# 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.	) ) CIV. A. NO. 1:21-cv-00756-PLM-SJB
SAMUEL 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,	) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) )
Defendants.	) )

## PLAINTIFFS' UNOPPOSED MOTION TO EXCEED WORD LIMIT ON REPLY BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Plaintiff, Jeanna Norris, by and through her attorneys, the New Civil Liberties Alliance, and pursuant to W.D. Mich. LGenR 7.1(c), hereby respectfully requests that this Court permit her to exceed the word limit set forth in W.D. Mich. LGenR 7.2(c) for her Reply Brief in Support of Motion for Preliminary Injunction, the word count of which is 8056. Pursuant to W.D. Mich. LGenR 7.1(d), Plaintiff's counsel conferred with counsel for the Defendants, and she has stated that they will not oppose this request to file an oversized brief. The basis and support for this Motion are set forth in greater detail in the Brief in Support submitted concurrently herewith as

required by W.D. Mich. LGenR 7.1(a). We have also attached a copy of the proposed Reply Brief in Support of Motion for Preliminary Injunction to this Motion as required by W.D. Mich. L.Gen.R. 5.7(f). Plaintiff is also submitting a proposed Order related to this unopposed Motion.

WHEREFORE, Plaintiff respectfully requests that she be allowed to file the attached Reply Brief that is 8,056 words in length, and for such other relief as is just under the circumstances.

Respectfully submitted,

## /s/ Jenin Younes

Jenin Younes\* Litigation Counsel Jenin.Younes@ncla.legal Admitted in this Court \*Admitted only in New York. DC practice limited to matters and proceedings before United States courts and agencies. Practicing under members of the District of Columbia Bar.

# <u>/s/ Harriet Hageman</u>

Harriet Hageman\* Senior Litigation Counsel Harriet.Hageman@ncla.legal Admitted in this Court \*Admitted only in Wyoming, Colorado, and Nebraska. Practice limited to matters and proceedings before United States Courts and agencies. Practicing under members of the District of Columbia Bar. Case 1:21-cv-00756-PLM-SJB ECF No. 11, PageID.558 Filed 09/15/21 Page 3 of 3

<u>/s/ John Vecchione</u> /s/ John Vecchione Senior Litigation Counsel John.Vecchione@ncla.legal Admission to this Court Forthcoming

NEW CIVIL LIBERTIES ALLIANCE 1225 19<sup>th</sup> Street NW, Suite 450 Washington, DC 20036 Telephone: (202) 869-5210 Facsimile: (202) 869-5238

Attorneys for Plaintiffs

## **CERTIFICATE OF SERVICE**

I hereby certify that on September 15, 2021, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel of record by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

> Anne K. Ricchiuto Stephanie L. Gutwein 300 North Meridian Street, Suite 2500 Indianapolis, IN 46204

Uriel Abt Michigan State University Office of the General Counsel 426 Auditorium Rd., Rm 494 East Lansing, MI 48824-2600

> <u>/s/ Harriet M. Hageman</u> Harriet M. Hageman

# 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.	) $(1.21 - 0.075)$ DIM CID
	) CIV. A. NO. 1:21-cv-00756-PLM-SJB
SAMUEL 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,	)
	)
	)
Defendants.	)

# BRIEF IN SUPPORT OF PLAINTIFFS' UNOPPOSED MOTION TO EXCEED WORD LIMIT ON REPLY BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Pursuant to W.D. Mich. LGenR 7.1(c) and (d) Plaintiff, Jeanna Norris, has filed an unopposed Motion with this Court seeking leave to file a Reply Brief in Support of Motion for Preliminary Injunction in excess of the word limit. Plaintiff's Reply Brief is attached hereto as required by W.D. Mich. LGenR 5.7(f) and is 8,056 words long as shown by the Certificate of Compliance required by W.D. Mich. LGenR 7.2(b)(ii) (set forth on page 27 of said Brief). In support of this Motion, Plaintiff states as follows:

- This case challenges Michigan State University's ("MSU") "COVID Directives" for the Fall 2021 semester.
- 2. MSU's COVID Directives require all faculty and staff, including Plaintiff, to have been vaccinated for the COVID-19 virus by August 31, 2021. Any faculty or staff member who fail to comply with this vaccine mandate are subject to discipline, up to and including termination of employment.
- 3. Plaintiff has already contracted and fully recovered from COVID-19, and has naturally acquired immunity. Plaintiff believes that such vaccination is not only unnecessary for her, but that it poses a risk of medical complications and other risks that she believes are unreasonable and unnecessary. While MSU provides certain exemptions to its COVID Directives, it does not recognize naturally acquired immunity as a reason to forego receiving such vaccine.
- 4. The issues involved in this case are not only legally and medically complex, but involve important constitutional, statutory and policy issues surrounding bodily autonomy, and potentially life altering medical complications and risks associated with being required to take a medically unnecessary vaccine
- 5. Plaintiff's Brief is designed to provide this Court with the most comprehensive analysis of the legal and medical issues involved. Considering the fact that we are in largely uncharted territory here, addressing unique questions of first impression (including, *inter alia*, a university's attempt to assume police powers not granted by statute, the medical ethics of requiring vaccines that are only approved under an "Emergency Use Authorization," and the significance of natural immunities in the context within which this case must be decided), as well as complicated scientific issues, it is imperative that Plaintiff be given

every opportunity to present her arguments as she seeks to save her livelihood and her physical health.

- 6. The issues before the Court are of the utmost importance to both Plaintiff and MSU as we navigate through COVID-19 going forward.
- 7. Considering what is at stake, it is imperative that this Court have all of the relevant information and analysis before it as it analyzes Plaintiff's request that the *status quo* be maintained as this case wends its way through the longer litigation process.
- 8. The number of words devoted to each issue is not excessive. Plaintiff's analysis will assist this Court in evaluating the merits of her Motion for Preliminary Injunction.
- 9. Put simply, Plaintiff requires more than the allotted 4300 words to provide a comprehensive legal and factual analysis to help this Court to make the right decision.
- The comprehensive analysis in Plaintiff's Reply Brief will ensure that the parties have sufficient time to make their arguments and present their evidence during the September 22, 2021 hearing.
- 11. Plaintiff has conferred with opposing counsel. She has graciously agreed that Defendants will not oppose this Motion so long as Plaintiff's Brief is in the range of 8600 words or less. Plaintiff's Reply Brief is 8,056 words (excluding the caption, etc., as identified in W.D. Mich. LGenR 7.2(c)).
- 12. Modification of the word limit is within this Court's discretion. *See* W.D. Mich. LGenR7.1(c). This Court should exercise such discretion here, and find that there is good cause supporting Plaintiff's request.

Plaintiff respectfully requests that this Court grant her Motion to Exceed Page Limits and accept the Reply Brief for Filing.

Respectfully submitted,

## <u>/s/ Jenin Younes</u>

Jenin Younes\* Litigation Counsel Jenin.Younes@ncla.legal Admitted in this Court \*Admitted only in New York. DC practice limited to matters and proceedings before United States courts and agencies. Practicing under members of the District of Columbia Bar.

# <u>/s/ Harriet Hageman</u>

Harriet Hageman\* Senior Litigation Counsel Harriet.Hageman@ncla.legal Admitted in this Court \*Admitted only in Wyoming, Colorado, and Nebraska. Practice limited to matters and proceedings before United States Courts and agencies. Practicing under members of the District of Columbia Bar.

<u>/s/ John Vecchione</u> John Vecchione Senior Litigation Counsel John.Vecchione@ncla.legal Admitted in this Court

<u>/s/ John Vecchione</u> /s/ John Vecchione Senior Litigation Counsel John.Vecchione@ncla.legal Admission to this Court Forthcoming

NEW CIVIL LIBERTIES ALLIANCE 1225 19<sup>th</sup> Street NW, Suite 450 Washington, DC 20036 Telephone: (202) 869-5210 Facsimile: (202) 869-5238

Attorneys for Plaintiffs

# **CERTIFICATE OF SERVICE**

I hereby certify that on September 15, 2021, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel of record by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

> Anne K. Ricchiuto Stephanie L. Gutwein 300 North Meridian Street, Suite 2500 Indianapolis, IN 46204

Uriel Abt Michigan State University Office of the General Counsel 426 Auditorium Rd., Rm 494 East Lansing, MI 48824-2600

> <u>/s/ Harriet M. Hageman</u> Harriet M. Hageman

# 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.21-cv-00756-PLM
SAMUEL STANLEY, JR., in his official capacity as President of	)
Michigan State University; DIANNE	)
BYRUM, in her official capacity as Chair	ý)
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.	)

# PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION (HEARING SCHEDULED 9/22/21)

# TABLE OF CONTENTS

ARGUMENT1
I. Plaintiff Has Established a Substantial Likelihood of Success on the Merits 1
A. PLAINTIFF HAS A FUNDAMENTAL, CONSTITUTIONAL RIGHT TO BODILY AUTONOMY AND TO DECLINE MEDICAL TREATMENT
1. Strict Scrutiny Is the Correct Standard of Review
a. <i>Jacobson</i> Is Inapplicable Here1
b. MSU Does Not Wield Michigan's Public-Health Police Powers
c. Apart from <i>Jacobson's</i> Inapplicability and the Absence of a Police Power Delegation, Only Appropriately Tailored Measures Serving a Compelling Government Interest Can Meet Constitutional Muster Here
2. Contrary to Defendants' Contentions, the Most Up-to-Date Science Establishes that Natural Immunity Is as Robust and Durable as That Acquired Through the Most Effective Vaccines, So MSU Has No Compelling Interest in Requiring Plaintiff to Receive a Vaccine Against Her Doctor's Advice
B. DEFENDANTS' DIRECTIVE IMPOSES AN UNCONSTITUTIONAL CONDITION ON PLAINTIFF 14
C. DEFENDANTS' POLICY IS PREEMPTED BY THE FEDERAL EUA STATUTE 17
II. Plaintiff Will Suffer Irreparable Harm If the Court Does Not Grant Her Motion for a Preliminary Injunction
III. The Balance of Equities Weighs in Favor of Granting Plaintiff's Motion
CONCLUSION

### ARGUMENT

The Motion for Preliminary Injunction should be granted. Exercising her constitutional and statutory rights of informed consent, Plaintiff Norris and those similarly situated (along with millions of other Americans) do not wish to take a COVID-19 vaccine because they have recovered from COVID-19 and have natural immunity to it. Forcing Plaintiff to choose between her job and ability to support her family, and an unnecessary medical intervention, Defendants have issued an ill-conceived "Directive," mandating vaccination of all employees. This is *not* a wrongful termination or damages suit. This is a suit for prospective declaratory and injunctive relief so that Plaintiff can maintain her constitutional and statutory rights to bodily integrity and informed consent, invasion of which inherently constitutes irreparable harm. Strict scrutiny must be applied to MSU's unlawful policy, which does not account for natural immunity. Under this standard, the Directive must be invalidated so that those harmed by it can return, undisturbed, to their roles as productive MSU employees. Indeed, the Directive is so flawed, crafted from blind reliance on federal guidance documents that are not law, that its refusal to take account of the scientific fact and immunological consequences of natural immunity cannot withstand any form of scrutiny.

# I. PLAINTIFF HAS ESTABLISHED A SUBSTANTIAL LIKELIHOOD OF SUCCESS ON THE MERITS

# A. Plaintiff Has a Fundamental, Constitutional Right to Bodily Autonomy and to Decline Medical Treatment

1. Strict Scrutiny Is the Correct Standard of Review

a. Jacobson Is Inapplicable Here. Plaintiff has already explained at length why Jacobson v. Massachusetts, 197 U.S. 11 (1905), Plaintiff has already explained at length why Jacobson v. Massachusetts, 197 U.S. 11 (1905) does not apply to her case, namely that it involved legislative action, no ability to demonstrate natural immunity, and a one-time fine (See Plaintiff's Brief in

Support of Motion for a Preliminary Injunction ("Plaintiff's Br.") at 16-19; Complaint ("Compl.")). Ignoring these crucial distinctions, Defendants assert that "rational basis scrutiny applies to vaccination requirements." (Defendant's Response in Opposition to Plaintiff's Motion for a Preliminary Injunction ("Def. Opp.") at 11). But *Jacobson* predates the creation of tiers of scrutiny. Additionally, *Jacobson* did not address the ensuing 115 years of Supreme Court precedent recognizing and expanding constitutional rights to bodily integrity. While this Court determined at the TRO stage that rational basis scrutiny applied here, with all respect to the Court, its TRO decision was wrong on that point. As explicated below, strict scrutiny is the standard by which Plaintiff's constitutional claims, which trace to post-*Jacobson* developments in the law, must be analyzed.

b. MSU Does Not Wield Michigan's Public-Health Police Powers. Jacobson is irrelevant for another, even more fundamental reason. Jacobson deferred to an exercise of the police power by the Massachusetts Legislature. Jacobson, 197 U.S. 11. But MSU is not the Michigan Legislature and it operates under no delegation of Michigan's police power in the area of public health. Thus, even if Jacobson could be read so broadly as to stand for the proposition that all legislatively mandated vaccine mandates are subject to rational basis scrutiny (which it does not), that proposition still does not save MSU's Directive since it was not the product of legislative action. MSU does not have independent police power, and no Michigan statutes endow MSU—through its governing Board of Trustees—with such authority. See MCLA 390.101 through .123, ch. 390 (entitled "Universities and Colleges"). The Michigan Supreme Court takes a very cautious approach to delegations of the state police power. See, e.g., In re Certified Questions from U.S. Dist. Ct., W. Dist. of Mich., S. Div., 958 N.W.2d 1, 20 (2020) (holding that

emergency powers of governor act violated the State's separation of powers which limits the ability of the Executive to wield the legislative police power).

While Michigan law permits delegation of the state's police power, any such grant of authority must be clearly stated and delineated. As relevant here, it is clear that the University has been given powers to oversee education and finances (*see, e.g.*, Mich. Comp. Laws Ann. § 390.108 (educational matters), 390.118 & 390.120 (finances)), but MSU has no delegated power to regulate employee or student public health.<sup>1</sup> As clearly stated in *G.F. Redmond & Co. v. Michigan Sec.* 

Comm'n, 192 N.W. 688, 689 (1923):

The power to carry out a legislative policy enacted into law under the police power may be delegated to an administrative board under quite general language, so long as the exact policy is clearly made apparent, and the administrative board may carry out in its action the policy declared and delegated, *but it cannot assume it has been vested with power beyond expressed legislative delegation*, and must ever seek its way in the light shed by the legislative mandate.

In sum, MSU has no authority to implement the vaccine mandate here.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Additionally, compare the general but limited powers of the MSU Board of Trustees to MCLA 390.105, 390.111, and 390.112 (sometimes calling MSU the "Michigan agricultural college," MCLA 390.101, which is another name for MSU). Those limited powers refer to MSU's oversight of a university farm and the swamp lands in certain Michigan counties. MCLA 390.105, 390.111, and 390.112. But the police power over those types of lands is expressly delegated to the Michigan State Board of Agriculture, not to MSU. This reveals that the Michigan Legislature knows how to make broader police power delegations concerning MSU operations when it so chooses. See also MCLA 333.9205a(3)-(4) (permitting all Michigan institutions of higher education to make information available to students regarding "meningococcal disease and other diseases about which the department [of Health and Human Services may recommend immunization or immunization information") (emphasis added); MCLA 333.2611(3)(i) (same Michigan department can establish a non-profit corporation that can coordinate research with any public university in the state on public health policies and programs) (emphasis added). Accordingly, the absence of a statutory delegation of mandate-like, public-health powers to MSU or other state universities means those powers are reserved to the Michigan Legislature and its Department of Health and Human Services. Providing information and conducting research are far lesser powers than the power to mandate vaccination.

<sup>&</sup>lt;sup>2</sup> And having failed to cite any Michigan legislative delegations to support the Directive, MSU has thus waived the argument that it is exerting delegated public-health police power in all events. *See* 

Not only does MSU lack the police power entrusted to the State Legislature, its Directive has been crafted based on a flawed understanding of the enforceability of federal agency guidance against a state institution. To begin with, the federal government does not possess police power. See, e.g., United States v. Morrison, 529 U.S. 598, 618 (2000) (referring to "the police power, which the Founders denied the National Government and reposed in the States"). The Centers for Disease Control ("CDC") and Department of Education guidance documents that MSU cites are not final agency action, are unreviewable by the federal courts, and for those reasons, do not carry the force of law, and thus cannot form the foundation-let alone the justification-for Defendants' policy. See Christensen v. Harris County, 529 U.S. 576, 587 (2000) ("[W]e confront an interpretation contained in an opinion letter, not one arrived at after, for example, a formal adjudication or notice-and-comment rulemaking. Interpretations such as those in opinion letters like interpretations contained in policy statements, agency manuals, and enforcement guidelines, ... lack the force of law ....").<sup>3</sup> The CDC and Department of Education guidance documents that MSU purports to rely on, see Def. Opp. Br. at 6-8, were simply not issued in accord with APA notice-and-comment procedures.

Just yesterday, Dr. Marty Makary, a surgeon and professor at Johns Hopkins University, published a piece documenting the CDC's ineptitude throughout the pandemic. *See* Marty

*Vaughn v. Lawrenceburg Power Sys.*, 269 F.3d 703, 714 (6th Cir. 2001); *United States v. Skaggs*, 327 F.R.D. 165, 176 (S.D. Ohio 2018) ("due to the absence of privilege arguments in the government's opposition brief, the Court assumes that any privilege has been waived").

<sup>&</sup>lt;sup>3</sup> See also National Min. Ass'n v. McCarthy, 758 F.3d 243 (D.C. Cir. 2014) ("[W]e may review agency action under the APA [Administrative Procedure Act] only if it is final" and "final guidance" from EPA did not equate to final agency action under 5 U.S.C. § 704); Appalachian Power Co. v. EPA, 208 F.3d 1015, 1020 (D.C. Cir. 2000) ("Only 'legislative rules' have the force and effect of law . . . . A 'legislative rule' is one the agency has duly promulgated in compliance with the procedures laid down in the statute or in the [APA].").

Makary, *Covid Confusion at the CDC*, THE WALL STREET JOURNAL (Sept. 14, 2021), *available at* https://www.wsj.com/articles/covid-19-coronavirus-breakthrough-vaccine-natural-immunity-cdc -fauci-biden-failure-11631548306 (last visited Sept, 14, 2021). "Sound data from the CDC has been especially lacking on natural immunity from prior Covid infection," Makary observes. He describes the Israeli study that Dr. Zervos, Defendants' expert, claims is unpersuasive because it is awaiting peer review (*see* Declaration of Marcus Zervos, M.D., attached to Def. Opp. as Ex. A ("Zervos Decl.") at ¶ 64) as "the most powerful and scientifically rigorous study on the subject to date." Makary further explains that "[i]n a sample of more than 700,000 people, natural immunity was 27 times more effective than vaccinated immunity in preventing symptomatic infections." Id.

(Emphasis added). Yet:

U.S. public health officials continue to dismiss natural immunity, insisting that those who have recovered from Covid must still get the vaccine. Policy makers and public health leaders, and the media voices that parrot them, *are inexplicably sticking to their original hypothesis that natural immunity is fleeting, even as at least 15 studies show it lasts.* 

Id. (emphasis added).

Makary also elucidates the way in which CDC's data from Kentucky has been twisted to support vaccination of the naturally immune (Zervos does the same (Zervos Decl. ¶ 40)). "[D]espite having data on all 50 states, the CDC only reported data from Kentucky" and Makary asks whether perhaps "Kentucky was the only state that produced the desired result?" *Id.* In any event, the rate of infection in each group ("vaccinated *and* naturally immune" and "only naturally immune") was 0.01%, meaning that infections were exceedingly rare in both groups during the short, two-month time period in which the cherry-picked study was conducted.

Aside from CDC's observable track record of disregarding the scientific evidence with respect to naturally acquired immunity to COVID-19, federal guidance can neither form the basis

for state action nor substitute for lack of a legislative delegation under Michigan law. Thus, MSU has circumvented the state legislative process, turning a non-binding (and wrongheaded) federal agency suggestion into an enforceable mandate that school employees must give up their constitutional rights to bodily autonomy—or their jobs—even after devoting years or decades of their lives to serving MSU. The University cannot demand that this Court accord to it the same deferential standard that applies to a legislative act, while evading the democratic safeguards that the public scrutiny, floor debate, and passage of such an act entail.<sup>4</sup>

One of the reasons that some legislative action (though not that which invades rights of bodily integrity) is afforded only rational basis review is that such decisions are made by elected officials accountable to the public. *See FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313-14 (1993) ("Where there are plausible reasons for *Congress's action*, our inquiry is at an end") (cleaned up and emphasis added). But MSU's Directive was developed in precisely the opposite manner. Indeed, to this day, Plaintiff does not know who created the Directive and upon what information those unknown drafters proceeded. While Defendants tout the credentials of Drs. Stanley (MSU's President) and Zervos, they do not assert that these two came up with the Directive, either alone or along with others. (*See* Def. Opp. at 9, 16).<sup>5</sup> And, Dr. Stanley's opinion

<sup>&</sup>lt;sup>4</sup> As we explain below, strict scrutiny applies without regard to whether the Michigan Legislature or MSU as an administrator adopts MSU's Directive. But at the very least, in order to wrap themselves in *Jacobson*, MSU would either have to *be* the Legislature or point to a clear delegation from the Michigan Legislature. It cannot do either.

<sup>&</sup>lt;sup>5</sup> Defendants principally rely on two cases to support their contentions: *Klaassen* and *Harris (see* Def. Opp. at 13-15). But the application of rational basis review in *Klaassen v. Trustees of Ind. Univ.*, No. 1:21-cv-238, 2021 WL 3073926 (N.D. Ind. July 18, 2021), is not binding in this court. Furthermore, the court did not address (and reject) an argument that rational basis review would only attach if the university vaccine mandate there was the product of the Indiana Legislature. Finally, that case may have involved different delegations of authority from those presented here. *See also* Pl. Br. in *Klaassen* at 46-52 (Dkt. # 7, *Klaassen*, 2021 WL 3073926). Furthermore, the central argument in that case was not about natural immunity, and the plaintiffs were students, not

about the basis for the Directive is irrelevant under the governing Michigan statute because as MSU's President, he is only an *ex officio* member of the Board "without the right to vote." MCLA 390.102.

The cases that Defendants cite to support the proposition that the rational basis standard applies to vaccine mandates likewise do not support their contention. (*See* Def. Opp. at 11-15). *Nikolao v. Lyon*, 875 F.3d 310 (6th Cir. 2017), involved a challenge to a Michigan State Law requiring vaccination of schoolchildren. And even *TJM 64, Inc. v. Harris*, 475 F. Supp. 3d 828, 834 (W.D. Tenn. 2020), applied rational basis review to an order issued by a *county public health department*. *TJM 64* contains no indication that the Western District of Tennessee considered whether the county public health department was operating under delegated police power. It is far more likely that such a delegation existed in that Tennessee case than it would here as to MSU because *TJM 64* involved the enactment of a public health department. MSU is not the equivalent of a public health department by any stretch.

c. Apart from *Jacobson's* Inapplicability and the Absence of a Police Power Delegation, Only Appropriately Tailored Measures Serving a Compelling Government Interest Can Meet Constitutional Muster Here. The functional equivalent of strict scrutiny applies to Plaintiff's constitutional claims:

Although the Supreme Court has declined formally to label its review in this context as "strict scrutiny," *see Riggins v. Nevada*, 504 U.S. 127, 136 (1992), the cases still ask whether the government has adequately demonstrated a *compelling need* for the intrusion, *a lack of reasonable alternatives*, *as well as procedural and medical safeguards*, *see id.* at 135–36. *See also Washington v. Harper*, 494 U.S. 210, 229 (1990) ("The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty" requiring an important and legitimate state interest); *Cruzan v. Dir., Mo. Dep't of Health*, 497

employees. These same points also apply to *Harris v. University of Mass.*, 2021 WL 3848012 (D. Massachusetts 2021).

U.S. 261, 269, 281 (1990) ("This notion of bodily integrity has been embodied in the requirement that *informed consent* is generally required for medical treatment," but state also has interest in life and informed consent).<sup>[6]</sup>

*Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 506 (6th Cir. 2012) (emphasis added). Vaccine mandates are a fundamental intrusion into bodily integrity, as receiving an injection obviously entails such an incursion. Indeed, for more than a century the Supreme Court has recognized that invasion of one's body can constitute "an indignity, an assault, and a trespass" prohibited at common law. *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 252 (1891). *See Washington v. Glucksberg*, 521 U.S. 702 (1997) ("[T]he Fourteenth Amendment 'forbids the government to infringe … fundamental liberty interests at all, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest."). *See also Vacco v. Quill*, 521 U.S. 793, 807 (1997) (reaffirming holding of *Cruzan v. Dir., Mo. Dep't of Public Health*, 497 U.S. 261, 278 (1990), stating that "our assumption of a right to refuse treatment was grounded … on well-established, traditional rights to bodily integrity and freedom from unwanted touching.").

True, as Defendants observe, the Court in *Washington v. Harper*, 494 U.S. 210, 211 (1990), ultimately permitted the forcible injection of an antipsychotic medicine into a prison inmate because it agreed the government was pursuing a compelling interest in that case. And in *Glucksberg*, the Court held that because physician-assisted suicide was *not* deeply rooted in our country's traditions, the plaintiff had no fundamental right to it. Here, however, MSU cannot demonstrate a compelling government interest in forcing vaccines on employees with naturally

<sup>&</sup>lt;sup>6</sup> Compare, e.g., Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 546 (1993) (government policy can survive strict scrutiny only if it advances compelling interests that the policy is narrowly tailored to achieve).

acquired immunity because they pose no risk to others. Nor can MSU demonstrate that its Directive is narrowly tailored (or cannot be improved by the use of "reasonable alternatives" and "appropriate medical safeguards," *DeWine*, 696 F.3d at 506), given that it permits many of its employees to work off campus in the COVID-19 era. *See, e.g.*, MSU Office of the President, Message, <u>https://president.msu.edu/communications/messages-statements/2020\_community\_letters/2020\_03\_23\_coronavirus\_update.html</u> (last visited Sept. 14, 2021).

Defendants argue that Plaintiff:

[U]rges that strict scrutiny is warranted, without citing any authority suggesting that she has a *fundamental right to defy an employer's vaccination requirement*. Instead, she relies upon cases recognizing rights to bodily autonomy and to refuse medical treatment *under certain circumstances*.

(Def. Opp. at 12) (emphasis added). Defendants thus appear to acknowledge that while one has a fundamental right to decline a specific doctor's recommendation (the "certain circumstances"), a statute mandating a particular medical treatment for an entire population or group of people can circumvent any right to refuse said treatment. Setting aside the fact that no such statute exists in this case, since we dealing with a mere administrative policy unauthorized by a proper police power delegation, Defendants' view of the world would permit the government to *institutionalize entire classes of medical treatment* by law, forcing it on individuals and overriding ordinary individualized doctor-patient consultations. But this policymaking at the grand scale makes the intrusion on basic rights to bodily autonomy *more constitutionally dubious*, not less.

In any event, assuming *arguendo* that only rational basis level of analysis should be applied, MSU's Directive cannot surmount even that bar. As discussed extensively in Plaintiff's opening brief in support of a preliminary injunction and its supporting expert declarations, there is no reason to treat an individual with demonstrable, naturally acquired immunity any different from

a vaccinated person. (*See* Plaintiff's Br. at 12-20). Immunity is immunity is immunity. Indeed, this is why vaccine efficacy is measured *with reference to natural immunity* in scientific testing. (*See* Compl. at ¶¶ 32-50). Hence, MSU's Directive, which explicitly disregards naturally acquired immunity, is simply irrational and unscientific.

Even if naturally acquired immunity provides a lower level of protection than the Pfizer and Moderna vaccines (a point which Plaintiff does not concede, since all evidence points to the contrary), there is no rational basis for treating Ms. Norris differently from someone who has received the Sinovac, Sinopharm, or Janssen vaccines, which are not FDA approved and confer only minimal levels of immune protection. Accordingly, Plaintiff has shown that the "means chosen to effectuate a legitimate purpose are not rationally related to that purpose." *Love v. Beshear*, 989 F. Supp. 2d 536, 547-48 (W.D. Ky. 2014) ("Rational basis review, while deferential, is not toothless.").

Defendants argue that they have a compelling interest in the mandatory vaccination policy, in part due to "practical considerations," asserting that Plaintiff "invites MSU to put itself in the untenable position of," *inter alia*, "tracking the date of every COVID infection among its staff; requiring periodic antibody testing of those individuals; monitoring those results for declining antibodies; and determining when immunization is necessary[.]" (*See* Def. Opp. at 19-20). In fact, a more coherent policy would subject *all* employees to these antibody tests, since immunity following vaccination *also appears to wane*. At the very least, it cannot be argued in good faith that any well-established body of evidence establishes that immunity achieved through WHO-approved vaccines is long-lasting while assuming—based on no science whatsoever—that natural immunity evaporates rapidly. Indeed, the scientific community is increasingly realizing that boosters will be required, as the currently available vaccines have failed to provide durable

protection against COVID-19 infection. (See Reply Declaration of Dr. Hooman Noorchashm ("Noorchashm Reply"), Attachment A, at ¶¶ 7, 52-53, 55).

Furthermore, vaccination is unequivocally a *medical procedure*. As Dr. Noorchashm explains, medical treatments should never be prescribed on a one-size-fits-all basis. (See Declaration of Dr. Hooman Noorchashm at ¶ 11, 32 (attached to Plaintiff's Br. as Ex. B) ("Noorchashm Decl.")). If Defendants find themselves in an untenable position as a result of their decision to require that all employees and students undergo the same medical procedure, they should not at the same time be able to complain that they may need to allow employee- or studentspecific accommodations where those individuals can show that they already have natural immunity levels equivalent to or higher than vaccine-based immunity. Plaintiff will not object to a system that puts the burden of proof on members of the MSU community to demonstrate individually that they possess the antibodies. Our position is that MSU cannot get away with pretending that naturally acquired immunity is irrelevant, as that is tantamount to arguing the extreme and unfounded position that vaccine-based immunity protects others, while naturally acquired immunity does not. That is not the science. (See Joint Declaration of Drs. Martin Kulldorff and Jayanta Bhattacharya at ¶¶ 15-24 (attached to Plaintiff's Br. as Ex. A) ("Joint Decl."); Noorchashm Reply at ¶¶ 1-7, 21-46).

2. Contrary to Defendants' Contentions, the Most Up-to-Date Science Establishes that Natural Immunity Is as Robust and Durable as That Acquired Through the Most Effective Vaccines, So MSU Has No Compelling Interest in Requiring Plaintiff to Receive a Vaccine Against Her Doctor's Advice

Defendants devote a substantial portion of their Opposition to claiming that "[v]accinating individuals against COVID-19 is currently the leading prevention strategy to protect individuals from the virus and end the pandemic" (Def. Opp. Br. at 3-9) and that "stemming the spread of

COVID-19 is unquestionably a compelling interest." (Def. Opp. at 14).<sup>7</sup> While that may be so, Defendants have not shown and cannot show that Plaintiff presents a greater risk to herself or the community than a vaccinated individual.<sup>8,9</sup>

Through Dr. Zervos, Defendants claim that vaccination can boost or improve naturally acquired immunity. (Def. Opp. at 6-7). However, simply possessing higher antibody levels does not necessarily translate into clinical benefit, which is why the epidemiological data demonstrates that those with naturally acquired immunity only rarely become re-infected (*see* Noorchashm Reply ¶¶ 9-30). The idea that more antibodies equates to greater immunological protection both simple-minded and wrong. (Noorchashm Reply ¶ 4; Joint Decl. ¶¶ 17-18).

Nevertheless, even assuming *arguendo* that enhancing antibodies does provide additional protection, that still does not justify mandating vaccination of naturally immune people. Indeed, everyone's antibody levels could, in this way, be heightened by receiving a vaccine every week, but we recognize that at some point a mandate of that type is not warranted, because any benefit

<sup>&</sup>lt;sup>7</sup> Defendants cite *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) to support this claim. That case did not address a vaccine mandate but rather limitations on church capacity. Plaintiff is not contending that quelling the spread of COVID-19 is not a compelling interest in the abstract, but rather that there is no compelling interest in forcing the vaccines on those with naturally acquired immunity and likewise no such interest in insisting upon a "one size fits all" approach to the public health challenges COVID-19 poses.

<sup>&</sup>lt;sup>8</sup> Defendants misleadingly quote Plaintiff's assertion that MSU's policy lacks a valid public health basis, claiming that is "bizarre." But Plaintiff did not claim that mitigating spread of COVID-19 is not a legitimate public health aim, only that *requiring those with naturally acquired immunity to receive a vaccine* is not a valid public health measure.

<sup>&</sup>lt;sup>9</sup> Without making a specific argument, Defendants cite to President Biden's federal vaccine mandate, imposed by an Executive Order just a few days ago, on September 9, 2021. It ought to be noted that many legal scholars have questioned the legality of this mandate, and approximately 26 States and counting have indicated that they intend to immediately challenge the OSHA part of the President's mandate when that is reduced to final agency action.

to third parties is too marginal to justify forcing such vaccinations. The same logic applies to vaccination of those with naturally acquired immunity. (*see* Noorchashm Reply ¶ 2, 4, 6-7).

Defendants do not even engage with Plaintiff's point that their acceptance of vaccines such as the Sinovac, Sinopharm, and Janssen vaccines is illogical, if preventing the spread of COVID-19 is indeed the Directive's true goal. If concern about transmission is the guiding principle, then why do Defendants consider these vaccines—two of which are only about 50% effective at preventing infection—sufficient to fulfill its mandate, while treating naturally acquired immunity as non-existent? Plaintiff and those similarly situated are entitled to probe into what lies behind the Directive. What emerges might show that MSU is more concerned about continuing its influx of foreign-student tuition dollars, which is assisted by accepting these inferior vaccines approved for use abroad, than by a pure public-health rationale.

Dr. Zervos's and Defendants' specious claim that the duration of naturally acquired immunity is unknown, justifying the university's mandate, also fails. (*See* Def. Opp. at 6-7; Zervos Decl. ¶¶ 42-51]). As Drs. Bhattacharya and Kulldorff explain, we *also* do not know how long immunity from the vaccines lasts. (Joint Decl. ¶ 15). Considerable evidence—including the study from Israel cited in Plaintiff's opening brief—indicates that vaccine-acquired immunity wanes after a number of months. (Joint Decl. ¶¶ 19-20). A study from Qatar likewise found no statistical difference in the risk of reinfection between those who had been vaccinated versus those who had been previously infected. (Joint Decl. fn. 15). Indeed, every purported unknown with respect to naturally acquired immunity that Dr. Zervos alleges in his declaration is equally true as to the vaccines.

Finally, as Dr. Zervos undoubtedly knows, immunity is multi-faceted and antibodies constitute only one aspect. Even when antibody levels wane, studies demonstrate prolonged

immunity from memory T and B cells, bone barrow plasma cells, spike-specific neutralizing antibodies, and IgG+ memory B cells. (Joint Decl. ¶ 17; Noorchashm Reply ¶ 4). That is why all epidemiological observational studies indicate that natural immunity is durable and long-lasting—there is no evidence whatsoever that cellular immunity wanes over time. *See* Interview of Dorry Segev, M.D., "COVID-19 Vaccines and Immunocompromised People," *Johns Hopkins Bloomberg School of Public Health* (July 14, 2021), *available at* bit.ly/3lgAfeC (last visited Sept. 12, 2021) ("antibodies are the tip of the immunologic iceberg, and a lot is going on under the surface that we cannot measure."). (Joint Decl. ¶ 18-24; Noorchashm Reply ¶ 21-42).

To summarize, all of the real-world, observational data establishes that, if curbing the spread of coronavirus is indeed the goal, naturally acquired immunity serves that end as well or better than vaccination. Accordingly, Defendants cannot show a compelling interest in subjecting Plaintiff and those similarly situated (i.e., those with naturally acquired immunity) to their Directive.

## B. DEFENDANTS' DIRECTIVE IMPOSES AN UNCONSTITUTIONAL CONDITION ON PLAINTIFF

Defendants assert that, in order to establish that the Directive constitutes an unconstitutional condition, Plaintiff must identify an enumerated constitutional right that she is being coerced to relinquish. But that is a misreading of the prevailing case law. In *Memorial Hosp. v. Maricopa County*, 415 U.S. 250 (1974), the Court concluded that the county impermissibly burdened the plaintiffs' rights to travel by extending healthcare benefits only to indigent, ill individuals who had been residents for at least one year. As the right to travel is *not* an enumerated right in the strictest sense (unless it is sufficient that it is encompassed by the liberty interests protected by the Fourteenth Amendment, which is equally true of rights to bodily autonomy), it is obvious that the court in *Koontz v. St. Johns River Water Management District*,

570 U.S. 595, 604 (2013), meant an *established* constitutional right when it referred to the existence of an "enumerated" right. As discussed, Plaintiff's rights to bodily autonomy and to decline medical treatment are well-established rights protected by heightened scrutiny.

Defendants also argue that Plaintiff does not have a fundamental right to public employment, so the Directive does not create an unconstitutional condition. (*See* Def. Opp. 21-22). That argument, too, misses the mark. Unconstitutional conditions doctrine prohibits a state actor from premising the grant of certain benefits (or the withholding of certain detriments) upon an individual's surrendering her constitutional rights. The benefits/detriments in question do not have to stem from fundamental constitutional rights or, indeed, from any form of constitutional rights. The focus is on the financial (or other conditional) pressure put on the holders of constitutional rights. In *Speiser v. Randall*, 357 U.S. 513 (1958), for instance, the benefit was a state property tax exemption. Obviously, there is neither a fundamental nor constitutionally recognized right of any person to receive a property tax exemption. Likewise, in *Perry v. Sinderman*, 408 U.S. 593, 597 (1972), the Court expressly stated that

this Court has made clear that even though a person has no "right" to a valuable government benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person that infringes his constitutionally protected interests[.]

The Court went on to observe that it had "applied the principle of denials to public employment," *id.* at 597, which is precisely the issue here.

Moreover, in *Maricopa County*, 415 U.S. at 259, the Court held that medical care is a "basic necessity of life" and therefore appropriately considered the subject of an unconstitutional condition. If medical care is a "basic necessity of life," so is the job that pays the bills of not only Plaintiff, but her husband and stepchildren. And that leverage is being wrongfully applied to

convince her to surrender her constitutional right to exercise informed consent and to decline a COVID vaccine. The fact that *Speiser* involved leveraging against a First Amendment right is of no consequence. Government regulators are endlessly creative, and they should not be able to evade their obligation to observe constitutional strictures by asserting that a mandate is non-mandatory simply because it proceeds by way of applying financial leverage—here, in the extreme—rather than via outright edict.

Citing Nasierowski Bros. Inv. Co. v. City of Sterling Heights, 949 F.2d 890. 896 (6th Cir. 1992), Defendants also argue that MSU's policy is "generally applicable," affecting "all MSU students, faculty, and staff 'equally." Accordingly, they contend, Plaintiff possesses no procedural due process right to be heard. (See Def. Opp. at 22-23). But this argument is predicated upon a misunderstanding of Plaintiff's position. She contends that *because* she possesses naturally acquired immunity to COVID-19, MSU's policy does not affect her equally, as in her case the vaccine is medically unnecessary and poses a risk of harm to her (see Reply Decl. Noorchashm 8-12, 16-20, 49). Furthermore, MSU's Directive is *not* generally applicable; it has carved out exemptions based on certain medical conditions and religious beliefs from its mandate. See Fulton v. City of Phila., Pa., 141 S. Ct. 1868 (2021) ("A law is not generally applicable if it invites the government to consider the particular reasons for a person's conduct by providing a mechanism for individualized exceptions") (internal citations and quotation marks omitted). Fulton rejected arguments that government action should be viewed with lenity (put otherwise, that it should possess heightened powers) when (1) regulating its internal operations, id. at 1878, and (2) entering into employment contracts. Id. That MSU can (in this case properly within its delegated police power to manage MSU's finances) decide on its employees' salaries and type of work they perform is constitutionally irrelevant. MSU is not the equivalent of a private employer and does not enjoy the rights such an employer may possess to impose a COVID vaccine mandate.

Finally, without citing any authority, Defendants argue that Plaintiff is not entitled to be heard at this stage in the proceedings, since she "has not, and cannot, allege that she would be disciplined without being offered further process." (Def. Opp. at 24). But Defendants' Directive specifically states that those who do not comply with their vaccine mandate will face disciplinary action, including termination. That is immediate and direct, not speculative. Plaintiff-the family's primary breadwinner-should not have to wait until she is actually fired to seek relief. Compare Abbott Labs. v. Gardner, 387 U.S. 136 (1967) (holding that drug companies could bring a pre-enforcement review challenge where "the regulation [wa]s directed at them in particular; it require[d] them to make significant changes in their everyday business practices; [and] if they fail to observe the ... rule they are clearly exposed to the imposition of strong sanctions"). The same is true, by analogy, to the famed Abbott Labs ripeness case here. The Directive applies to Norris (as well as other MSU employees) in particular; they must make a significant change in their medical choices (by taking an unwanted and for-them medically unnecessary vaccine); and if they do not comply with the Directive, Norris and those similarly situated are exposed to severe economic sanctions.

### C. DEFENDANTS' POLICY IS PREEMPTED BY THE FEDERAL EUA STATUTE

In addition to her constitutional claims, Plaintiff also possesses a statutory right to informed consent—a right protected by preemption doctrine. *See* Complaint at Count III. Such a preemption claim provides *stronger* rights to Plaintiff than the baseline level applicable to constitutional strictures because no balancing of competing government interests (whether tested by strict or rational basis scrutiny) can defeat such rights. Plaintiff and those similarly situated

possess an absolute, statutory right to refuse an EUA-approved vaccine. This makes sense because such vaccines are subjected only to an abbreviated form of review, and basic medical ethics dictate that individuals should not be forced to take such medical products.

Defendants claim that the informed consent provision of the EUA statute, 21 U.S.C. § 360bbb-3, means only that the health care worker administering the vaccine must obtain consent in a literal sense and convey the risks and benefits associated with the vaccine before inoculating the patient. (See Def. Opp. at 24-25). This arid reading of the statute makes a mockery of it. Some individuals may be able to easily withstand unemployment to avoid taking a vaccine but many Americans are not so fortunate. Ms. Norris and other prospective class members are simply not the sorts of workers able to take on a job like Defendants—*i.e.*, as an MSU Board Member working for no pay. See MCLA 390.103 ("The members of the board of trustees shall serve without compensation, but shall receive the actual and necessary expenses [they incur]."). Plaintiff class members will in most cases not be able to risk being thrown into unemployment for long periods, jeopardizing their family's health insurance and, worse yet, being pushed into poverty. In short, the Directive is unmistakably coercive and impliedly preempted by the EUA statute. See Geier v. American Honda Motor Co., 529 U.S. 861, 872-73 (2000) (local tort law impliedly preempted by a federal automobile safety standard); Yates v. Ortho-McNeil-Janssen Pharms., Inc., 808 F.2d 281, 297-98 (6th Cir. 2015) (New York law impliedly preempted by federal regulatory law because it was impossible to unilaterally alter drug dosage without violating FDA regulations).

Defendants next claim that because the Pfizer Comirnaty vaccine has been fully approved, Plaintiff's preemption claim is moot. (*See* Def. Opp. at 26). But, as Plaintiff argued, the Comirnaty is *not actually available*. (*See* Plaintiff's Br. at 27-28). In reality, if she is to receive a vaccine somewhere in Michigan (or any other part of the country, for that matter), it would undoubtedly be one of the three that remain approved only for emergency use (the Pfizer BioNTech, Moderna, and Janssen vaccines). Though Defendants claim that FDA's description of the vaccines as "legally distinct," "does not result in an actual legal distinction that saves [Plaintiff's] claim," they do not further unpack that argument. Typically, one legally distinct category is treated one way while a different legal category is treated another. Just so here. EUA vaccines, by statute, extend to recipients the right to accept or reject. By contrast, fully approved vaccines are not accompanied by statutory informed-consent protections. Hence, whether or not the Pfizer BioNTech and Comirnaty vaccines are factually identical is irrelevant. The *legal point* is that the former requires informed consent as a matter of the EUA statute and the latter does not.<sup>10</sup> No provision of the EUA statute, nor any judicial decision, holds that when an EUA vaccine is of the same formulation as an unavailable but approved vaccine, informed-consent rights no longer exist. Rather, the EUA statute requires EUA-approved vaccines to be withdrawn from the market once a fully approved alternative is available. The negative effect this would have on EUA-approved BioNTech, Moderna and Janssen vaccines may explain the slow roll-out of Comirnaty, but it does not justify a bait-and-switch under which the Pfizer BioNTech vaccine is treated as though it is Comirnaty.

Finally, it is important to note that MSU distances itself from the Office of Legal Counsel's opinion, which disregards the implied preemption effect of the EUA statute. (Def. Opp. Br. at 25 n.14). Instead, MSU's principal defense to preemption is the overly facile and legally irrelevant

<sup>&</sup>lt;sup>10</sup> Even if the Comirnaty vaccine *were* commercially available, Plaintiff would challenge MSU's Directive on EUA grounds for two reasons: (1) it would raise entirely new legal issues and ensuing infirmities if MSU were functionally requiring employees to take *a particular vaccine* manufactured by a *single company*; and (2) even if *statutory* informed-consent requirements were no longer applicable in the wake of the coupling of (a) full approval *and* (b) commercial availability, Plaintiffs would possess their same *constitutional* rights to exercise informed consent set out in the first two causes of action mounted in the Complaint.

point that the Comirnaty vaccine has received full FDA approval. Plaintiff also notes that the Comirnaty is not commercially available because if it were, then all of the three EUA vaccines could no longer lawfully be sold—an outcome that the FDA and Pfizer may be trying to avoid because that would significantly reduce the COVID-19 vaccine supply and *worsen* the public health. *See* 21 U.S.C. § 360bbb-3(c)(3) (EUA authorization "only if … there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition … .").<sup>11</sup>

# II. PLAINTIFF WILL SUFFER IRREPARABLE HARM IF THE COURT DOES NOT GRANT HER MOTION FOR A PRELIMINARY INJUNCTION

In its TRO decision, this Court appeared to consider Plaintiff's claimed irreparable harm in the context of a wrongful-termination case. *See Norris v. Stanley*, 2021 WL 3891615 (W.D. Michigan 2021) (order denying preliminary injunction). But, with all due respect, this is not such a case. Rather, it is a *constitutional case*. As Plaintiff explained in her primary brief, being coerced into surrendering constitutional rights constitutes an irreparable harm, as the governing case law clearly establishes. (*See* Plaintiff's Br. at 32). *See also Overstreet v. Lexington-Fayette Urban County Gov't*, 305 F.3d 566, 578 (6th Cir. 2002) ("[A] plaintiff can demonstrate that a denial of a preliminary injunction will cause irreparable harm if the claim is based upon a violation of the plaintiff's constitutional rights."); *Hartman v. Acton*, \_\_F. Supp. 3d \_\_\_, 2020 WL 1932896, \*4 (S.D. Ohio Apr. 21, 2020) ("Furthermore, where irreparable harm is based upon a violation of a

<sup>&</sup>lt;sup>11</sup> See also FDA, Emergency Use Authorization for Vaccines Explained, available at https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccinesexplained (last visited Sept. 15, 2021) ("Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.") (emphasis added).

plaintiff's constitutional rights, that violation, no matter how temporary, is sufficient to show irreparable harm.").

Even apart from that simple point that the existence of a constitutional claim, if colorable, will *ipso facto* result in irreparable harm, there are two ways of looking at the injury in this case:

One possibility is that Plaintiff will, in actuality, be terminated, and her family deprived of its main source of income and its chosen health insurance, while her stepdaughter (and eventually her other stepchildren as they reach college age) will forfeit the tuition break Ms. Norris's status as an MSU employee brings. Even if this were a damages case (and it is not—Plaintiff class seeks only prospective declaratory and injunctive relief), it is highly unlikely that the class could recover both front and back pay *and* lost tuition reimbursement, to say nothing of the fact that while litigation is going forward, the children of MSU employees currently attending MSU may have to uproot their lives by transferring to less-expensive schools or suffering the harm and lost opportunities associated with putting their college careers on hold.

The other possibility is that Plaintiff will come under such duress to receive the vaccine as disciplinary proceedings progress that she will reluctantly agree to accept the vaccine, and as a result will endure irreparable injury to her body. As Dr. Noorchashm attests, receiving the vaccine, especially where a recipient employee possesses naturally acquired immunity, could result in adverse consequences, including permanent ones (*see* Noorchashm Decl. ¶¶ 12, 19-27; Noorchashm Reply ¶¶ 17-20; Joint Decl. ¶¶ 25-28). Not only is this the case because *all* medical interventions entail some risk, but various studies have shown heightened risk of adverse events in individuals who have recovered from COVID-19. Indeed, since Plaintiff initially filed her complaint and preliminary injunction motion, a new study was published concluding that "the preponderance of evidence suggests that a non-negligible subset of COVID-recovered Americans

are, in fact, susceptible to adverse events following vaccination in excess of that which is experienced by COVID-naïve persons." (Noorchashm Reply ¶¶ 18-19). Dr. Noorchashm, who has consulted with Plaintiff and reviewed her serological screening results (Noorchashm Decl. ¶ 7), concluded that vaccination presents a "non-negligible risk of potentially irreversible harm to Jeanna Norris" and that this risk is only medically ethical if she willingly accepts it, and if leaving her unvaccinated would create a risk beyond that presented by individuals who are vaccinated but do not have naturally acquired immunity (Noorchashm Decl. ¶ 20). Note too that Michigan law exempts children (traditionally and generally the class of people subject to vaccine mandates) from immunization requirements "for any period of time as to which a physical certifies that a specific immunization is or may be determinantal to the child's health or is not appropriate." MCLA § 333.9215 (2021).

Assuming for the sake of argument that the chance is small, the fact that she *could* suffer long-term, adverse consequences warrants granting a preliminary injunction here to temporarily freeze the *status quo* until this litigation can be fully resolved on the merits. Defendants cannot claim in good faith that there is *no chance* she will experience such an incident.

Under either of these scenarios, Plaintiff has established irreparable harm even if the nature of the legal rights she is trying to vindicate are put to one side. Indeed, her injures are comparable to those that this Court found constituted irreparable injury in a case brought by student athletes against Western Michigan University. *See* Order Granting TRO *in Dahl v. Board of Trustees of Western Michigan University*, No. 1:21-cv-757, slip op. at 1 (W. D. Mich. 2021) ("[P]layers will not be able to participate in intercollegiate sports. WMU also states that the players will not lose their scholarship for the academic year.") And, of course, it would be legal error to ignore the constitutional dimension of this case, since that alone is enough to warrant a finding of irreparable

harm, a point this Court recognized in the *Dahl* litigation as well. *See id.* at 5-6 ("Having found a likelihood of success on the merits of Plaintiff's Free Exercise Claim, the balance of the factors weighs in favor of emergency injunctive relief. Where parties seek injunctive relief and allege a constitutional violation, the outcomes often turn on the likelihood of success on the merits, usually making it unnecessary to dwell on the remaining three factors.") (cleaned up). Plaintiff's claim in this case is every bit as constitutional as the *Kahl* claim.

### III. THE BALANCE OF EQUITIES WEIGHS IN FAVOR OF GRANTING PLAINTIFF'S MOTION

Defendants' hyperbolic statement that its "interest and obligation in keeping its students, faculty, and staff safe, alive, and healthy" outweighs the harm to one individual in receiving a vaccination, seeking an exemption, or finding alternate employment entirely misses the mark. Plaintiff presents no health risk to anyone whatsoever because she possesses naturally acquired immunity to COVID-19, or at least no risk greater than that posed by vaccinated employees. She also works remotely, and Defendants are wholly in charge of whether she is ordered back on campus (*see* Declaration of Douglas Landis, attached to Opp. Br. as Ex. B at ¶¶ 7-10). While this case works its way through the legal process, no harm will befall anyone if Plaintiff's motion for a preliminary injunction is granted. And there are larger questions at issue here: (a) Plaintiff will move in due course for class certification; and (b) as the retention of the Faegre firm by MSU indicates, this case is not only about Plaintiff, but implicates an issue of national significance: whether individuals who can demonstrate naturally acquired immunity through antibody tests should be exempt from vaccine mandates.

Plaintiff would have applied for a medical exemption, but MSU specifically states that it does not recognize naturally acquired immunity among the bases for such an exemption. This forced Plaintiff onto the path of litigation. Other universities and institutions are recognizing naturally acquired immunity in crafting their policies. And, both Drs. Gottlieb (formerly head of the FDA) and Fauci of the National Institutes of Health have recently conceded that naturally acquired immunity should be part of any vaccine-mandate policy.<sup>12</sup> Just yesterday the CDC appears to have embarked on the beginning of a journey toward recognizing the scientific fact of naturally acquired immunity, as it tweeted that an individual who has had COVID-19 within the past three months need not get tested after exposure to the virus. *See* CDC (@cdc.gov), Twitter (Sept. 14, 2021), *available at* https://twitter.com/CDCgov/status/1437793535688908806?s=20.

#### \* \* \*

During times of crisis, our constitutional and civil rights should not take a backseat. *See Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 68 (2020) (Gorsuch, J., concurring) ("Even if the Constitution has taken a holiday during this pandemic, it cannot become a sabbatical.").

Usually, when the range of commentators reflect calmly, such scholars, judges, historians, and even journalists look back agree that some measures, enacted with little forethought to fight the latest crisis, did not make sense and, in fact, caused great unintended harm. In other words, they eventually have to concede that rationality gave way in part to fear and panic. Plaintiff posits that this is just such a scenario.

Ms. Norris and many others like her have naturally acquired immunity: not speculative or ephemeral immunity, but demonstrable and lasting resistance, provable by objective scientific tests that were not available when *Jacobson* was handed down. Thus, the pertinent scientific evidence

<sup>&</sup>lt;sup>12</sup> See Anderson Cooper interview with Sanjay Gupta and Anthony Fauci, *CNN* (Sept. 10, 2021), *available at* https://dailycaller.com/2021/09/10/fauci-doesnt-answer-recovered-covid-required-take-vaccine/ (last visited Sept. 12, 2021).

demonstrates that she and others similarly situated present a heightened danger to no one. In light of all of this, the preliminary injunction should be granted, for "even in a pandemic, the Constitution cannot be put away and forgotten." *Roman Catholic Diocese of Brooklyn*, 141 S. Ct. at 68 (per curiam).

## CONCLUSION

For the reasons set out above, the Court should enter a preliminary injunction against Defendants' Directive.

September 15, 2021

Respectfully submitted,

<u>/s/ Jenin Younes</u> Jenin Younes Litigation Counsel Jenin.Younes@ncla.legal Admitted in this Court \* Admitted only in New York. DC practice limited to matters and proceedings before United States courts and agencies. Practicing under members of the District of Columbia Bar.

<u>/s/ Harriet Hageman</u> /s/ Harriet Hageman,\* MSB #87482 Senior Litigation Counsel *Admitted in this Court* Harriet.Hageman@ncla.legal \* Admitted only in Wyoming, Colorado, and Nebraska. Practice limited to matters and proceedings before United States Courts and agencies. Practicing under members of the District of Columbia Bar.

/s/ John Vecchione

John Vecchione Senior Litigation Counsel John.Vecchione@ncla.legal Admitted in this Court

NEW CIVIL LIBERTIES ALLIANCE 1225 19<sup>th</sup> Street NW, Suite 450 Washington, DC 20036 Telephone: (202) 869-5210 Facsimile: (202) 869-5238

Attorneys for Plaintiffs

Case 1:21-cv-00756-PLM-SJB ECF No. 11-2, PageID.592 Filed 09/15/21 Page 29 of 29

## **CERTIFICATE OF COMPLIANCE PURSUANT TO CIV. L. R. 7.2(a)&(b)**

I hereby certify that this Brief contains 8,056 words, as produced by and counted by the Microsoft Word Office 365 software.

/s/ Jenin Younes

#### Declaration of Hooman Noorchashm MD, PhD.

#### Introduction

1. The purpose of COVID-19 vaccination is to induce protective, antigen-specific immunity to SARS-CoV-2. It is thus achievement of adequate *immunity* to the virus, and not vaccination, *per se*, that is the primary and true objective of our national vaccine strategy to combat the COVID-19 pandemic.

2. Accordingly, to best protect Americans against infection, there is only one justifiable reason for *mandating vaccination* of COVID-recovered individuals who demonstrate the existence of antigen-specific immunity to SARS-CoV-2: that is, if their immunity from a natural infection is *clinically inferior* to the immunity induced through COVID-19 vaccination in previously uninfected persons. For if acquired immunity from infection is clinically equivalent to that induced by vaccine immunity, and very certainly if vaccination is inferior in inducing protective immunity against SARS-CoV-2 infection, then it is a violation of medical ethics and individual bodily autonomy to force vaccination on the unwilling subset of naturally immune persons by threatening their livelihoods. (*See* Noorchashm Decl. ¶¶ 8-12).

# To Only Assume That Immunity Acquired from Natural Infection Is Inferior to That Acquired through Vaccination Is Incorrect

3. It is a fundamental error to *assume* that acquired natural immunity to SARS-CoV-2 in COVID-recovered persons is clinically inferior to full vaccination in COVID-naïve persons. In fact, as I will establish in this declaration, the weight and preponderance of the evidence clearly points to equivalency, if not inferiority of vaccination when compared to acquired immunity from a natural infection.

4. When assessing the clinical *equivalency* of vaccination vs. natural infection, the only metric that can correctly be used is the said group's *clinical susceptibility to subsequent COVID-19 infection*. For example, "fully vaccinated" individuals may harbor a larger quantity of antibodies against SARS-CoV-2 than those who are naturally infected. Indeed, this has been my clinical experience when evaluating the COVID-19 antibody serologies of many fully vaccinated patients. This observation, however, *does not* imply superiority of *clinical protection* against subsequent infection in the vaccinated with more antibodies – nor does it imply a more durable and diverse immune response to the virus in the vaccinated. In fact, the basic science of immunology predicts that an immune response to the whole of the SARS-CoV-2 virus, as occurs via natural infection, would be more diverse and long-standing than vaccination against any one particular protein (i.e., the Spike antigen used in the COVID-19 vaccines). The reality of this last point was demonstrated that naturally immune persons are 27 times more protected than fully vaccinated persons from subsequent infection by SARS-CoV-2.

5. When contemplating MSU's vaccine mandate as applied to immune, COVID-recovered persons *against their wishes*, and especially when a loss of employment is being threatened by the state or its affiliates, the correct comparisons must be considered.

6. It is incorrect and irrelevant to claim that any *additional* level of protection afforded the subset/class of COVID-recovered persons by an added vaccination justifies a mandate. Vaccine mandates, as applied to those with naturally acquired immunity, rest on the false presumption that they are less protected than vaccinated individuals who are COVID-naïve and have no naturally acquired immunity.

2

7. While encouraging "bullet-proofing" of either the naturally immune or the previously vaccinated via the use of booster shots might make sense for some, adding such marginal level of immunity protection ought to remain in the sphere of individual choice, not state mandate.

8. Dr. Zervos cites a study by Deng et al., *Transmission, infectivity, and neutralization of a spike L452R SARS-CoV-2 variant* (June 24, 2021), https://pubmed.ncbi.nlm.nih.gov/33991487/ (Zervos Decl. ¶ 39), which is one of several demonstrating that booster vaccination in persons with acquired natural immunity leads to an increase in blood antibody levels. Another such study was conducted by Leonidas Stamatatos, et al., *mRNA vaccination boosts cross-variant neutralizing antibodies elicited by SARS-CoV-2 infection* (Mar. 25, 2021). Though both studies demonstrate that booster vaccination in the COVID-recovered and already immune could lead to an increase in antibody levels, it is a serious scientific, analytical and clinical error to conflate this increase in bloos antibody levels with the unsubstantiated theory that vaccination of COVID-recovered individuals is needed to achieve immunity equivalent to that attained through vaccination of COVID-naïve persons.

## <u>COVID- Recovered Individuals Enjoy Protection at Least Equivalent to That Achieved Through</u> <u>Full Vaccination</u>

9. Goldberg, *et al.* released a study from Israel—a nation that undertook a massive vaccination campaign.<sup>1</sup> During the study period, previously infected individuals were explicitly excluded from vaccination.

10. This methodology allowed for a large volume of participants and prospective comparison of COVID-naive vaccinated individuals to COVID-recovered unvaccinated individuals.

<sup>&</sup>lt;sup>1</sup> Goldberg, et al.: Yair Goldberg, Micha Mandel, Yonatan Woodbridge, Ronen Fluss, Ilya Novikov, Rami Yaari, Arnona Ziv, Laurence Freedman, Amit Huppert "Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel." *medRxiv* 2021.04.20.21255670; doi:

11. The overall study population included 6.3 million individuals 18 years and older and utilized a dynamic cohort model that accounted for individuals' progression through first dose to full vaccination status. The statistical methodology was robust, executing a Poisson regression, and adjusting for age, gender, prior PCR test results, and municipal risk. Overall, the results found excellent vaccine efficacy in the *not previously infected*, *vaccinated* (NPI/V) group of 92.8%, 94.2%, 94.4% and 93.7% against infection, hospitalization, severe illness and death, respectively.

12. However, protection in the *previously infected and unvaccinated* (PI/UV) cohort was superior, with 94.8%, 94.1%, 96.4% against infection, hospitalization and severe illness. The trend of superior protection acquired from natural immunity held up across every age range, for all severities of illness. Additionally, this study was conducted during the Israeli surge of the B.1.1.7 (Alpha) variant, suggesting robust natural immunity to variants.

13. Shrestha *et. al.* performed an observational study in the context of occupational health, set at the Cleveland Clinic, OH, USA.<sup>2</sup> A total of 52,238 employees were enrolled, of which 2,579 had recovered from a SARS-CoV-2 infection. Of these individuals, 53% remained unvaccinated during the course of the observation period.

14. Throughout the entire study, not a single previously infected individual (0%) presented with reinfection, regardless of vaccination status – that is, *previously infected and vaccinated* (PI/V) or *previously infected and unvaccinated* (PI/UV). Consequently, the risk reduction by previous infection was effectively 100%. Conversely, the *not previously infected and vaccinated* (NPI/V) cohort had a breakthrough of 0.7%. As expected, the vast majority of individuals who tested positive were in the *not previously infected and unvaccinated* (NPI/UV) cohort.

<sup>&</sup>lt;sup>2</sup> Shrestha *et al.*: Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Paul Terpeluk, Steven M. Gordon, "Necessity of COVID-19 vaccination in previously infected individuals," *medRxiv* 2021.06.01.21258176; doi: https://doi.org/10.1101/2021.06.01.21258176,

15. Lumley, *et al.* represents a high-quality observational cohort study, performed at Oxford University Hospitals, that evaluated the incidence of SARS-CoV-2 reinfection in 13,109 HCWs, stratified by serological and vaccination (one and two doses) status.<sup>3</sup> Of note, this study coincided with the B.1.1.7 surge (Alpha) in the United Kingdom.

16. There were a total of 327 infections in the study group, with 326 infections occurring in the seronegative unvaccinated or partially vaccinated group, and only one reinfection in the seropositive group. There were no infections in the vaccinated, seronegative group.

17. The authors calculated a 90% and 85% risk reduction for vaccination in seronegative and seropositives, respectively, without statistical difference [P=0.96]). Additionally, the authors conducted a study on viral loads in symptomatic infection and found the pre-vaccination cohort with evidence of established immunity had the lowest viral loads in infected persons across the study. The authors concluded that "Natural immunity resulting in detectable anti-spike antibodies and two-dose vaccine does both provide robust protection against SARS-CoV-2 infection, including the B.1.1.7 variant".

18. Cavanaugh, *et al.* presented a case-control study from Kentucky.<sup>4</sup> Dr. Zervos appears to posit that this study justifies individuals with naturally acquired immunity receiving a vaccine by mandate. That is an incorrect understanding of the study's results.

<sup>&</sup>lt;sup>3</sup> Lumley, *et al.*: Lumley SF, Rodger G, Constantinides B, Sanderson N, Chau KK, Street TL, O'Donnell D, Howarth A, Hatch SB, Marsden BD, Cox S, James T, Warren F, Peck LJ, Ritter TG, de Toledo Z, Warren L, Axten D, Cornall RJ, Jones EY, Stuart DI, Screaton G, Ebner D, Hoosdally S, Chand M, Crook DW, O'Donnell AM, Conlon CP, Pouwels KB, Walker AS, Peto TEA, Hopkins S, Walker TM, Stoesser NE, Matthews PC, Jeffery K, Eyre DW. "An observational cohort study on the incidence of SARS-CoV-2 infection and B.1.1.7 variant infection in healthcare workers by antibody and vaccination status." *Clin Infect Dis.* 2021 Jul 3:ciab608. doi: 10.1093/cid/ciab608. Epub ahead of print. PMID: 34216472.

<sup>&</sup>lt;sup>4</sup> Cavanaugh, *et al.*: Cavanaugh AM, Spicer KB, Thoroughman D, Glick C, Winter K. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination - Kentucky, May-June 2021.

19. The study used a linked state infection and vaccination databases, reconciled by name and date of birth. The authors identified 246 total "case" reinfections in May and June 2021, drawn from all Kentucky residents aged  $\geq$ 18 years, with a positive SARS-CoV-2 test in 2020. Casepatients were then matched 1:2 to a control (492 individuals) consisting of non-reinfected patients, based on sex, age, and date of initial positive test. Unvaccinated individuals accounted for 72.8% of case-patients, whereas only 57.7% of the controls were unvaccinated. This calculates to an adjusted odds ratio (OR) of 2.34 (95% CI 1.58-3.47). The authors suggest, that "among persons with previous SARS-CoV-2 infection, full vaccination provides additional protection against reinfection."

20. While Cavanaugh *et. al.* was specifically designed to assess for superiority of vaccination versus non-vaccination in previously infected individuals, the study had several limitations. First, the study represents a single-state experience drawing only 246 reinfected patients in May and June of 2021 (out of potentially 275,000 eligible), based upon a database matching algorithm, by which inefficient matching (e.g., duplicate names, incomplete records, etc.) could lead to disproportionate selection bias in this small sample.

21. Second, the control group was not confirmed "test-negative," and vaccinated individuals (symptomatic or asymptomatic) may be less inclined to get tested. Consequently, the case and control groups are not matched according to their likelihood of getting tested, which is a critical confounder.

22. Third, case matching was only performed on the basis of age, gender, and month of previous infection; however, there are a number of other salient parameters that should have been

MMWR Morb Mortal Wkly Rep. 2021 Aug 13;70(32):1081-1083. doi: 10.15585/mmwr.mm7032e1. PMID: 34383732; PMCID: PMC8360277.

addressed. For example, race, socioeconomics, and geography are all variables that could impact whether someone gets vaccinated and/or gets tested.

23. Fourth, only reinfections reported in May and June of 2021 were used to identify case subjects, even though vaccinations were made available beginning December 2020.

24. Satwik, et al. reported a small observational study, performed on HCWs at one tertiary hospital in New Dehli, India, where primarily the Astra-Zeneca (ChAdOx1 nCov-19) vaccination was available for 4,296 employees.<sup>5</sup> The authors report an effectiveness of 93% [95% CI 87-96%] versus two does vaccination efficacy of 24% [95% CI 6-38%], for all symptomatic infections. For moderate to severe disease, the effectiveness of previous infection was 89% [95% CI 57 to 97] versus 65% [95% CI 42-79%] for two-dose vaccination. There were no deaths in the previous infection or two-dose cohort. This study is notable for its setting during the B.1.617.2 (Delta) variant surge, experienced in India during this time. A separate study performed simultaneously at this institution noted approximately a 50% penetration of the Delta variant. The underwhelming vaccine efficacy observed in this study aligned with others pertaining to the Delta variant during the same observation period [28]. The limitations of this study are its relatively small size within a group of HCWs, lack of adjustments for basic demographics, testing of symptomatic individuals only, and primary use of the ChAdOx1 nCov-19 vaccine, which differs from other studies in this review. Nevertheless, the authors conclude that "[previous infection offered] higher protection than that offered by single or double dose vaccine."

<sup>&</sup>lt;sup>5</sup> Satwik, *et al.*: Satwik R, Satwik A, Katoch S., Saluja S, "ChAdOx1 nCoV-19 Effectiveness During An Unprecedented Surge In Sars Cov-2 Infections" *European Journal of Internal Medicine*, August 15, 2021DOI:https://doi.org/10.1016/j.ejim.2021.08.005.

25. Gazit, *et al.* recently presented a retrospective observational study, with a matched cohort analysis, in Israel during the Delta surge.<sup>6</sup> The authors defined three groups: (1) never infected and two doses of vaccination (Pfizer), (2) previously infected and never vaccinated, and (3) previously infected and one dose of vaccination (Pfizer).

26. These groups then underwent a matched cohort comparison, controlling for age, gender, geographic area, and socioeconomic status. When comparing the vaccinated COVID-naive group with the unvaccinated COVID-recovered in a matched timing analysis, they found a 13.06 (95% CI 8.08-21.11, P<0.001) increased risk of infection in the vaccinated cohort. For symptomatic infections only, the risk increased to 27.02-fold [95%CI12.7-57.5]). When time matching was removed, there still was a 5.96 [95% CI 4.85-7.33, P<0.001] increased risk of infection in the vaccinated no prior infection group.

27. Finally, the researchers compared vaccination to non-vaccination in previously infected individuals, and found a 0.53-fold risk reduction (95%CI 0.3-0.92, P<0.05). However, the absolute risk reduction was only 0.1% (17 cases/14,029 subjects). Similarly, for symptomatic individuals the risk was reduced 0.68-fold (95%CI 0.38-1.21) with an absolute risk reduction of 0.04%, without reaching statistical significance. The authors bluntly conclude, "This 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 ... [the previously infected] given a single dose of the vaccine gained additional protection against the Delta variant."

<sup>&</sup>lt;sup>6</sup> Gazit, *et al.*: Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon "Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections" *medRxiv* 2021.08.24.21262415; doi: https://doi.org/10.1101/2021.08.24.21262415.

28. The Gazit *et. al.* study was designed to specifically answer pertinent clinical questions, using a robust methodology and adjustments. The strength of the study is the size of the cohorts and its matched design, allowing for multivariable adjustments. The limitations of the study include its applicability primarily to the Delta variant and Pfizer vaccine only. As the authors only reported total events without respect to time, there could be time-varying complicating factors that alter the result.

29. The conclusion from the above-reviewed studies is that there is no advantage to vaccination of the COVID-19 recovered in comparison to the vaccinated but COVID naive. Also, though vaccination in the COVID-recovered may provide some incremental protective benefit, the size of this benefit is medically marginal. To be clear, it is not my opinion that COVID-naïve individuals should seek infection as a means of achieving immunity and to bypass vaccination – because the morbidity/mortality cost of so doing is prohibitive. *However, these studies and the fundamentals of immunological science should compel our various levels of government as well as American corporations to accept that COVID-recovered individuals are at least equally protected from subsequent infection as their vaccinated COVID-naïve counterparts.* 

## Many Leaders in the Field Recognize the Efficacy of Naturally Acquired Immunity to SARS-CoV-2

30. Professor Paul Offit of the Children's Hospital of Philadelphia is widely considered to be the leading international expert in the immunology of vaccines. He also serves as an influential member of the FDA's Vaccines and Related Biological Products Advisory Committee. Dr. Offit is known for being an advocate of vaccines. 31. Dr. Offit has several times explicitly stated that naturally acquired immunity to SARS-CoV-2 is highly effective at preventing reinfection.<sup>7</sup>

32. Two large health systems in the US have elected to accept a history of COVID-recovery and acquired antibody immunity as grounds for exemption from a vaccine requirement: Kettering Health in Ohio, and Spectrum Health in Michigan.

33. Most European countries are following protocols set out in the "EU COVID-19 Certificate," exempting those with naturally acquired immunity from vaccine requirements.

## Forcing Ms. Norris to Undergo Vaccination as a Condition of Continued Employment, in the Setting of a Prior COVID Infection is Unscientific and Unethical

34. In my previous declaration to the court, I attested that Ms. Norris' level of antibody immunity to SARS-CoV-2 Spike protein falls within the distribution range of the hundreds of COVID-recovered Americans whose COVID-19 serologies I have evaluated as an immunologist and physician at this point in time. (*see* Noorchashm Decl. ¶ 7).

35. There is no reason to believe that she presents a higher risk of re-infection than any other COVID-recovered individual or any fully vaccinated individual. Nor is there any reason to believe that as a COVID-recovered and already immune person she poses any higher a risk of infecting any member of her community than a fully

36. In my opinion, it is not clinically or ethically justifiable for MSU, or any other state or federal agency, to force vaccinations on COVID-recovered Americans with serological evidence of natural immunity. Because such vaccination represents a medically unnecessary treatment (as described above), any adverse event or complication associated with vaccination – a known feature

<sup>&</sup>lt;sup>7</sup> (1) <u>https://www.youtube.com/watch?v=v8eOQSRVh\_s&t=460s;</u>

<sup>(2)</sup> https://www.youtube.com/watch?v=2JecWxAxwL8&t=1s;

<sup>(3)</sup> https://www.youtube.com/watch?v=zR1eHMekNdI

of any vaccine or medical treatment – unnecessary medical treatments are best classified as bodily harm.

37. It is true that both "fully vaccinated" and "COVID-recovered" persons will derive some marginal added benefit of protection from booster vaccination.

38. In the case of both the J&J and mRNA vaccines, we already know that efficacy rates range from 70-90%, meaning that these vaccines are anywhere from 10-30% ineffective at preventing subsequent infection. Certainly, it is abundantly clear that many vaccinated persons remain susceptible to infection (i.e., they are susceptible to "breakthrough") – albeit, apparently, with a lower intensity of COVID-19 disease.

39. Emerging data suggests that it is very likely that fully-vaccinated persons would benefit significantly from booster vaccination given the 10-30% inefficacy of inducing immunity in the existing vaccines – as well as the emerging evidence of waning vaccine immunity.

40. On the other hand, based on an analysis my colleagues and I performed, the risk reduction from booster vaccination in COVID-recovered persons is modest. This was most tangibly seen in our pooled Number Needed to Treat (NNT) analysis, which included the Cavanaugh (Kentucky) study, where 218 recovered individuals would need to be vaccinated in order to prevent one case of COVID annually. The equivalent figure for COVID-naïve individuals is only 6.5 individuals who would need to be vaccinated in order to prevent one case of COVID annually. This represents a 33.5-fold difference in the absolute effect size between COVID-naïve and COVID-recovered individuals. (*See* attached manuscript submitted for peer review on 9/14/21).

41. While it is already clear that natural immunity to COVID-19 lasts for a very long time, there is ample evidence that COVID-19 vaccine immunity is waning quickly.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> The following papers make this point quite clearly:

42. In fact, a statistically robust recent study from Israel demonstrates that fully-vaccinated persons are nearly 27 times more susceptible to subsequent infection by the Delta variant than their COVID-recovered and naturally immune counterparts.<sup>9</sup> This recent study clearly indicates that the fully-vaccinated are far more susceptible to re-infection than COVID-recovered and already immune counterparts. Therefore, if anyone, it is the previously vaccinated who should be aggressively offered booster shots. Additionally, the fundamental finding of this study is that, in fact, vaccine immunity is inferior to acquired natural immunity.

43. Thus, though it may be reasonable to offer already immune Americans (i.e., either "fully vaccinated" or COVID-recovered) added booster vaccinations electively, and especially to offer this option to the vaccinated subset, where immunity seems to wane in a substantial number, the benefit derived from such added vaccination cannot serve as the basis for the current vaccine mandates being placed on Americans.

## <u>Mandating Vaccination of Individuals with Naturally Acquired Immunity Violates Principles of</u> <u>Medical Ethics</u>

44. When any medical procedure or treatment is offered to any person, the prerequisite is establishment of *medical necessity* for the treatment by physicians or public health officials. Without adequate establishment of medical necessity, offering a treatment is unethical and prohibited in Western medical practice. (*See* Noorchashm Decl. ¶¶ 8-11).

45. The reason for this prohibition is that offering an unnecessary medical treatment is not only a violation of the medical ethical principle of *beneficence*, it opens the *unnecessarily* treated patient

<sup>(1)</sup> https://www.science.org/doi/10.1126/science.abf4063

<sup>(2) &</sup>lt;u>https://www.nature.com/articles/d41586-021-01442-9</u>

<sup>(3) &</sup>lt;u>https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s\_cid=mm7034e4\_w</u>

<sup>(4) &</sup>lt;u>https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e5.htm?s\_cid=mm7034e5\_w</u>.

<sup>&</sup>lt;sup>9</sup> <u>https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf</u>

to the risk of totally avoidable complications that are present in all medical treatments. The complications inflicted when patients are treated unnecessarily thus changes from an unfortunate and unavoidable adverse event (a side effect) into an unambiguous direct effect—a "harm." From that perspective, mandating an unnecessary medical procedure not only violates the medical ethical principle of *beneficence*, it also violates the principle of non-*maleficence*.

46. To coercively mandate, at risk of loss of employment or education opportunities, an unnecessary medical treatment is also a violation of the medical ethical principle of *autonomy*.

47. Moreover, because an unnecessary medical treatment neither stands to benefit the patient, nor society as a whole, and only leaves the door open to totally avoidable adverse events from the medicine, it is also a violation of the medical ethical principle of *justice*.

48. In sum, it is a well-established medical precept, accepted by most reasonable American physicians, that forcing an unnecessary (or even marginally beneficial) medical treatment on any person is a serious violation of basic medical ethics in the United States.

### It Is a "Standard of Care" That Persons Recently Convalescent from Transient Viral Infections, Such as SARS-CoV-2, Need Not Be Urgently Vaccinated

49. Under normal circumstances, vaccines are administered 1) prior to the emergence of infections, 2) for the purpose of preventing illness upon exposure to the causal virus. Certainly, most reasonable physicians understand that persons who have recently acquired viral infections are immune and do not need to be vaccinated – at least not within any urgent timeframe. This is true of Influenza, Measles, Mumps, Rubella, and even more persistent infections like Herpes Zoster and HPV.

50. In fact, many physicians, including myself, deem it an unsafe "breach of standard" to indiscriminately vaccinate any recently or concurrently infected and convalesced persons. At the very least, most reasonable physicians consider vaccination of already infected persons to be

unnecessary. This conclusion also now represents conventional wisdom that most of the general public has come to understand over the past century of vaccination practice in the western hemisphere. But, in 2021 during this pandemic viral outbreak, our nation seems to have abandoned this rational approach to vaccination. This is a critical error that is causing unjustifiable harm, on a systemic basis, to a subset of Americans representing a minority of the population.

51. In my previous declaration to the court on behalf of Ms. Norris, I listed studies demonstrating an increased incidence of adverse reactions in previously infected, COVID-recovered persons. Since then, an important study has been published in the prestigious peer-review journal, *Nature*, by Efrati *et al.*<sup>10</sup>

52. In this paper, the authors state very clearly that "short-term severe symptoms that required medical attention were found in 6.8% among the post-infected individuals, while none were found in the infection naïve population." That is, when COVID-recovered persons are vaccinated to "boost" their immunity, a subset of them develop "severe symptoms" for a time requiring medical attention to which their COVID-naïve counterparts are not susceptible.

53. The evidence is that a non-negligible subset of COVID-recovered Americans are, in fact, susceptible to adverse events following vaccination in excess of that which is experienced by COVID-naïve persons. Dr. Zervos's assertion that "there is no evidence from the literature, clinical trial information or published real world experience with vaccines" for an increased risk of adverse events in the previously/recently infected is false.

54. Naturally immune individuals such as Ms. Norris are at heightened risk of side effects as demonstrated by <u>https://www.nature.com/articles/s41598-021-96129-6</u> and the other studies referred to in my initial declaration to the court. (*See* Noorchashm Decl. ¶ 12-28).

<sup>&</sup>lt;sup>10</sup> https://www.nature.com/articles/s41598-021-96129-6

55. Additionally, many anecdotal cases of severe harm have been documented and verified in the press wherein concurrently or recently SARS-CoV-2 infected Americans experienced catastrophic complications. These includes the widely publicized cases of Dr. J. Barton Williams of TN, Mr. Everest Romney of UT and Mr. Christopher Sarmiento of NM. These individuals all had verified recent COVID-19 infections at the time of their vaccination, which triggered their complications or deaths.

56. As a result, it is my professional opinion as a physician, immunologist and public health advocate that there is a non-negligible risk of potentially irreversible harm to Ms. Jeanna Norris (and the class of Americans in her situation), if she were to undergo COVID-19 vaccination in light of her prior recent infection within the past year. This risk is only acceptable if: 1) she willingly accepts it for herself, and 2) leaving her unvaccinated would pose a risk of harm to herself and the broader society, above that posed by "fully-vaccinated" COVID-naïve persons who are relieved of all restrictions by MSU and the state. Neither of those scenarios exist here.

# I hereby declare under penalty of perjury under the laws of the United States of America that the following is true and correct (28 U.S.C. § 1746):

Hooman Noorchashm MD, PhD

### 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.	) ) CIV. A. NO. 1:21-cv-00756-PLM-SJB
SAMUEL 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,	)
	)
	)
Defendants.	)

## ORDER GRANTING PLAINTIFFS' UNOPPOSED MOTION TO EXCEED WORD LIMIT ON REPLY BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

THIS MATTER, having come before the Court on Plaintiff, Jeanna Norris's Unopposed

Motion to Exceed the Word Limit on Reply Brief in Support of Motion for Preliminary Injunction;

BEING FULLY ADVISED IN THE PREMISES, and pursuant to W.D. Mich. LGenR

7.1(c), this Court hereby GRANTS said Motion and accepts Plaintiff's Reply Brief for filing.

<u>/s/ Paul L. Maloney</u> Paul L. Maloney, District Court Judge