization. (Joint Decl. ¶ 19).

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). 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).

While the CDC and the media have touted a study from Kentucky as proof that those with naturally acquired immunity should get vaccinated, that study is being misconstrued and misleadingly characterized. That is because the Kentucky study compared individuals who had only natural immunity to those who had natural immunity *and* had received the vaccine. The proper approach would have been to compare those with only naturally acquired immunity to those with only vaccine-acquired immunity. Hence, the CDC's conclusion from the Kentucky study is unwarranted. As Drs. Bhattacharya and Kulldorff explain, although individuals with naturally acquired immunity who received a vaccine showed increased antibody levels, "[t]his does not mean that the vaccine [further] increases protection against symptomatic disease, hospitalizations or deaths." (Joint Decl. ¶ 37; Noorchashm Decl. ¶ 29, 31). Furthermore, as discussed at length in the complaint, many of the vaccines that MSU considers acceptable are far inferior to natural immunity. *See* Complaint ¶¶ 51-56.

Drs. Bhattacharya and Kulldorff explain, that there is no valid 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).

C. COVID-19 VACCINES’ SIDE EFFECTS, THE PRINCIPLE OF MEDICAL NECESSITY, AND PLAINTIFF’S NATURAL IMMUNITY

All medical procedures carry some risk of adverse effects, and the COVID-19 vaccines are no exception. For this reason, a fundamental tenet of medical ethics is that of “medical necessity,” which requires public health agents to utilize “the least intrusive” means possible to achieve a given end, because every medical procedure carries some risk. (Noorchashm Decl. ¶ 19; Joint Decl. ¶¶ 25-28, 43). *See* Complaint ¶¶ 73-75.

Although 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 include minor side effects, as well as rarer ones requiring hospitalization or causing death. (Joint Decl. ¶¶ 26-28). Other side effects may occur that remain unknown at this time. (Joint Decl. ¶¶ 26-28). As Drs. Bhattacharya and Kulldorff observe, “[a]ctive investigation to check for safety problems is still ongoing.” (Joint Decl. ¶ 26). Thus, COVID-19 recovered patients with detectable levels of antibodies should not be required to receive vaccines, as “[f]or them, it simply adds a risk[.]” (Joint Decl. ¶ 9).

None of the three vaccines in use in the United States has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. (Noorchashm Decl. ¶30, Attachment B). Indeed, trials conducted so far have *specifically excluded* survivors of previous COVID-19 infections. (Noorchashm Decl. ¶ 28). Existing clinical reports and studies indicate that individuals with a prior infection and natural immunity face an *elevated* risk of adverse effects from the vaccine, compared to those who have never contracted COVID-19. (Noorchashm Decl. ¶¶ 21-28; Joint Decl. ¶ 27). This is consistent with general immunological

understandings, which recognize that “vaccinating a person who is recently or concurrently infected [with any virus] can reactivate, or exacerbate, a harmful inflammatory response to the virus. This is NOT a theoretical concern.” (Noorchashm Decl. ¶ 27). The heightened risk of adverse effects appears to result from “preexisting immunity to SARS-CoV-2 [, which] may trigger unexpectedly intense, albeit very 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).

Plaintiff is a supervisory Administrative Assistant and Fiscal Officer at MSU, where she has been employed for eight years. (Norris Decl. ¶ 1). She is stepmother to her husband’s five children, and the family’s primary breadwinner. (Norris Decl. ¶ 3). In November of 2020, she contracted COVID-19 (Norris Decl. ¶ 8).

On August 20, 2021, Plaintiff consulted with Dr. Hooman Noorchashm, an immunologist who previously worked at Harvard University and University of Pennsylvania. Dr. Noorchashm prescribed Plaintiff a full COVID-19 serological screening, which confirmed her previous diagnosis (Noorchashm Decl. ¶ 7(f), (g) & 13). Dr. Noorchashm, as well as Dr. Bhattacharya, concluded that Plaintiff is protected by natural immunity. (Noorchashm Decl. ¶ 7(g) & 13; Joint Decl. ¶ 44). Dr. Bhattacharya explained that Plaintiff’s lab results “indicate the presence of both spike-protein and nucleocapsid protein antibodies; the latter is a reliable sign of previous natural infection.” Concluding that “there is no good reason that [Plaintiff] should be vaccinated,” he opines that “[a]t the very least, the decision should be left to [Plaintiff] and her doctors without coercion applied by the University.” (Joint Decl. ¶ 44).

Based on his analysis of Plaintiff’s antibodies screening test and overall medical history, Dr. Noorchashm concluded that *it is medically unnecessary* for Plaintiff to undergo a full-course

vaccination procedure to protect herself or the community from infection. (Noorchashm Decl. ¶¶ 12-35). Because every medical procedure carries a risk of adverse consequences, and due to the heightened risk as a result of her naturally acquired immunity, vaccinating Plaintiff violates the rules governing medical ethics (Noorchashm Decl. ¶ 34-35).

D. MSU’S IMPOSITION OF A BLANKET VACCINE REQUIREMENT AS PART OF ITS COVID-19 DIRECTIVES FOR FALL 2021

MSU is a public research university located in East Lansing, Michigan. On July 30, 2021, the University announced via email and on its website, its “COVID directives” for the Fall 2021 term. (Attachment E). The directives were finalized on MSU’s website on August 5, 2021, and included a vaccine mandate (“the Directive”), and “FAQs” to address individuals’ concerns. (Attachments F-G).

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

MSU accepts all FDA-authorized as well as all WHO-approved vaccines. (Attachments E-G). To obtain a medical exemption, an individual must demonstrate: (1) A documented anaphylactic allergic reaction or other severe adverse reaction to any COVID-19 vaccine; (2) A documented allergy to a component of a COVID-19 vaccine; (3) Another documented medical condition that constitutes a disability under the Americans with Disabilities Act; or (4) A limited-term inability to receive a vaccine such as pregnancy or breastfeeding. (Attachment H).

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 G). Employees who do not comply with the vaccine requirements are subject to disciplinary action, including termination of employment. (Attachment G).

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 G).

Also, 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 G). Even employees who have arranged to work remotely during the fall semester must either be vaccinated or obtain a religious or medical exemption. (Attachment G).

Plaintiff requires relief on a tight timeline because MSU did not announce even an early-peek, truncated version of its Directive until a mere month before the August 31, 2021 deadline that it set for employees to receive the vaccine. (Attachments E-G). The earlier versions contained less information than that posted on MSU’s website only three weeks before the deadline. And Plaintiff was not informed that the Directive applied to her, as a remote employee, until August 5.

E. PLAINTIFF HAS EXPERIENCED, AND WILL CONTINUE TO EXPERIENCE, CONCRETE AND PARTICULARIZED HARM AS A DIRECT CONSEQUENCE OF MSU’S DIRECTIVE

MSU’s Directive places Plaintiff in the position of having to choose between her health, her bodily autonomy, and her career. Either she must ignore the advice of her doctor and receive the vaccine—a prospect that endangers her health and is causing her significant emotional distress—or she faces disciplinary action, including termination of her employment, upon which

her family relies. The Directive unmistakably places such coercive pressure on Plaintiff to subject herself to receiving the vaccine that it amounts to an ineluctable mandate. It is obviously designed for that purpose and to have that impact. By threatening adverse professional and personal consequences, MSU's Directive harms Plaintiff's bodily autonomy and dignity; it forces her to endure the stress and anxiety of choosing between her career and her health.

II. ARGUMENT

A. JURISDICTION AND EQUITABLE RELIEF

This court possesses federal question jurisdiction on numerous grounds—constitutional, statutory, and nonstatutory. *See* 28 U.S.C. §§ 1331, 1343(a)(3)-(4); *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); Complaint ¶¶ 8-12; *cf* 28 U.S.C. § 2201-2202 (making available declaratory and related injunctive relief); 42 U.S.C. § 1983 (providing a cause of action against state actors).

Rule 65(a) of the Federal Rules of Civil Procedure allows a court to issue a preliminary injunction after notice has been provided to an adverse party. A preliminary injunction is appropriate if: (1) there is a substantial likelihood of success on the merits; (2) it is necessary to prevent irreparable injury; (3) the threatened injury outweighs the harm the preliminary injunction would cause the other litigant; and (4) the preliminary injunction would not be averse to the public interest. *See Nken v. Holder*, 556 U.S. 418, 434 (2009); *Liberty Coins v. Goodman*, 748 F.3d 682, 689-90 (6th Cir. 2014).

Because MSU has threatened disciplinary action imminently if Plaintiff does not comply, she also requests that the Court issue a TRO to immediately preserve the *status quo*, as otherwise she will suffer immediate and irreparable injury, including but not limited to the loss of her constitutional rights and bodily autonomy (*see* Norris Decl. ¶¶ 10, 15-17). *See* Fed. R. Civ. P.

65(b)(1)(A). Alternatively, she requests an “administrative stay” for the same reasons (irreparable harm). *See, e.g., KindHearts for Charitable Humanitarian Dev. v. Geithner*, 676 F. Supp. 2d 649 (N.D. Ohio 2009) (“The power to stay administrative action is similar to the power to stay judicial action”).

To be clear, Plaintiff is requesting that a TRO (or administrative stay), especially of the proof-of-vaccination mandate, be entered before August 31, 2021, to run until a preliminary injunction can be briefed and entered. This would allow this Court to schedule the remainder of preliminary-injunction briefing as befits its schedule and other matters on its docket. And Plaintiff further prays that as soon as possible after August 31, 2021, a preliminary injunction be issued, designed to stay in place pending the full merits resolution of this litigation.

B. PLAINTIFF HAS A SUBSTANTIAL LIKELIHOOD OF SUCCESS ON THE MERITS

1. MSU’s Policy Violates Plaintiff’s Constitutional Rights to Refuse Unwanted and Unnecessary Medical Care

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 key 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 also* 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.”).

Subsequent Supreme Court decisions are explicit that the Constitution protects a person’s right to “refus[e] unwanted medical care.” *Cruzan*, 497 U.S. at 278. 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). 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).

“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 (6th Cir. 2007). Coercing employees to receive a vaccine—especially those that have been authorized only for emergency use (*see infra*, Point III)—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 they already possess natural immunity to that virus, violates the liberty and privacy interests that the Ninth and Fourteenth Amendments protect. And coercing employees to do so when a vaccine could also *cause harm* to a recipient with natural immunity adds injury to constitutional insult. The goal of Defendants’ Directive is clear: to improve the prevalence of immunity to COVID-19 on campus. The focus should therefore be on *immunity*, by whatever mechanism it is acquired.

The blithe statement on the FAQ page to the effect that vaccinating a naturally immune individual provides “additional protection”—without citation to *any* scientific data—cannot overcome the vast amount of scientific literature that Plaintiff has provided to establish otherwise. And, as all three of the experts weighing in on this issue 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, and it does not establish any discernible additional benefit from vaccinating individuals who possess naturally acquired immunity. (Joint Decl. ¶ 37; Noorchashm Decl. ¶ 29-31). *See* US Centers for Disease Control (2021) "Frequently Asked Questions About COVID19 Vaccination." *Centers for Disease Control* (Aug. 19, 2021), available at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html> (last visited Aug. 26, 2021).

Nor can Defendants show that the Directive is narrowly tailored to a compelling governmental interest. Any benefit that MSU may gain in promoting *immunity* on campus does not extend to vaccinating those individuals who *already have immunity* from the virus—particularly those who can demonstrate such immunity through antibody screenings. To hold otherwise forces us into a never-ending loop: if one shot of the vaccine is good, a second shot of the vaccine is even better, a third shot will provide even more benefits (allegedly), and a fourth cannot be far behind. If *vaccination* is the goal rather than *immunity*, what will prevent the University from ordering an ever-increasing number of booster shots per COVID season? By contrast, focusing on the degree of immunity does not make vaccines an end in themselves but instead recognizes that they are but one means to the praiseworthy end of promoting immunity.

Indeed, MSU's Directive implicitly acknowledges that it lacks a valid public-health basis. 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). In other words, MSU does not even pretend that the mandate is about protecting others, Plaintiff's natural immunity aside. Thus, the Directive infringes on Plaintiff's bodily autonomy without even providing a public health justification.

Another reason 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). 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 nature of the University’s position that naturally acquired immunity cannot be recognized, but even inferior vaccine-acquired immunity will be.

Nor does MSU provide any sound reasoning for the claim that its Directive will protect those who cannot be vaccinated. *First*, college campuses are rarely frequented by individuals under 12 years of age. *Second*, MSU has not provided any information about the number of immunocompromised people living and working on campus, rendering this justification flimsy. *Finally*, as MSU acknowledges, vaccinated individuals can also spread COVID-19. It is thus unclear just how a vaccine mandate will protect the unspecified individuals who are too immunocompromised to receive the vaccine and yet are living or working on campus. In sum, MSU’s justifications for its Directive are not only speculative, but logically incoherent.

Another reason the Directive lacks any constitutional validity is that many of the vaccines that MSU accepts (Janssen, Sinovac, and Sinopharm) vaccines have lower efficacy rates—when it comes to preventing infection—than does naturally acquired immunity. That renders Plaintiff far less likely to contract or spread the virus than those in the MSU community who have been immunized with these inferior vaccines that MSU readily accepts. Yet she is subject to termination while her colleagues who have received these vaccines, and thus pose a *greater* danger, are not.

Furthermore, as Drs. Bhattacharya and Kulldorff attest, the CDC’s statement that “we do not know how long [natural immunity] will last” is “specious,” as we have no more evidence about the duration of vaccine immunity. Worse yet for MSU’s position, scientists estimate the length of vaccine-induced immunity *based upon their observations about the durability of natural immunity*. (Joint Decl. ¶ 23). The CDC provides no evidence or studies to refute the extraordinary amount of evidence establishing 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, 37; Joint Decl. at ¶¶ 15-24).⁴

The State of Michigan’s public policy has also traditionally reflected that it lacks any interest in vaccinating persons for a disease to which they carry antibodies. For instance, Michigan’s law passed by the state legislature mandating the vaccination of school children *explicitly exempts* from the requirements those who can demonstrate existing immunity through serological testing that measures immunity. MICH. ADMIN. CODE R. 325.176 (2021). It is difficult to see even the rational basis for a merely administrative Directive that lacks a natural-immunity exemption where the State permits such an exception from public-school vaccine requirements.

Not only does MSU lack interest in requiring naturally immune employees to receive a COVID-19 vaccine, but Defendants cannot show that the Directive is narrowly tailored to any compelling governmental goal. 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.

⁴ See Complaint ¶¶ 116-17.

By failing to tailor its Directive to only those individuals who lack immunity, MSU forces employees, such as Plaintiff, who have robust natural immunity, to choose between their health, their personal autonomy, and their careers.

The Government is likely to argue that vaccine mandates are permitted under *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), in which the Court held that a city could fine people who refused to get a vaccine for smallpox. *Jacobson*, however, differed in several crucial respects. The penalty for declining the smallpox vaccine was a one-time, \$5 fine, about \$146 in today's currency. See *The Inflation Calculator*, <https://westegg.com/inflation/infl.cgi?money=5&first=1905&final=2020> (last visited Aug. 4, 2021). It is certainly very different from the punishment here, which imposes permanent damage to Plaintiff's career and her livelihood, upon which her family relies.

Moreover, in *Jacobson*, the city was held to have established a cognizable and compelling interest in mandating the vaccine. While Jacobson had a rational fear due to a vaccine injury he had suffered as a child, Jacobson *had not consulted a doctor and did not have natural immunity*.⁵ Moreover, the smallpox vaccine was highly effective at preventing spread of a disease that was *killing approximately 30%* of those infected and disfiguring a large proportion of survivors. See *Smallpox*, WIKIPEDIA, available at <https://en.wikipedia.org/wiki/Smallpox> (last visited Aug. 2, 2021). Surely, courts recognize that the government must have *some* legitimate interest before it can mandate vaccines. For instance, if a state actor required all employees be injected with saline solution, courts undoubtedly would consider those employees' rights to bodily autonomy to prevail over such a policy, since no interest in enforcing it would exist.

⁵ James Stoner, "Vaccination, the Law, and the Common Good," *Law and Liberty* (Aug. 26, 2021), available at <https://lawliberty.org/vaccination-the-law-and-the-common-good/> (last visited Aug. 27, 2021).

Here, Plaintiff possesses natural immunity, so neither she nor the community would benefit from her receiving the vaccine. Moreover, as discussed, it is evident that the COVID-19 vaccines are less effective at preventing infection (and thereby spread of the disease) than natural immunity is at preventing re-infection, and the disease has a significantly lower infection fatality rate. Indeed, *Jacobson itself* recognized that “it is easy, for instance, to [imagine] the case of an adult who is embraced by the mere words of the act,” but where administering the mandated vaccination to such an adult, with a “*particular condition of his health or body[,] would be cruel and inhuman.*” (emphasis added). 197 U.S. at 38.⁶ That is precisely the situation presented here: accordingly, even *Jacobson* militates in Plaintiff’s favor. Medically unnecessary interventions are inhumane interventions.

It should also be noted that Justice Holmes later used the ruling in *Jacobson* to justify the holding in *Buck v. Bell*, a decision infamous as it upheld a Virginia law permitting the forced sterilization of mentally ill women. 274 U.S. 200 (1927) (“It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind.”). While that egregious precedent alone does not invalidate *Jacobson*, the fact that we now recognize forced

⁶ From that perspective—avoiding what would otherwise be “cruel and inhuman” coercion, *Jacobson*’s \$5 fine served merely to test whether a potential vaccine recipient truly harbored a well-founded fear that taking the vaccine could worsen his or her health. (Compare to the reason why insurance companies require co-pays; they demand that patients share healthcare costs with insurers and thus do not overuse medical services.) But the consequences that Plaintiff faces here for noncompliance are not remotely on the order of paying to MSU a less than \$150 fee in today’s dollars designed to disincentivize irrational refusals to get vaccinated. Plaintiff’s desire to avoid taking the vaccine is objectively more than well-founded; indeed, it is the better view of the state of the science. MSU’s mandate thus crosses the line over into the “cruel and inhuman” constitutional territory into which *Jacobson* dared not tread. This is why Dr. Noorchashm sees the issues presented by this case as deeply implicating medical ethics. (Noorchashm Decl. ¶¶ 8-42).

sterilization crosses *Jacobson*'s line into "cruel and inhuman" territory certainly should give pause to those advocating for a broader reading of *Jacobson* or, worse yet, to those advocating that *Jacobson* resolved, for all time, any and every legal dispute about mandatory-vaccination policies of any stripe. For no less than Justice Holmes thought that the power to forcibly sterilize flowed directly from the logic of *Jacobson*. ("The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes Three generations of imbeciles are enough."). *Buck* cannot possibly still be good law, and if *Jacobson* dictated the outcome in *Buck*, then *Jacobson* is also far from unimpeachable precedent.

Nor is the holding in *Klaassen*, 2021 WL 3073926 (order denying preliminary injunction), another case that opposing counsel is likely to cite as resolving the matter in MSU's favor, persuasive here. That was a case in which several student plaintiffs challenged Indiana University's vaccine mandate. But the question of natural immunity was not a significant issue in *Klaassen*. Although one student alleged his natural immunity should exempt him from the university's vaccine mandate, the issue was not litigated extensively, and there was no expert testimony as to the additional harms that the vaccine could cause him, rendering that case distinguishable from this one. *See id.* at 27.

Moreover, that *Klaassen* was brought on behalf of students, not university employees, implicates a different set of issues. Both the District Court and Court of Appeals' decisions addressed the fact that students are often required to provide proof of vaccination, and to follow various rules and procedures as a condition of enrollment and attendance. *See Klaassen v. Trustees of Indiana Univ.*, No. 20-2326, 2021 WL 3281209 (7th Cir. August 2, 2021) (affirming denial of preliminary injunction); *see also Klaassen*, 2021 WL 3073926 at *45-46. Finally, there is a fundamental difference, on the one hand, between students having to enroll in a different university

and, on the other, terminating an existing employee who refuses to undergo an unnecessary medical procedure that poses a risk of harm to her.

The paucity of any legitimate rationale whatsoever for forcing Plaintiff to receive the vaccine, juxtaposed with the lack of medical necessity and infringement upon her bodily autonomy and liberty interests, establishes that she has a substantial likelihood of prevailing on the merits as to this claim.

2. MSU’s Directive Constitutes an Unconstitutional Condition, Burdening Plaintiff’s Enumerated Rights by Coercively Withholding Benefits If She Exercises Them

Unconstitutional conditions case law often references the existence of varying degrees of coercion. According to that body of law, MSU cannot impair Plaintiff’s right 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) (holding unconstitutional a state residency requirement impinging on the constitutionally guaranteed right to interstate travel, in the absence of a compelling state interest).

The Due Process Clause of the Fourteenth Amendment provides that no state may “deprive any person of life, liberty, or property, without due process of law . . .” U.S. Const., amend. XIV, sec. 1. Plaintiff possesses both a liberty interest in her bodily integrity and a property interest in her career. *See Perry v. Sinderman*, 408 U.S. 592, 597 (1972) (explaining that it was impermissible for a college to “refuse[] to renew the teaching contract . . . as a reprisal for the exercise of constitutionally protected rights.”). Often less appreciated in legal circles is that, to prevail, unconstitutional conditions claims do not need to establish that a challenged government policy

amounts to coercion. Instead, it is sufficient that the challenged 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. This is especially true when a government actor couples an unconstitutional condition with a procedural system stacked against the right-holder.

For example, 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; and (c) California was not even obligated to provide veterans with the exemption but rather the exemption was a mere privilege. The *Speiser* Court deemed the oath condition unconstitutional 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.

The Court answered that 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 [For] 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.

Here, the unconstitutional conditions doctrine and due process rights *combine* to invalidate the Directive. MSU has not and cannot show that Plaintiff being forced to take the vaccine reduces any risk that she will become infected with and spread the virus to MSU students and personnel.

See also Lawrence v. Texas, 539 U.S. 558, 562 (2003) (Due Process Clause protects “liberty of the person both in its spatial and in its more transcendent dimensions.”).

Similar to the California law in *Speiser*, which “create[d] 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 Plaintiff’s health (and thus to her liberty interests) as well as threatening her with various forms of penalties and other detriments (which impinge on her property interests). Indeed, more so than in *Speiser*, the factual issues involved in this case are complex. As *Speiser* asks: “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 this by the Supreme Court of how unconstitutional conditions doctrine and Due Process intersect. *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.”). Michigan State similarly possesses no compelling interest that could justify its flawed Directive that, without due process, will inevitably result in at least some unwarranted medical intrusions into the bodies of members of the MSU community.

Perhaps nowhere is this more apparent than in MSU’s unsubstantiated statement that those who have previously contracted COVID-19 must receive the vaccine because it provides “additional protection.” (Attachment G). Drs. Bhattacharya and Dr. Martin Kulldorff easily pierce this thin assertion via their assessment of the CDC’s similar claim and the recent Kentucky study, as failing to “address any of scientific evidence we have provided in our declaration, herein, about the lack of necessity for recovered COVID patients to be vaccinated.” (Joint Decl. ¶ 38). The doctors also note that even the CDC website acknowledges that “[w]e don’t know how long

protection lasts for those who are vaccinated.” (Joint Decl. ¶ 41). Furthermore, this webpage “help[s] people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who already has been infected and recovered will benefit on net from the additional protection provided by vaccination. On this point, the CDC’s statement in its FAQ is non-responsive, and ignores the scientific evidence.” (Joint Decl. ¶ 42).

Additionally, by formulating a Directive without bothering to cite any science whatsoever—though readily understandable on MSU’s part, since no such science exists—MSU is saying that even though strong scientific data supports Plaintiff’s claims to durable natural immunity, she must prove her position at the level of 100% certainty, which is impracticable and amounts to MSU’s imposing an irrebuttable presumption that no one with even robust natural immunity is eligible for a medical exemption. This sort of irrebuttable presumption also violates Plaintiff’s rights to procedural due process of law. *See Wieman v. Updegraff*, 344 U.S. 183, 190 (1952) (“If the rule be expressed as a presumption of disloyalty, it is a conclusive one.”) (invalidating the state action being challenged). Moreover, no vaccine recipient is held to such a standard, and the evidence accumulates every day that those who have received the vaccine—especially some months ago—are *not* immune to infection.

For these reasons, MSU cannot constitutionally flip the burden of proof and require Plaintiff to establish that it is safe for her to perform her work. By setting up such a process, the Directive boils down to a concurrent procedural due process of law violation coupled with an

unconstitutional condition burdening Plaintiff's liberty interest in remaining free of unwanted medical interventions.

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. 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. Whatever MSU is trying to decree through its unconstitutional-conditions sleight of hand, Plaintiff remains a University community member with natural immunity as a matter of pre-Directive fact (just as the *Speiser* petitioners remained veterans as a matter of pre-tax-law fact). And the existence of such immunity fully serves the purposes of the public-health protection that MSU claims to be pursuing. *See Perry*, 408 U.S. at 597 (holding that the government “may not deny a benefit to a person on a basis that infringes his constitutionally protected interests”); *Updegraff*, 344 U.S. at 192 (“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.”); *see also id.* at 191 (“Indiscriminate classification of innocent with [prohibited] activity must fall as an assertion of arbitrary power” and thus “offends due process.”).

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

test.⁷ For the Directive is not a mere 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 Plaintiff can try to overcome. Rather, the Directive amounts to a *conclusive presumption* and thus a procedural due process of law violation that vaccination (even as to vaccines of far-lesser efficacy) is required unless the risks of the vaccine to a particular recipient warrant a special exception. But what if Plaintiff and others with natural immunity possess equal or higher levels of antibodies than many of those who took one or more of the various inferior vaccines? And why has MSU deemed all vaccines to be equally protective in the fictitious presumption it has established? Finally, is there any scientific basis for the presumptions MSU has built into its Directive? The Directive answers none of these questions. It does not even try.

For these 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, allocating burden of proof responsibility to those with natural immunity like Plaintiff, coupled with MSU's stacking the process with presumptions that Plaintiff has shown are scientifically unwarranted, contravene 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"); *Updegraff*, 344 U.S. at 192 ("[C]onstitutional

⁷ Such antibody testing was not feasible more than a century ago when *Jacobson* was decided, as diagnostic antibody testing was not invented until the 1970's. *See also 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).

protection does extend to the public servant whose exclusion pursuant to a statute is patently arbitrary or discriminatory”).

3. MSU’s Policy Is Preempted by the Federal EUA Statute and Thus Barred by the United States Constitution’s Supremacy Clause

a. The EUA Statute Preempts MSU’s Directive

Defendants’ Directive requires Plaintiff to receive a vaccine to continue working for MSU without regard to her natural immunity or the advice of her doctor. She is threatened with disciplinary action if she declines to comply with these arbitrary mandates. The Directive thus coerces or, at the very least, unduly pressures Plaintiff into getting vaccines that FDA approved only for emergency use.

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. “State law is preempted 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). 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). 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).

The federal 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). It expressly states (with emphasis) 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.*

That the Pfizer Comirnaty Vaccine has received full approval does not foreclose this argument since this approval does not extend to the Pfizer BioNTech, the vaccine that is actually available at present. Indeed, even Pfizer acknowledges that the two vaccines are “legally distinct.” (Attachment C). The claim that the two vaccines are interchangeable comes from a mere Guidance document, which does not carry force of law and which 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 (D.C. Cir. 2000). *See also 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*). Pfizer cannot convert a legally distinct product (the BioNTech) into a fully approved vaccine (the Comirnaty).

Moreover, Pfizer states 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). And because Comirnaty, the only fully FDA-approved vaccine, is not widely available, and certainly not to all members of the population, per the manufacturer’s own admission, the force of Plaintiff’s preemption argument under the EUA statute remains nearly as strong as it was prior to Comirnaty’s approval.

Since MSU’s Directive (a state program) coerces Plaintiff by premising enjoyment of her statutorily protected consent rights contingent upon receiving an experimental vaccine, it cannot

be reconciled with the letter or objectives of the EUA statute. *See* 21 U.S.C. § 360bbb-3. 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’s *forcing* Plaintiff to sustain significant injury to her career if she does not want to take the vaccine. 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

The Department of Justice’s Office of Legal Counsel (“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).

Of course, 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). Relatedly, the Justice Department until 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. 1, 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.”).

Moreover, the OLC Opinion is entirely silent on the issue of preemption. As such, it does not offer a persuasive legal view as to whether the MSU Policy is preempted by the EUA statute or not. 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 EUA vaccines can be mandated. OLC Op. at 3-4, 7.

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 he or she has the *option* to refuse the vaccine. *Id.* at 7-13. That stunted interpretation sidesteps the fact that the Policy’s employment consequences effectively coerce or at least unconstitutionally 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.

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. OLC’s obtuse reading of the statute blinks reality.

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 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).

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. *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991) (Congress “is understood to legislate against a background of common-law ... principles.”).

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 would nonetheless encounter various adverse consequences that violated unconstitutional conditions doctrine.

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. This 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)).

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.)).

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.

* * *

Defendants’ Policy 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).⁸

⁸ 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 in Nazi Germany. The

C. PLAINTIFF WILL SUFFER IRREPARABLE HARM ABSENT A PRELIMINARY INJUNCTION

To satisfy the irreparable harm requirement, Plaintiff need only demonstrate that absent a preliminary injunction, she is “likely to suffer irreparable harm before a decision on the merits can be rendered.” *Winter v. NRDC*, 555 U.S. 7, 22 (2008) (citation omitted). “A plaintiff’s harm from the denial of a preliminary injunction is irreparable if it is not fully compensable by monetary damages.” *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 550 (6th Cir. 2007). The deprivation of a constitutional right, “for even minimal periods of time, unquestionably constitutes irreparable injury.” *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

Either Plaintiff gives into MSU’s coercion and receives the vaccine, forcing her to endure infringement of her bodily autonomy, mental distress, and potential injury to her health, or she faces the threat of disciplinary action and harm to her career and all the related property interests therein. As discussed at length above, both options constitute violations of Plaintiff’s Ninth and Fourteenth Amendment rights. *See Rodriguez v. Providence Cmty. Corr., Inc.*, 155 F.Supp.3d 758 (M.D. Tenn. 2015) (“When an alleged deprivation of a constitutional right is involved ... most courts hold that no further showing of irreparable injury is necessary.”); *Jessen v. Village of Lyndon Station*, 519 F. Supp, 1183, 1189 (W.D. Wis. 1981) (finding irreparable injury where plaintiff stood to lose a property right without due process).

Likewise, a preliminary injunction is needed to protect Plaintiff from the unconstitutional conditions MSU’s Directive has placed upon her. *See Alliance for Open Soc. Int’l., Inc. v. USAID*, 651 F.3d 218 (2d Cir. 2011) (upholding grant of preliminary injunction in unconstitutional

Nuremberg Code expressly states that “[t]he *voluntary* consent of the human subject is *absolutely essential*” (emphasis added) and prohibits experimental treatments on anyone using “force, fraud, deceit, duress, overreaching, or other ulterior forms of constraint or coercion.” The Directive likewise violates the Helsinki Declaration. *See* Compl. at ¶¶ 192-193.

conditions case). A preliminary injunction is also warranted to protect Plaintiff's statutory rights, which are being infringed upon by a Directive that is preempted by federal law. *See Edgar v MITE Corp.*, 457 U.S. 624 (1982) (affirming in case where lower court had issued preliminary injunction against a state statute allegedly preempted by federal law); *National Steel Corp. v. Long*, 689 F. Supp. 729 (W.D. Mich. 1988) (noting that preliminary injunction was initially entered in preemption case).

Accordingly, MSU's Policy constitutes a direct and unequivocal infringement upon Plaintiff's constitutional rights, and she need make no additional showing to establish irreparable injury.

D. THE BALANCE OF EQUITIES (INCLUDING THE PUBLIC INTEREST) WEIGHS HEAVILY IN PLAINTIFF'S FAVOR

A preliminary injunction is proper when "the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20. "These factors merge when the Government is the opposing party." *Nken*, 556 U.S. at 435.

"[T]here is a strong public interest in requiring that the plaintiffs' constitutional rights no longer be violated[.]" *Laube v. Haley*, 234 F. Supp. 2d 1227, 1252 (M.D. Ala. 2002); *see also Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) ("[I]t is always in the public interest to prevent the violation of a party's constitutional rights."); *Republican Party of Minn. v. White*, 416 F.3d 738, 753 (8th Cir. 2005) ("It can hardly be argued that seeking to uphold a constitutional protection ... is not per se a compelling state interest."); *Rodriquez*, 155 F. Supp.3d at 771 ("enforcing constitutional rights serves the public interest and the Court does not find such an obvious point to require much more explanation.").

On the other hand, MSU has no interest whatsoever in forcing Plaintiff to get vaccinated, as discussed at length above.

MSU's Directive is unconstitutional and thus the balance of equities weighs heavily in favor of the preliminary injunction.

III. CONCLUSION

For the reasons set out above, the Court should enter a preliminary injunction against MSU's Directive. A form of order is attached as an exhibit to the preliminary injunction motion.

August 27, 2021

Respectfully submitted,

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Admission to this Court forthcoming

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I hereby certify that this Brief contains 10,800 words, as produced by and counted by the Microsoft Word Office 365 software.

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