No. 22-1200

In the United States Court of Appeals for the Sixth Circuit

JEANNA NORRIS, ET AL., Plaintiffs-Appellants,

v.

SAMUEL STANLEY, ET AL. Defendants-Appellees.

On Appeal from the United States District Court for the Western District of Michigan

Plaintiffs-Appellants' Opening Brief

Oral Argument Requested Jenin Younes

July 5, 2022

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STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs-Appellants Jeanna Norris, Kraig Ehm, and D'Ann Rohrer respectfully request oral argument because it will assist the Court in its review of the issues presented by this appeal.

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David Rosenberg, Natural Infection vs. Vaccination: Which Gives More Protection?, ISRAELNATIONALNEWS.COM (July 13, 2021), available at https://www.israelnationalnews.com/News/News.aspx/309762 (last visited June 28, 2022)
Fabio Angeli et al., SARS-CoV-2 Vaccines: Lights and Shadows, 88 EUR. J. INTERNAL MED. 1, 8 (2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8084611/ (last visited June 29, 2022)
FAQs about Influenza Vaccination Requirement for MSU Healthcare Workers, available at https://bit.ly/3IipMdz (last visited July 5, 2022)
Interview with Dr. Harvey Risch, Yale School of Medicine, INGRAHAM ANGLE (July 26, 2021) available at https://bit.ly/3zOL6Sx (last visited June 27, 2022)
Jennifer Block, Vaccinating people who have had covid-19: why doesn't natural immunity count in the US?, British Med. J. (Sept. 13, 2021), available at https://www.bmj.com/content/374/bmj.n2101 (last visited June 23, 2022)
John Locke, Second Treatise of Government (1690)
Judgment, U.S. v. Brandt (Nuremberg Military Tribunal, Case 1) (Aug. 19, 1947), available at https://bit.ly/3uqATvk (last visited July 5, 2022)
Nathan Jeffay, Israeli, UK Data Offer Mixed Signals on Vaccine's Potency Against Delta Strain, TIMES ISR. (July 22, 2021), available at bit.ly/3xg3uCg (last visited June 28, 2022)
Quarantine and Isolation, CDC (March 3, 2022), available at https://bit.ly/3bKkw6d (last visited July 5, 2022)

Roni Caryn Rabin, The Coronavirus Attacks Fat Tissue, Scientists Find, N.Y. TIMES (Dec. 8, 2021)	
Sally Lynn Meloch, An Analysis of Public College Athlete Drug Testing Programs Through the Unconstitutional Condition Doctrine and the Fourth Amendment, 60 S. CAL. L. REV. 815 (1987)	
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JURISDICTIONAL STATEMENT

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3)-(4), as well as 42 U.S.C. §§ 1983 and 1988 and under non-statutory equitable jurisdiction. (RE 55, PageID #1196, ¶ 10). The district court entered final judgment on February 22, 2022. (RE 70, PageID #1470). Plaintiffs timely filed a notice of appeal on March 14, 2022. (RE 72, PageID #1472). This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF ISSUES

- 1. Whether the district court erroneously concluded that Michigan State University's (MSU) vaccine mandate did not violate Plaintiffs' constitutional rights to informed consent, to decline unnecessary medical treatment and to bodily autonomy.
- 2. Whether conditioning Plaintiffs' continued employment by the state on vaccination against COVID-19 is unconstitutional.
- 3. Whether, because MSU's vaccine mandate deprives Plaintiffs of their rights under the federal Food, Drug, and Cosmetic Act, it is necessarily irrational.

STANDARD OF REVIEW

This Court reviews *de novo* a district court's order granting a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). *Solo v. United Parcel Serv. Co.*, 819 F.3d 788, 793 (6th Cir. 2016). In doing so, the Court must "construe the complaint in the light most favorable to the plaintiff, accept all well-pleaded factual allegations as true, and examine

whether the complaint contains 'sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

STATEMENT OF THE CASE

I. INTRODUCTION

In July of 2021, MSU issued a vaccine mandate requiring all employees and students, unless they receive an approved medical or religious exemption, to receive a COVID-19 vaccine. The mandate explicitly and categorically refused to consider immunity acquired through prior infection as a substitute for vaccination. Those who declined to get vaccinated were subject to discipline, including termination from employment.

Plaintiffs all were employees of MSU when the mandate was announced and had demonstrable naturally acquired immunity to the virus. For this reason, they declined to receive COVID-19 vaccinations. Disciplinary proceedings against them commenced, and two of the three eventually were terminated. Plaintiffs brought suit in federal district court challenging the mandate on federal constitutional and statutory grounds. The district court granted MSU's motion to dismiss the complaint. This appeal follows.

II. FACTUAL BACKGROUND

A. COVID-19 and the Vaccines

The novel coronavirus, which can cause the disease COVID-19, is a contagious virus spread mainly through person-to-person contact. It is not disputed that the virus,

even before advent of the vaccines, only presented a significant risk to individuals aged seventy or older and those with comorbidities such as obesity or diabetes. (Joint Declaration of Drs. Jayanta Bhattacharya and Martin Kulldorff ("Joint Decl."), RE 55-1, PageID #1252-53). Individuals under fifty faced, and continue to face, a negligible risk of a severe medical outcome from a coronavirus infection, akin to the types of risk that most people take in everyday life, such as driving a car. Smiriti Mallapaty, *The Coronavirus Is Most Deadly If You Are Older and Male*, 585 NATURE 16 (Aug. 28, 2020). In fact, a late 2020, *pre-vaccination* meta-analysis published by the World Health Organization (WHO) concluded that the survival rate for COVID-19 patients under seventy years of age was 99.95%. (Joint Decl., RE 55-1, PageID #1253). Hospitalization rates likewise are heavily age dependent. (*Id.*).

At the end of 2020 and beginning of 2021, the Food and Drug Administration (FDA) approved three vaccines pursuant to the federal Emergency Use Authorization (EUA) statute, 21 U.S.C. § 360bbb-3: the Pfizer BioNTech, Moderna, and Johnson & Johnson (Janssen) vaccines. (First Amended Complaint ("FAC"), RE 55, PageID #1198). Pfizer's Comirnaty Vaccine received full FDA approval on August 23, 2021. (*Id.*). The Comirnaty Vaccine was *not* widely available and remains unavailable as a

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¹ There has been significant confusion over whether the BioNTech and Comirnaty vaccines are, in actuality, the same. In a letter to Pfizer, the FDA stated that "the Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) have the same formulation. The products are legally distinct with certain differences that do not impact safety or effectiveness." (FAC, RE 55, PageID

practical matter. Pfizer itself has stated that "there is not sufficient approved [Comirnaty] vaccine available for distribution to this population in its entirety at the time of the reissuance of this EUA." (FAC, RE 55, PageID ##1199-1200).

EUAs allow the FDA to make a product available to the public following a truncated testing process, and based on the best available data, without waiting for all the evidence needed for full FDA approval or clearance. (FAC, RE 55, PageID ##1200-1201). Products granted an EUA, by definition, have *not* yet been proven safe and effective. (Plaintiffs' Response in Opposition to Defendant's Motion to Dismiss ("Plaintiffs' Opp."), RE 62, PageID #1378).

All medical procedures, including immunizations, carry some risk of side effects. The COVID-19 vaccines appear to be relatively safe at a population level, but as is the case for all medical interventions, some individual vaccine recipients will suffer adverse consequences. Such side effects may include minor and temporary reactions such as pain and swelling at the vaccination site, fatigue, headache, muscle pain, fever, and

at *3 n.5 (N.D. Fla. Nov. 12, 2021).

^{#1199).} Generally speaking, certain drugs that the public believes are identical—generic versions of brand name drugs for instance—do not need to be formulaically identical to be considered "equivalent." (*Id.*). Despite Pfizer's proclamations to the contrary, an analysis of the ingredients in the Comirnaty and BioNTech vaccines indicates they are not, in fact, identical. (*Id.*). A federal court recognized as much, explaining that inactive ingredients may differ in these circumstances, which can translate into a disparity in safety and efficacy. *See Doe v. Austin*, No. 3:21-cv-1211-AW-HTC, 2021 WL 5816632,

nausea, but can also cause (though fortunately not as often) serious side effects that result in hospitalization or death. (Joint Decl., RE 55-1, PageID #1258-59).

Any long-term side effects from these vaccines remain unknown due to their relatively recent development. (*Id.*). As explained by Professors of Medicine Jayanta Bhattacharya, M.D., Ph.D. (Stanford University) and Martin Kulldorff, Ph.D., (formerly of Harvard University), "[a]ctive investigation to check for safety problems is still ongoing." (*Id.* at 1259). Thus, COVID-19 recovered patients with detectable levels of antibodies should not be required to receive vaccines, as "[f]or them, it simply adds a risk," without any concomitant benefit. (*Id.* at 1252).

The above analysis is not controversial, but is consistent with immunological wisdom, which recognizes that "vaccinating a person who is recently or concurrently infected [with any virus] can reactivate, or exacerbate, a harmful inflammatory response to the virus. This is NOT a theoretical concern." (Declaration of Immunologist Hooman Noorchashm, MD ("Noorchashm Decl.," RE 55-1, PageID ##1277-78, 1297)) (capitalization in original). The heightened risk of adverse effects appears to result from "preexisting immunity to SARS-CoV-2 [, which] may trigger unexpectedly intense, albeit very rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals." Fabio Angeli et al., SARS-CoV-2 Vaccines: Lights and Shadows, 88 Eur. J. INTERNAL MED. 1, 8 (2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8084611/ (last visited June 29, 2022); see also Jennifer Block, Vaccinating people who have had covid-19: why doesn't natural

immunity count in the US?, BRITISH MED. J. (Sept. 13, 2021), available at https://www.bmj.com/content/374/bmj.n2101 (last visited June 23, 2022) (citing several experts and studies establishing that those who have previously been infected are more likely to experience adverse side effects from the vaccine).

It is precisely because vaccinating individuals who have experienced the actual disease adds risk without corresponding benefit that none of the three vaccines used in the United States has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. (Noorchashm Decl., RE 55-1, PageID ##1278-79). In fact, the clinical trials *specifically excluded* survivors of previous COVID-19 infections. (*Id.*). The Centers for Disease Control (CDC) itself sidelined the Johnson & Johnson vaccine at the tail end of 2021 over concerns about blood clotting issues, the pervasiveness of which were not known before. (Plaintiffs' Opp., RE 62, PageID #1381). More data has been coming out about vaccine-induced myocarditis, especially in younger people, menstrual irregularities the cause of which remains unknown, and the vaccines' lack of efficacy in preventing infection in children. (Joint Decl. RE No. 55-1, PageID #1259).

Furthermore, existing clinical reports and studies indicate that individuals with a prior infection and natural immunity face an *elevated* risk of adverse effects from the vaccine, compared with those who have never contracted COVID-19. (Joint Decl., RE 55-1, PageID #1260; Noorchashm Decl., RE 55-1, PageID ##1278-79). In fact, some experts believe that subsequent vaccination (especially a two-dose regimen) for those

who have been previously infected may cause "exhaustion," and in some cases even a deletion, of T-cells," leading to a depleted immune response. Block, *supra*; *see also* Alysia Finley, *Why the Rush for Toddler Vaccines*, WALL ST. J. (July 4, 2022) ("Scientists are also discovering that triple-vaccinated adults who were previously infected with the Wuhan variant have a weaker immune response to Omicron, leaving them more susceptible to reinfection. This phenomenon, called 'immunological imprinting,' could explain why children who received three Pfizer shots were more likely to get reinfected.").

Drs. Bhattacharya's and Kulldorff's conclusion is inescapable: "The critical point for our analysis—undisputed in the scientific literature—is that the vaccines do have side effects, some of which are severe and not all of which are necessarily known at this point in time." (Joint Decl., RE 55-1, PageID #1259).

B. Naturally Acquired Immunity

"Natural" immunity is an individual's natural biological response to an infection. (See Joint Decl., RE 55-1, PageID #1254). Naturally acquired and vaccine induced immunity utilize the same basic immunological mechanism—stimulating the immune system to generate an antibody response to the pathogen. (Id. at 1254-55). The effectiveness of any vaccine is measured by comparing the body's immune response to the vaccine to the body's immune response to the live pathogen. Vaccines for COVID-19 are no different; indeed, the level of antibodies in the blood of those who have naturally acquired immunity served as the benchmark for determining the efficacy of vaccines during clinical trials. (Id.).

As discussed extensively in the filings below and recognized historically in the context of other diseases, overwhelming scientific research establishes that immunity following a COVID-19 infection is superior to that attained through immunization with the currently available vaccines. (FAC, RE 55, PageID ##1202-10). "The evidence to date suggests that while vaccines—like natural immunity—provide strong protection against severe disease, they, unlike natural immunity, provide only short-lasting protection against subsequent infection and disease spread." (Declaration of Dr. Jayanta Bhattacharya ("Bhattacharya Decl."), RE 55-1, PageID #1390).

With the passage of time, data demonstrating that naturally acquired immunity is more durable and longer lasting than vaccine immunity, particularly against emerging variants, has accumulated. A study out of Israel from the summer of 2021 found that vaccinated individuals had a 13.1 times higher risk of testing positive, a 27 times greater risk of symptomatic disease, and around an 8.1 times higher risk of hospitalization than unvaccinated individuals with naturally acquired immunity. (Id. at 1257). The authors concluded "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." (Id.). See David Rosenberg, Natural Infection vs. Vaccination: Which Gives More Protection?, (July 2021), available ISRAELNATIONALNEWS.COM 13, at https://www.israelnationalnews.com/News/News.aspx/309762 (last visited June 28, 2022) (those who received BioNTech Vaccine were 6.72 times more likely to suffer

subsequent infection than those with natural immunity); Nathan Jeffay, Israeli, UK Data Offer Mixed Signals on Vaccine's Potency Against Delta Strain, TIMES ISR. (July 22, 2021), available at bit.ly/3xg3uCg (last visited June 28, 2022) (declining efficacy of Pfizer protection against infection). Similarly, a CDC study released in January not only demonstrated that vaccination provides no discernible benefit to the naturally immune, but it provided conclusive evidence that naturally acquired immunity confers superior protection against the Delta variant (including against transmission). (Transcript of Hearing on Motion to Dismiss ("2/11/22 Transcript"), RE 75, PageID ##1496-97). See Tomás M. León et al., COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis—California and New York, May-November 2021, CDC (Jan. 29, 2022), available at https://www.cdc.gov/mmwr/volumes/71/wr/ mm7104e1.htm (last visited June 29, 2022) ("[I]nfection-derived protection was greater after the highly transmissible Delta variant became predominant, coinciding with early declining of vaccine-induced immunity.").

Much of this can be explained by the fact that prolonged immunity following COVID-19 infection is mediated not only by antibodies, but also by T- and B- memory cells, bone marrow plasma cells, spike-specific neutralizing antibodies, and IgG+ memory B-cells following a COVID-19 infection. (Joint Decl., RE 55-1, PageID #1255); see also Interview with Dr. Harvey Risch, Yale School of Medicine, INGRAHAM ANGLE (July 26, 2021), available at https://bit.ly/3zOL6Sx (last visited June 27, 2022). It is because of these additional immunity mechanisms that new variants of COVID-19

resulting from the virus's mutation are unsuccessful in defeating natural immunity, (FAC, RE 55, PAGE ID #1205; Joint Decl., RE 55-1, PageID #1261), but are able to evade vaccines which only target the spike-protein of the original Wuhan variant. (Noorchashm Decl., RE 55-1, PageID ##1275-76). In short, these studies confirm the efficacy of natural immunity against reinfection of COVID-19 and show that almost all reinfections are less severe than first-time infections and virtually never require hospitalization. (Joint Decl., RE 55-1, PageID #1255).

Nor does vaccination of individuals who have recovered from COVID confer any appreciable benefit on third parties. Thus, CDC itself acknowledged that it was *unable to document even a single case* of a COVID-recovered, unvaccinated individual spreading the virus to another person. (Plaintiff's Opp., RE 62, PageID #1382).

C. The Plaintiffs and MSU's Vaccine Mandate

In July of 2021, Plaintiffs Jeanna Norris, Kraig Ehm, and D'Ann Rohrer were employed by MSU. (FAC, RE 55, PageID ##1211-13). All have recovered from COVID-19. (*Id.*). Plaintiffs' experts examined the results of their antibody tests and concluded that the three possessed naturally acquired immunity to COVID-19. (*Id.*).

MSU announced its "COVID Directives" for the Fall 2021 semester on July 30, 2021, requiring all students and employees to be fully vaccinated or to obtain an approved religious or medical exemption by August 31, 2021. (*Id.* at 1214). The University's "FAQs" page explicating the mandate stated that naturally acquired immunity was not a basis for an exemption because, according to MSU, vaccination

provides "additional protection." MSU made clear that non-compliant individuals would be subject to disciplinary action, up to and including termination of employment. (*Id.* at 1214-15). Even employees who had arranged to work remotely during the fall semester had to be vaccinated or obtain a religious or medical exemption. (*Id.*).

MSU also stated that the rationale for its policy was that, *inter alia*, "[t]he current vaccines remain highly effective in preventing hospitalizations, severe disease and death from the Delta variant of COVID-19." (*Id.*). At the same time, the University acknowledged that "new studies demonstrate[] both unvaccinated and vaccinated individuals can transmit the disease to those who cannot currently be vaccinated, including children less than 12 years old and immunocompromised individuals" and "new data reveal[s] the Delta variant can create breakthrough infections in vaccinated individuals." (*Id.* at 1215).

Any WHO-approved vaccine, including those that are not FDA-approved (e.g., Chinese-developed Sinovac and Sinopharm vaccines, which have approximately 50% efficacy rates) satisfy MSU's mandate. (FAC, RE 55, PageID ##1207-08).

Plaintiffs Ehm and Rohrer were terminated from their positions at MSU on November 3 and 5, respectively, for refusing to receive a COVID-19 vaccine. (Plaintiff's Opp., RE 62, PageID ##1384-85). Plaintiff Norris obtained a religious exemption the day after she requested one on November 18, 2021. (Plaintiff's Opp., RE 62, PageID #1384).

III. PRIOR PROCEEDINGS

Plaintiff Jeanna Norris filed suit in the United States District Court for the Western District of Michigan on August 27, 2021, seeking injunctive and declaratory relief, a preliminary injunction (PI), and a temporary restraining order against the mandate, which was set to take effect in mere days. (See Complaint, RE 1; TRO, RE 3; PI, RE 4-1). After the District Court denied the TRO and PI (see Orders, RE 7, 42), the latter following a hearing, an amended complaint was filed, adding co-plaintiffs Rohrer and Ehm. (FAC, RE 55). Plaintiffs raised three claims (those in the original complaint): (I) MSU's vaccine mandate deprived them of the right to refuse unwanted and medically unnecessary care under the Ninth and Fourteenth Amendments to the United States Constitution; (II) the mandate created an unconstitutional condition; and (III) because the mandate conflicted with the federal EUA statute, it was preempted. (Id.).

MSU filed a motion to dismiss, which Plaintiffs opposed. (Defendants' Motion to Dismiss ("Def. MTD"), RE 60; Plaintiff's Opp., RE 62; Defendants' Reply ("Def. Reply,"), RE 63). In two separate orders, the district court dismissed the action. (1/21/22 Opinion and Order Granting in Part and Reserving in Part on Defendants' Motion to Dismiss ("1/21/22 Order"), RE 64; 2/22/22 Opinion and Order Granting Motion to Dismiss ("2/22/22 Order"), RE 70, PageID #1461).

With respect to Count I, relying on Jacobson v. Massachusetts, 197 U.S. 11 (1905), and Kheriaty v. Regents of the University of California, No. SACV21-01368 JVS (KESx), 2021

WL 4714664 (C.D. Cal. Sept. 29, 2021), the district court held that rational basis review applied to MSU's mandate (1/21/22 Order, RE 64, at 1429-31), and concluded that it was not "irrational for MSU not to provide an exception to its vaccine mandate for individuals who nave naturally acquired immunity." (*Id.* at 1469). The district court reasoned that "[i]n achieving [its] stated legitimate goal of protecting its students and staff from COVID-19, it was plainly rational, *in July 2021 when MSU established the policy*, for MSU to rely on CDC guidance and require its students and staff to receive the COVID vaccination." (*Id.* at 1470) (emphasis added). The court, however:

... note[d] Plaintiff's recent filing of the CDC study regarding natural immunity, released nearly two years after the commencement of the pandemic. Why did it take two years, plaintiffs impliedly ask, in light of the CDC['s] laser focus on vaccines as the principle [sii] answer to minimize sickness and 'the spread'? A question outside the lane of the judiciary, but one which calls for an answer if the CDC's science is to provide the rational basis for employer actions in the future.

(*Id.*).

In dismissing Count II, the court agreed that the unconstitutional conditions doctrine can apply to unenumerated rights. (*Id.* at 1433). However, the court held that Plaintiffs were not entitled to employment at MSU, so they were not being coerced into waiving a constitutional right to receive a government benefit. (*Id.*). Finally, the court dismissed Count III on the ground that Plaintiffs were not being forced to take a vaccine; rather their continued employment remained contingent on doing so, which it contended was different. (*Id.* at 1436).

SUMMARY OF ARGUMENT

The district court adopted a misguided interpretation of *Jacobson*. Contrary to the court's holding, Jacobson does not stand for the proposition that vaccine mandates are always subject merely to rational basis review. Instead, Jacobson employed a balancing test, weighing the interests of the individual against those of the state. A subsequent body of case law, some of it applying Jacobson, confirms that policies infringing upon an individual's bodily autonomy, including vaccine mandates, are subject to this balancing test. See, e.g., Washington v. Harper, 494 U.S. 210, 229 (1990). These principles stem from the common-law right to refuse medical treatment and maintain control over what happens to one's person. See, e.g., Vacco v. Quill, 521 U.S. 793, 807 (1997). Accordingly, the court applied an erroneous standard of review here. Moreover, even if Jacobson had used rational basis review, the Supreme Court in that case explicitly stated that its ruling was confined to the facts presented there, including: that the disease in question (smallpox) had the potential to decimate the human population; that the vaccine stopped transmission and so widespread immunization might eradicate the virus; and that the plaintiff was a fit subject for vaccination. The Court did not hold that all vaccine mandates are subject merely to rational basis review. See Jacobson, 197 U.S. 11.

Assuming *arguendo* that rational basis review is the appropriate standard, MSU's policy cannot survive even that. Initially, the district court did not properly evaluate the motion to dismiss on this count. It claimed to be accepting factual allegations as true, but simultaneously based its decision on the existence of a "robust debate" about the

efficacy of naturally acquired immunity versus vaccine-acquired immunity. According to settled law, the court was obliged to construe all factual assertions in Plaintiffs' favor. See Ashcroft v. Ighal, 556 U.S. 662, 678 (2009). That includes the fact that naturally acquired immunity confers better protection against reinfection, including transmission of the virus, than vaccine-mediated immunity. Moreover, the cited studies all confirmed the superiority of naturally acquired immunity. That the CDC misleadingly appended conclusions to its recommendations along the lines of "everyone should get vaccinated anyway" does not change the scientific truth. Blind reliance upon unscientific agency guidance is *not* rational. An institution imposing a vaccine mandate as a condition of continued employment has an obligation to conduct some independent assessment of the evidence on its own. After all, the CDC does not have the authority to hire and fire MSU employees (nor did the CDC recommend firing people—let alone naturally immune people—for refusing a COVID-19 vaccine). For these reasons, it is irrational to terminate someone from employment who has naturally acquired immunity when her colleagues with inferior vaccine-induced immunity are permitted to keep their jobs.

The district court's decision was also predicated upon a misapprehension of the unconstitutional conditions doctrine. That a state government employee is at-will does not mean that the employee may be terminated for *improper* cause, which includes exercise of his constitutional rights. *See, e.g., Perry v. Sinderman*, 408 U.S. 593, 597 (1972). Rather, the public employee only must show that his employer's policy burdens a constitutional right, separate and apart from the employment itself. *See O'Hare Truck*

Serv., Inc. v. City of Northlake, 518 U.S. 712, 713 (1996). Because MSU's vaccine requirement burdened Plaintiffs' ability to exercise their rights to informed consent, to decline unnecessary medical treatment, and to maintain bodily autonomy, it created an obviously unconstitutional condition.

Finally, MSU's vaccine policy flies in the face of federal law, which explicitly eschews forcing people to take products authorized for use emergency use only (EUA products). *See* 21 U.S.C. § 360bbb-3. By predicating continued employment on taking EUA vaccines, MSU's mandate impedes the purpose and intent of the governing statute, and it is therefore intrinsically irrational.

STANDARD OF REVIEW

On a motion to dismiss a complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), the court must "construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff," *DirecTV*, *Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007), but "need not accept as true legal conclusions or unwarranted factual inferences," *Gregory v. Shelby County*, 220 F.3d 433, 446 (6th Cir. 2000).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (internal quotations omitted). The burden is on the defendant to show that the plaintiff has failed to state a claim for relief. *DirecTV*, *Inc.*, 487 F.3d at 476.

ARGUMENT

I. THE DISTRICT COURT ERRONEOUSLY CONCLUDED THAT MSU'S VACCINE MANDATE DID NOT VIOLATE PLAINTIFFS' CONSTITUTIONAL RIGHTS TO INFORMED CONSENT, TO DECLINE UNNECESSARY MEDICAL TREATMENT, AND TO MAINTAIN BODILY AUTONOMY

For well over a year, COVID-19 vaccine mandate proponents have cited *Jacobson* to substantiate their contention that all immunization requirements are subject only to rational basis review. But in actuality, Jacobson, which evaluated the constitutionality of a smallpox vaccine mandate, utilized what would now be recognized as a form of intermediate scrutiny: it balanced the state's interests against the individual's interests. Not only that, but subsequent cases involving forcible administration of medication have also employed this balancing test. See, e.g., Cruzan ex rel. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 278 (1990); Harper, 494 U.S. at 229. These courts in these cases based their reasoning on the common law recognition of rights to refuse medical care, and to "determine what shall be done with [one's] own body." Schloendorff v. Soc'y of N.Y. Hosp., 211 N.Y. 125, 129-30 (1914) (Cardozo, J.); see Washington v. Glucksberg, 521 U.S. 702, 722 n.17 (1997) (these rights are "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment"). Against this backdrop, it is obvious that the district court was wrong to unquestioningly and automatically rule that all COVID-19 vaccine mandates are subject only to rational basis review. Furthermore, even assuming arguendo (and dubitante) that rational basis review

is the correct standard, MSU's vaccine mandate failed to meet it—especially because it made no exception for individuals like Plaintiffs who have naturally acquired immunity to COVID-19. Given the evidence establishing the superiority of such immunity to that attained through vaccination, there is not and never was a rational connection between MSU's policy—terminating unvaccinated but COVID-recovered employees while allowing the vaccinated to retain their employment—and MSU's stated objective of protecting the campus community from COVID-19. In sum, Plaintiffs urge the Court to reject the lower court's wrongheaded interpretation of *Jacobson*, and to hold, consistent with Supreme Court precedent, that intermediate scrutiny applies to the vaccine mandate in question. Alternatively, Plaintiffs urge the Court to find MSU's policy unconstitutional even under rational basis review.

A. MSU's Vaccine Requirement Is Subject to Intermediate Scrutiny

The right to refuse treatment is deeply rooted in this Nation's history and tradition. *Glucksberg*, 521 U.S. at 721. This right derives from the "well-established, traditional rights to bodily integrity and freedom from unwanted touching." *Vacco*, 521 U.S. at 807.

At common law, even the touching of one person by another without consent and without legal justification was a battery. Before the turn of the century, this Court observed that "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."

Cruzan, 497 U.S. at 269 (quoting Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891); see also Mills v. Rogers, 457 U.S. 291, 295 (1982) ("Under the common law of torts, the right to refuse any medical treatment emerged from the doctrines of trespass and battery, which were applied to unauthorized touchings by a physician."); Schloendorff, 211 N.Y. at 129-30 (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."). The idea that a person must be secure in his own body long pre-dates the Constitution. See, e.g., John Locke, Second Treatise of Government § 27 (1690) ("[E]very man has a property in his own person: this nobody has any right to but himself.").

Furthermore, the right to refuse medical treatment is "implicit in the concept of ordered liberty." *Glucksberg*, 521 U.S. at 721. This right has been recognized as universal in *U.S. v. Brandt*, (Nuremberg Military Tribunal, Case 1). In that case, also known as Doctors' Trial, American military judges wrote that when evaluating a propriety of a medical procedure, "[t]he voluntary consent of the human subject is absolutely essential." Judgment at 181 (Aug. 19, 1947), *available at* https://bit.ly/3uqATvk (last visited July 5, 2022). All of this strongly suggests that there can be no liberty without an individual's right to control what is done with or to his body. And a "forcible

injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" *Harper*, 494 U.S. at 229.

Consistent with these common-law concepts and contrary to the district court's holding, *Jacobson* and its progeny employed a more searching scrutiny than rational basis when evaluating policies which implicate fundamental substantive due process rights under the Fourteenth Amendment, such as the rights to informed consent, to exercise control over one's person, and the right to decline unnecessary medical treatment (bodily autonomy or bodily integrity). *See Cruzan*, 497 U.S. at 278 (describing *Jacobson* as having "balanced an individual's interest in declining an unwanted smallpox vaccine against the State's interest in preventing disease"); *Guertin v. State*, 912 F.3d 907, 919 (6th Cir. 2019) ("[T]he central tenet of the Supreme Court's vast bodily integrity jurisprudence is balancing an individual's common law right to informed consent with tenable state interests, regardless of the manner in which the government intrudes upon an individual's body.").

To begin, the *Jacobson* Court did not actually use rational basis review when it contemplated the constitutionality of a Massachusetts smallpox vaccine mandate. *See* 197 U.S. 11. Of course, *Jacobson*, which was decided in 1905, preceded the invention of tiered scrutiny, and so had no occasion to formally indicate the standard of review it was employing. Nevertheless, the claim that it used a functional equivalent of rational basis review is demonstrably false.

To the contrary, the *Jacobson* Court explicitly discussed the requirement that the government demonstrate a "substantial relation" between its articulated goal and the law in question and recognized the "inherent right of every freeman to care for his own body and health in such a way as to him seems best[.]" 197 U.S. at 26. That is a far more exacting standard than rational basis, which requires only that the government articulate an interest and a rational connection between the challenged law and the government's interest. See generally FCC v. Beach Comme'ns, Inc., 508 U.S. 307 (1993); Williamson v. Lee Optical, 348 U.S. 483 (1955). Put otherwise, rational basis does not entail any assessment of the individual's liberty interests. And a "substantial relation" is a higher bar than a "rational connection." See In re Cincinnati Radiation Litigation, 874 F. Supp. 796, 813 (S.D. Ohio 1995) (explaining that, although Jacobson upheld compulsory vaccination, it had done so while "acknowledg[ing] that an aspect of fundamental liberty was at stake and that the government's burden was to provide more than minimal justification for its action.").

Even if *Jacobson* had applied rational basis level review to the law at issue—it did not—the opinion made clear that the result did not automatically vindicate every vaccine mandate. *See* 197 U.S. at 28 ("[I]t might be that an acknowledged power of a local community to protect itself against an epidemic threatening the safety of all might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere

for the protection of such persons."). In fact, the Court itself eschewed a broad interpretation of its holding, confining it to the specific facts of that case when it wrote that it was "decid[ing] *only* that the statute covers the present case, and that nothing clearly appears that would justify this court in holding it to be unconstitutional and inoperative in its application to the plaintiff in error." *Id.* at 39 (emphasis added).

In several respects, the circumstances presented in *Jacobson* are vastly different from those in this case. For one, *Jacobson* involved vaccination against smallpox, a disease that killed around 30 percent of those infected and posed a significant risk to the young and middle-aged. The high fatality rate, one that COVID-19 does not even begin to approach, factored into the Court's evaluation of the vaccine mandate. Indeed, the *Jacobson* Court explicitly contemplated the deadliness of smallpox, as it "acknowledged [the] power of a local community to protect itself against an epidemic *threatening the safety of all*." 197 U.S. at 28 (emphasis added). The Court also contemplated that vaccine mandates failing to make appropriate exceptions for people "not at the time a fit subject of vaccination" or whose health might be "seriously impair[ed]" by vaccination may not pass muster. *Id.* at 39. Plaintiffs' naturally acquired immunity renders them unfit subjects for vaccination. *See supra*, Part II (B).

Furthermore, in *Jacobson*, the Court was persuaded by the government's stated public health aim of *preventing spread* of the disease and possibly even "eradicat[ing]" it through compulsory vaccination. *See* 197 U.S. at 28, 32 ("[T]he principle of vaccination as a means to prevent the spread of smallpox has been enforced in many states" and

"[i]f vaccination *strongly* tends to prevent the transmission or spread of this disease, it logically follows that children may be refused admission to the public schools until they have been vaccinated.") (emphasis added). By demanding that a vaccine strongly tend to prevent transmission, the court again required a substantial relation between the government's aim and the policy adopted.

Second, unlike in *Jacobson*, when it comes to COVID, there is no "common belief ... that [vaccination] has a decided tendency to prevent the spread of this fearful disease, and to render it less dangerous to those who contract it." Id. at 34 (quoting Viemeister v. White, 72 N.E. 97, 98 (N.Y. 1904)). To the contrary, the general consensus is that COVID vaccines do not "prevent the spread." (Bhattacharya Decl., RE 55-1, PageID #1390) (emphasis added). See Missouri v. Biden, No. 4:21-cv-01329, 2021 WL 5564501, at * 15-16 (E.D. Mo. Nov. 29, 2021), vacated and remanded on other grounds, No. 21-3725, 2022 WL 1093036 (8th Cir. Apr. 11, 2022) (noting that "the lack of data regarding vaccination status and transmissibility—in general—is concerning" and quoting the Centers for Medicare and Medicaid Service's own statements acknowledging that "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known" and "the continued efficacy of the vaccine is uncertain."). Nor does the vaccine "render [COVID] less dangerous to those who" have already had it. To the contrary, subsequent vaccination (especially a two-dose regimen) for those who have been previously infected may cause "exhaustion,' and in

some cases even a deletion, of T-cells," leading to a depleted immune response. Block, *supra*.

As vaccine-induced immunity wanes rather rapidly, boosters are needed to sustain antibody levels, necessitating repeated intrusion into the individual's body. That was not the case in *Jacobson* (nor has it ever been the case with prior vaccines that were mandated). Accordingly, MSU's mandate, unlike the vaccination requirement in *Jacobson*, could not be justified on the ground that forcing an individual to get vaccinated provides protection to others or otherwise achieves MSU's stated aim of protecting its community from COVID-19.² That is especially true given that Plaintiffs already possessed naturally acquired immunity, which is far more effective when it comes to hindering third-party transmission. (*See* Bhattacharya Decl., RE 55-1, PageID #1390).

Third, Jacobson involved a challenge to a statute that explicitly authorized a local board of health to "require and enforce the vaccination and revaccination of all the inhabitants thereof." 197 U.S. at 12. The Jacobson Court even expressly stated that it would not second-guess legislative action in this context. Id. at 25 ("[T]he police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.") (emphasis added).

² The connection between the mandate and MSU's stated goal becomes even more tenuous given that even employees working remotely, like Ms. Norris, were subject to the mandate. (*See* FAC, RE 55, PageID #1214-15).

In *Jacobson*, the Commonwealth of Massachusetts had exercised its police powers through the normal democratic process and the body authorized by the Constitution and laws of that state to enact rules and regulations protecting the population's welfare. In contrast, MSU's vaccine mandate was issued by administrative diktat, following federal guidance from unelected administrators. No statute or regulation specifically authorized MSU to do this, and no legal authority is even identified in the directive promulgated on July 30, 2021. Quite to the contrary, the claimed authority to issue such a mandate is at odds with the Michigan Supreme Court, which held that a statute that invested the Governor of Michigan—the Chief Executive of the State—"with sufficiently broad power of action in the exercise of the police power of the state to provide adequate control over persons and conditions during such periods of impending or actual public crisis or disaster," MCL 10.32, unconstitutionally delegated legislative powers of the state to the Executive Branch. In re Certified Questions from U.S. Dist. Ct., 958 N.W.2d 1, 24 (Mich. 2020). Whatever respect for police power the Court may have accorded to a valid *legislative* enactment in *Jacobson* is simply misplaced in the context of an administrative *ukase* authorized by no valid legal source of police power.⁴

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³ As it happens, in reaching this conclusion, the Michigan Supreme Court relied on an opinion from the Supreme Judicial Court of Massachusetts (the very state where *Jacobson* originated) which also held that even war "supplies no excuse for confusing legislative powers with executive powers." *Op. of the Justs.*, 52 N.E.2d 974, 978 (Mass. 1944).

⁴ To be clear, the issue here is not how the State of Michigan ought to allocate its considerable police powers as that issue rests squarely with the State. *Cf. Berger v. N.C.*

In misinterpreting *Jacobson*, the district court also ignored significant case law that has developed since 1905 which confirms that any injection into an individual's body constitutes a violation of her rights to bodily integrity, to informed consent, and to decline medical treatment and therefore implicates constitutional due process interests. *See Harper*, 494 U.S. at 229 ("[A] forcible injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty."); *Guertin*, 912 F.3d at 919 ("We have never retreated ... from our recognition that *any* compelled intrusion into the human body implicates significant, constitutionally protected interests.") (quoting *Missouri v. McNeely*, 549 U.S. 141, 159 (2013)) (alterations in original).

In *Harper*, the Court, in evaluating a mentally ill prison inmate's claim that forcibly injecting him with psychotropic drugs violated his right to due process of law, applied a more searching level of scrutiny than rational basis. The Court explained that whatever interest the State has in prison safety and security must be balanced against the prisoner's liberty and medical rights, writing that "the Due Process Clause permits the State to treat a prison inmate who has a serious mental illness with antipsychotic drugs against his will, if the inmate is dangerous to himself or others *and the treatment is in the inmate's medical interest.*" *Harper*, 494 U.S. at 242 (emphasis added). This approach is not the functional equivalent of rational basis review, which subordinates the rights

State Conf. of the NAACP, No. 21-248, 2022 WL 2251306, at *3 (U.S. June 23, 2022) ("Within wide constitutional bounds, States are free to structure themselves as they wish.").

of the individual, asking only whether the government has an interest and can articulate some nexus between the interest and the challenged law. *See also Heinrich ex rel. Heinrich v. Sweet*, 62 F. Supp. 2d 282, 313 (D. Mass. 1999) ("The Supreme Court balances invasions of an individual's interest in bodily integrity against the state's interests in pursuing its invasive conduct."). Rather, this is an equivalent of intermediate scrutiny which requires courts to first "ask whether a given privacy-implicating law is substantially related to an important government interest[, and second to] balance that interest against the individual's interest in privacy." *Hancock v. Cnty. of Rensselaer*, 882 F.3d 58, 65 (2d Cir. 2018).

In *Riggins v. Nevada*, the Court took a similar approach to that in *Harper*, explaining that the Fourteenth Amendment prohibited forcing antipsychotic drugs on a convicted prisoner "absent a finding of overriding justification and a determination of medical appropriateness" and evidence that there were no "less intrusive alternatives." 504 U.S. 127, 135 (1992). The Court castigated the district court for neglecting to take into account possible alternatives to forced medication or "indicat[ing] a finding that safety considerations or other compelling concerns outweighed Riggins' interest in freedom from unwanted antipsychotic drugs." *Id.* at 136.

In Sell v. United States, the Court summarized the holdings of Riggins and Harper, explaining that the government may forcibly administer psychotropic drugs to a mentally ill inmate "but only if the treatment is medically appropriate, is substantially unlikely to have side effects that may undermine the fairness of the trial, and taking

account of less intrusive alternatives, is necessary significantly to further important governmental trial-related interests." 539 U.S. 166 (2003). Additionally, "a court must find that *important* government interests are at stake." *Id.* at 180. In contrast, rational basis review does not compel the court to find the interest in question important, let alone require consideration of alternatives.

The history and the Riggins, Harper, Cruzan, and Sell line of cases stand for the proposition that there is a fundamental liberty interest in consenting to treatment and refusing unwanted medication. The reasoning in these cases, as well as the principles announced by the American Military Tribunal at Nuremberg is applicable to all medical procedures including vaccinations. The law requires courts to assess the medical propriety of treatment: government cannot simply require people to take any medication, regardless of consent, medical necessity and various other circumstances, merely because it can articulate an interest—here, ostensibly mitigating spread and severity of COVID-19. Rather, the means chosen to accomplish that interest must be (1) efficacious in achieving the articulated goal, and (2) balanced against individuals' constitutional rights to bodily autonomy. See Schmerber v. California, 384 U.S. 757, 772 (1966) ("The integrity of an individual's person is a cherished value in our society. That we today hold that the Constitution does not forbid the States minor intrusions into an individual's body under stringently limited conditions in no way indicates that it permits more substantial intrusions, or intrusions under other conditions."); see also Coburn ex rel. Coburn v. Agustin, 627 F. Supp. 983, 993-94 (D. Kan. 1985) ("The United States

Supreme Court has long exhibited an attentiveness to intimate personal liberties and rights regarding bodily integrity.").

Contrary to these precedents, the district court in this case did not, though it was obliged to, consider Plaintiffs' medical interests or the efficacy of MSU's approach in accomplishing its aim of preventing COVID deaths. Instead, the court below incorrectly relied on *Kheriaty*, which held that although the University of California's vaccination policy implicated the challenger's liberty interests, the right to avoid the vaccine was not fundamental and therefore did not warrant a level of review exceeding rational basis. 2021 WL 4714664, at *7.5 But the district court in *Kheriaty* employed the same erroneous analysis of *Jacobson* and other precedent, so by relying on it, the court below simply perpetuated and compounded the error. Given binding precedent from the Supreme Court requiring judges to balance Plaintiffs' interests against those of MSU, it was legal error to rely on the non-binding (and incorrect) decision of another

⁵ An appeal is currently pending the Ninth Circuit. See Kheriaty v. Regents of Univ. of Cal., No. 22-55001 (9th Cir. appeal docketed Jan. 3, 2022).

⁶ It goes without saying that the decision in *Kheriaty* was not binding on the court here. *See Camreta v. Greene*, 563 U.S. 692, 709 n.7 (2011) ("A decision of a federal district court judge is not binding precedent in either a different judicial district, the same judicial district, or even the same judge in a different case."); *see also United States v. Johnson*, 34 F. Supp. 2d 535, 538 n.3 (E.D. Mich. 1998) ("[D]istrict court judges are not bound by decisions of other district judges; it is federal appellate courts, not federal district courts, that are charged with responsibility for maintaining uniformity of the law.").

district court which dispensed with the balancing inquiry. This Court should, therefore, reverse the order granting the motion to dismiss and remand for further proceedings.

B. In Any Event, MSU's Vaccine Mandate Fails Rational Basis Review

Plaintiffs maintain that rational basis review is not the appropriate standard by which to evaluate their claim that MSU's vaccine mandate violates their constitutional rights to informed consent, bodily integrity, and the right to refuse unnecessary medical treatments. Nevertheless, even *if* rational basis applies to their claim in this section, Plaintiffs' claim should *still* prevail, because MSU's mandate doesn't satisfy even this less stringent standard.

Under the rational-basis test, Plaintiffs have the burden to prove either: a) that there is no conceivable legitimate purpose for the law at issue; or b) that the means chosen to effectuate that purpose are not rationally related to it. *Love v. Beshear*, 989 F. Supp. 2d 536, 547 (W.D. Ky. 2014). "Rational basis review, while deferential, is not 'toothless," *Peoples Rights Org., Inc. v. City of Columbus*, 152 F.3d 522, 532 (6th Cir. 1998) (quoting *Mathews v. Lucas*, 427 U.S. 495, 506 (1976)), and courts "insist on knowing the relation between the classification adopted and the object to be attained," *Romer v. Evans*, 517 U.S. 620, 632 (1996). Requiring this information "ensure[s] that classifications are not drawn for the purpose of disadvantaging the group burdened by the law." *Romer*, 517 U.S. at 633.

As an initial matter, when assessing the rationality of MSU's vaccine mandate, the court did not—as it was obliged to do—construe the factual allegations in the light

most favorable to Plaintiffs. *See DirecTV*, 487 F.3d at 476. Had it done so, the court would have accepted Plaintiffs' position, substantiated by declarations written by three experts in the fields of epidemiology and immunology, as well as *CDC's own studies*, that naturally acquired immunity is superior to that attained through vaccination, both in terms of preventing transmission and reducing the severity of disease.

Instead, the court treated the quality of naturally acquired immunity as the subject of a "robust scientific debate," (2/22/22 Order, RE 64, PageID # 1469), which the court then resolved in favor of MSU. But Plaintiffs did not concede the existence of a "robust scientific debate," much less that MSU had the better scientific argument. Rather, it was and remains their position that scientific data establish the superiority of naturally acquired immunity to that attained via vaccination (and certainly to most of the inferior foreign vaccines that MSU accepts), but that at times institutions and agencies such as the CDC have misrepresented the results of the pertinent research in their single-minded quest to zealously assert that every man, woman, and child should receive a COVID-19 vaccine. (Plaintiff's Opp., RE 62, PageID ##1394-96; 2/11/22 Transcript, RE 75, PageID ##1495-1503, 1511-12). The court's failure to accept this factual allegation at the motion-to-dismiss stage (one which was substantiated via expert declarations, no less) warped its analysis of a rational nexus between the purpose of the policy and the vaccine mandate.

The district court found that MSU's "stated legitimate goal" was "protecting its students and staff from COVID-19." (2/22/22 Order, RE 70, PageID ##1469-70).

The University's webpage, like the court's decision, conflates transmission with risk to the individual when it discusses vaccination as a strategy to prevent deaths and hospitalization. Respondents' motion to dismiss makes the same mistake. It states that "COVID-19 is still a threat to people who are *unvaccinated*." (Def. MTD, RE 60, PageID #135) (emphasis added). But if COVID-19 poses a threat only to the unvaccinated—and the vaccines protect any individual who receives them, as MSU contends—then there is no state interest in mandating vaccines for the benefit of third parties.

The government (including a state actor like MSU) is not entitled, without a compelling reason, to insert itself into employees' personal health decisions, especially ones that affect employees' very bodies.⁷ To hold otherwise would endow the State with carte blanche to wield limitless power over the lives of citizens. Why, if the individual's physical health is subject to mandate, should not daily exercise or consumption of green vegetables be required? *Cf. NFIB v. Sebelius*, 567 U.S. 519, 660 (2012) (Scalia, Thomas, Kennedy, & Alito, JJ., dissenting) ("[T]he failure of some to eat broccoli may be found to deprive them of a newly discovered cancer-fighting chemical which only that food contains, producing health-care costs that are a burden on the rest

⁷ One can imagine a case where a state employer imposes a health or fitness requirement which is directly relevant to the employee's duties, *e.g.*, physical fitness standards for campus police officers. *See, e.g.*, *EEOC v. Com. of Pa.*, 768 F.2d 514, 518 (3d Cir. 1985) (noting that Pennsylvania State Police could not impose an arbitrary retirement age, but could "monitor the health and physical prowess" of its officers). This, however, is not such a case as there is no claim that COVID vaccination is in any way related to Plaintiffs' job duties.

of us"). Obesity is one of the most significant risk factors for a severe COVID-19 infection, but no serious person has suggested mandating BMI below a certain level; to even consider such a concept is ludicrous. *Id.* at 553-54 (opinion of Roberts, C.J.); *see also* Roni Caryn Rabin, *The Coronavirus Attacks Fat Tissue, Scientists Find*, N.Y. TIMES (Dec. 8, 2021).

MSU's policy is even less rational when applied to Plaintiffs, who have naturally acquired immunity, superior to that of their vaccinated but not naturally immune counterparts. The complaint clearly alleges that naturally immune individuals have a lower risk of becoming re-infected and transmitting the virus than vaccinated individuals. (See FAC, RE 55, PageID ##1202-10). It does so through the declarations of three eminent experts in the disciplines of epidemiology and immunology, and citations to numerous studies. The complaint also contends that the vaccines can cause adverse effects, and though rare, they can cause severe ones, including death, and further, that individuals with naturally acquired immunity, as compared to those who have never recovered from COVID-19, face an elevated risk of such events. (FAC, RE 55, PageID #1210-11). The complaint, also through the expert declarations, explains that any theoretical benefit the vaccine provides to the naturally immune is so small as to be outweighed by the elevated risks. At a minimum, the negligible benefit does not warrant overriding an individual's autonomy by threatening her with loss of her job (and commensurate income) should she refuse informed consent and decline to subject herself to an unnecessary medical procedure. (*Id.* at 1205-07).

Nor does MSU require influenza vaccination even for its healthcare workers. MSU admits that "[a]bout 50,000 deaths in this country occur from influenza each year, many of which could be prevented by immunization of healthcare workers." FAQs about Influenza Vaccination Requirement for MSU Healthcare Workers, *available at* https://bit.ly/3IipMdz (last visited July 5, 2022). Nevertheless, MSU gives employees an option—be vaccinated or "wear an MSU-supplied mask when working in patient care areas." No such option is given to any MSU employees when it comes to the COVID vaccine, despite the fact that the overall risk from this disease is negligible. (Joint Decl., RE 55-1, PageID #1253).

These facts vitiate the claim that there is *any* rational basis for MSU's vaccine mandate. Forcing a COVID-recovered person to take a vaccine that provides no benefit either individually or to third parties, while carrying some risk of adverse effects, however slight, is not rational. The approach MSU has taken means that the university could mandate the vaccine for each employee every day—because doing so would boost their antibody levels. Plaintiffs' experts' supporting declarations, which at this stage must be credited, "negate[] every conceivable basis which might support' MSU's policy with respect to naturally immune individuals. *See Beach Comme'ns*, 508 U.S. at 307.

The district court's determination that simply because the CDC recommends that naturally immune people get vaccinated, MSU's policy was rational, cannot be correct. Plaintiffs explained at length that the CDC's recommendation was based on a nearly indiscernible and statistically insignificant antibody boost—which does not

necessarily translate into a clinical benefit—following vaccination. Once again, Plaintiffs' factual allegations (which were not mere unsupported assertions, but substantiated by declarations of three experts, and myriad studies cited in the complaint) should have been accepted as true.

But even more fundamentally, if under rational basis review agency recommendations from mere guidance documents are treated as unassailable truths, such that government entities may force their employees to follow them on pain of losing their jobs, then there is no available path to challenge bad government science, and we may as well dispense with the concept of judicial review of agency action altogether. In such a dystopian scenario, the CDC has effectively insulated itself from judicial review by touting its views merely as guidance rather than as judicially reviewable final agency action. Meanwhile, institutions across the country, using that very guidance, mandate that the naturally immune get the vaccine—and, like MSU, they rely on the guidance as a shield when their decision to fire people is challenged. It would be difficult for the government to create a more perfect example of a Catch-22.

But even if CDC's guidance did *ipso facto* make MSU policies crafted in reliance on it rational, MSU cannot take advantage of this defense because at least two of the vaccines that MSU accepts as compliant with its mandate (Sinovac and Sinopharm) were never approved nor recommended by the FDA nor the CDC. Nor does MSU follow the CDC's guidance when it comes to recognizing natural immunity in certain contexts, such as dispensing with quarantine requirements for individuals who

recovered from COVID-19 within 90 days. *See Quarantine and Isolation*, CDC (March 3, 2022), *available at* https://bit.ly/3bKkw6d (last visited July 5, 2022). MSU cannot claim that its policies are rational because they are based on CDC guidance, when those policies conveniently eschew such guidance when it suits the university (which presumably does not want to lose tuition from foreign students and so accepts demonstrably inferior foreign vaccines that do not stop the spread of the virus).⁸ Had the district court analyzed this issue, as it was obliged to do, by making all factual inferences in Plaintiffs' favor, it would have denied the motion to dismiss.

Finally, while Plaintiffs maintain that MSU's vaccine mandate, at least insofar as it did not carve out an exemption for the naturally immune, was always irrational, the district court's decision raises another issue. The court suggested, in a final footnote, that were it to decide the case based on the scientific evidence available at the time of the hearing on the motion to dismiss—February, 2022—it may have reached a different conclusion as to the rationality of the mandate. However, it considered itself bound by

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⁸ Acceptance of the Sinopharm and Sinovac vaccines strongly suggests that MSU's policy is motivated by little more than administrative convenience, as it may be easier on the bureaucracy to permit foreign students to enroll upon arrival rather than subjecting them to 2-3 week waiting period while they undergo the full vaccination protocol. Similarly, it may well be easier to require current employees to get vaccinated than to spend time evaluating their antibody levels. However, "personal liberties . . . of plaintiff[s] . . . are of paramount importance They should not be made to yield to mere convenience or expediency, nor sacrificed to the exigencies of special circumstances, even though some abuses may exist, if their elimination requires the arbitrary violation of these constitutional liberties."). *Backman v. Bateman*, 263 P.2d 561, 563 (Utah 1953).

the state of scientific knowledge as of July 2021, when MSU crafted its vaccine mandate. This decision was also legal error.

The Supreme Court has held that, especially when assessing constitutional challenges, courts can (and should) take facts and circumstances into account that have changed since the law or ordinance was enacted. In *Chastleton Corp. v. Sinclair*, 264 U.S. 543, 547 (1924), the Court considered the constitutionality of a law designed to address an emergency after that emergency had ended. Stating that it was "not at liberty to shut its eyes to an obvious mistake, when the validity of the law depends upon the truth of what is declared," the Court held that "[a] law depending upon the existence [of a] ... certain state of facts to uphold it may cease to operate if ... the facts change even though valid when passed." *Id.* at 547-48.

Likewise, in *Nashville, C. & St. L. Ry. v. Walters*, the Court faulted the Supreme Court of Tennessee for refusing to consider a change in circumstances as "[a] statute valid as to one set of facts may be invalid as to another. A statute valid when enacted may become invalid by a change in the conditions to which it is applied. The police power is subject to the constitutional limitation that it may not be exerted arbitrarily or unreasonably." 294 U.S. 405, 415 (1935).

And much more recently, in the context of COVID-19, Justice Gorsuch addressed New York Governor Cuomo's executive order restricting attendance at houses of worship writing in a concurring opinion that "[n]ow, as we round out 2020 and face the prospect of entering a second calendar year living in the pandemic's

shadow, that rationale [for the order] has expired according to its own terms." Roman Cath. Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring). In other words, Justice Gorsuch was looking at the constitutionality of the order at the time the Court itself was addressing the matter, not the time the order was issued more than six months before. See also United States v. Carolene Prods., Co., 304 U.S. 144, 153 (1938) ("[T]he constitutionality of a statute predicated upon the existence of a particular state of facts may be challenged by showing to the court that those facts have ceased to exist.").

The court's final footnote indicated that even it did not believe that implementing CDC's former recommendations as policy or law was still rational at the time the matter was litigated. It considered the question of why the CDC took two years to concede that naturally acquired immunity provides protection against minimizing sickness and transmission to fall "outside the lane of the judiciary," but "one which calls for an answer if the CDC's science is to provide the rational basis for employer actions in the future." (2/22/22 Order, RE 70, PageID #1470). In other words, the court itself acknowledged that "the CDC's science" might not constitute a rational basis.

To summarize, the district court incorrectly based its determination on the assumption that it could only look at the science available as of July 2021. First, the scientific knowledge at that time rendered MSU's vaccine mandate irrational, insofar as it failed to exempt the naturally immune, especially if the factual inferences were drawn

in Plaintiffs' favor, as they ought to have been. Second, the district court was in fact obliged to consider the most up-to-date science—that available to it in February 2022—particularly since MSU had not changed its mandate by permitting the naturally immune to forgo vaccination without discipline. As the court implied, MSU's vaccine mandate failed rational basis review at the time the court dismissed this case. In short, the court's failure to analyze MSU's policy at the time of litigation (rather than at the time of the original enactment) was error.

II. CONDITIONING PLAINTIFFS' CONTINUED EMPLOYMENT BY THE STATE ON VACCINATION AGAINST COVID-19 IS UNCONSTITUTIONAL

The district court erred when it held that, due to their status as "at will employees," Plaintiffs "are not constitutionally entitled" to their continued employment at Michigan State University, and therefore, "[t]he MSU vaccine policy does not coerce Plaintiffs into waiving their constitutional rights to bodily autonomy and to decline medical treatment." (1/21/22 Order, RE 64, PageID #1433). The district court rejected Plaintiffs' claims on the ground that continued public employment is not a "benefit such as a tax exemption, medical treatment, or some sort of governmental funding." (*Id.*). According to the district court, because Plaintiffs had no underlying right to continued employment, such employment could not be a "benefit." (*Id.*). This conclusion is wrong for at least three reasons.

First, the district court's analysis cannot be squared with the governing Supreme Court precedent, which "[f]or at least [three quarters of a] century ... has made clear that even though a person has no 'right' to a valuable governmental 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." *Perry*, 408 U.S. at 597. "It is by now black letter law that 'a state cannot condition public employment on a basis that infringes the employee's constitutionally protected interest" *Nichols v. Dancer*, 657 F.3d 929, 932 (9th Cir. 2011) (quoting *Connick v. Myers*, 461 U.S. 138, 142 (1983)); *see Spesier v. Randall*, 357 U.S. 513 (1958) (invalidating loyalty oath as a condition for veterans to obtain property tax exemption, to which veterans did not have a right, but rather was a privilege).

Under the unconstitutional conditions doctrine, the mere fact that employment can be terminated at any time without cause does not mean that an employee can be terminated for an *improper* cause. *See O'Hare*, 518 U.S. at 713 ("While government officials may terminate at-will relationships, unmodified by any legal constraints,

⁹ The court below appears to have analyzed Plaintiffs' unconstitutional condition claim as a due process claim. The two issues, however, are distinct and subject to distinct analytical frameworks. *See Perry*, 408 U.S. at 599 (the "lack of formal contractual or tenure security in continued employment ... though irrelevant to his free speech claim, is highly relevant to [the] procedural due process claim"); *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 569 (1972) ("The requirements of procedural due process apply only to the deprivation of interests encompassed by the Fourteenth Amendment's protection of liberty and property.").

without cause, it does not follow that this discretion can be exercised to impose conditions on expressing, or not expressing, specific political views."); see also Joyner v. Lancaster, 553 F. Supp. 809, 816 (M.D. N.C.1982), aff'd, 815 F.2d 20 (4th Cir. 1987) ("[S]heriffs can neither impose unconstitutional conditions upon public employment such as requiring employees to relinquish their rights of free speech and association nor discharge employees for a constitutionally infirm reason."). Thus, a public employee cannot be terminated in retaliation for speech that the government dislikes, see O'Hare, 518 U.S. at 717, or a refusal to consent to an unreasonable search, see United States v. Scott, 450 F.3d 863, 868 (9th Cir. 2006). This principle applies in the context of public employment "regardless of the public employee's contractual or other claim to a job." Perry, 408 U.S. at 597. Thus, public employment cannot be denied or withdrawn for refusing an unconstitutional demand to submit to unnecessary medical treatment.

The district court never cited *Perry*, *O'Hare*, nor their progeny, much less attempted to distinguish those cases from Plaintiffs' claims, despite the fact that those claims fall squarely within the ambit of binding Supreme Court precedent. This failing alone provides sufficient basis to reverse the judgment below.

Second, even if the district court were dealing with a case of first impression, its decision runs contrary to the basic logic of the unconstitutional conditions doctrine, which does not require that a plaintiff bringing a claim under this doctrine establish entitlement to continued employment. Rather, to succeed on such a claim, a public employee need show only that the burdened right "is protected by the Constitution and

that he or she suffered 'adverse employment action' for exercising the right." *McCabe* v. Sharrett, 12 F.3d 1558, 1562 (11th Cir. 1994). In other words, the employee must demonstrate that a constitutional right other than the employment itself is being burdened by imposition of a significant cost (in the form of potential job loss) on the exercise of that right.¹⁰

And this only makes sense. An employee who has a property or liberty interest in the job itself would not need to complain that the employer is forcing him to give up some *other* constitutional right in exchange for remaining employed. Such an employee could simply allege that the employer is *directly* violating the property or liberty interest in the *employment itself*. Thus, a tenured employee who is terminated for whatever reason could bring suit alleging deprivation of property. (The governmental entity would then be able to present evidence that the deprivation was consistent with the contract and accomplished through the appropriate procedures). *See Roth*, 408 U.S. at 569; *Speiser*, 357 U.S. at 525-26 ("Where one party has at stake an interest of transcending value—as a criminal defendant his liberty—this margin of error is reduced as to him by the

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¹⁰ In many ways the doctrine is similar to prohibitions on sexual harassment in the workplace: while an employer may fire an "at will" employee for any reason, an attempt to condition continued employment on submitting to demands for sexual favors is flatly illegal. *See Keppler v. Hinsdale Twp. High Sch. Dist. 86*, 715 F. Supp. 862, 867 (N.D. Ill. 1989) ("[A]n employer may not force an employee to engage in sexual relations on threat of losing her job, and an employer may not penalize an employee who rejects his sexual advance."). That is so not because an "employee" has a *right* to continued employment, but because it is improper to extract consent to sexual activity through threats to a person's livelihood. *Id*.

process of placing on the other party the burden of producing a sufficiency of proof in the first instance Due process commands that no man shall lose his liberty unless the Government has borne the burden of producing the evidence and convincing the factfinder of his guilt.").

To illustrate the point, imagine a law that requires a person to hop on his foot for fifteen seconds prior to being able to cast a ballot in an election. Such a law could be challenged on the ground that the person's constitutional right to vote is being infringed, irrespective of whether the foot-hopping requirement is onerous or not. The courts would resolve such a case by inquiring into the scope of the right to vote itself, and upon ascertaining that scope, determining whether the requirement to hop on one's foot treads on that right.

In contrast, an "untenured" or "at will" employee can never complain of a direct violation of the right to continued employment precisely because such a right does not exist for him. Thus, the termination of an "at will" employee does not deprive him of a property right. *See Perry*, 408 U.S. at 599. But the fact that an "at will" government employee does not have a property right in his job does not mean that he, by virtue of taking the "King's shilling" has "surrender[ed] [his other] constitutionally protected rights," *Wren v. Jones*, 635 F.2d 1277, 1282 (7th Cir. 1980), whether to freedom of speech or bodily autonomy and the right to refuse unnecessary medical treatment.

To return to the prior example, imagine a law requiring anyone who wishes to hop on his foot in a public park to first recite the Pledge of Allegiance. Of course, there

is no constitutional right to hop on one's foot in public. But that would not end the inquiry. Rather, a court would have to evaluate such a law by asking whether the plaintiff is being coerced into reciting the Pledge of Allegiance (which he has a constitutional right not to recite) by dangling in front of him the permission to hop in a public park. See Koontz v. St. Johns River Water Mgmt. Dist., 570 U.S. 595, 604 (2013) (The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up") (emphasis added). The question therefore is not whether MSU had the right to terminate the Plaintiffs, but whether it had a right to do so based on Plaintiffs' refusal to get vaccinated. The district court erred because it apparently concluded Plaintiffs' at-will status freed MSU from all constitutional restraints in the employer-employee relationships—and so fundamentally misapprehended the legal principles at stake.

Finally, the district court's analysis of the unconstitutional conditions claim is erroneous because, if taken to its logical conclusion, it would permit the government to punish any untenured employee for the exercise of almost any constitutional right. For example, under the district court's reasoning, MSU theoretically could establish a policy that any employee who demands a jury trial in any federal civil proceeding could be terminated. Similarly, according to the district court's logic, any employee who declines to cede a portion of his real property to the university, without compensation, could be dismissed. For that matter, MSU could adopt a policy requiring termination of any person who, following medical advice, decides to get vaccinated against some disease.

The possibilities are as endless as they are terrifying, and their recitation suffices to show that the district court misapplied the law of unconstitutional conditions.

To be sure, in order to prevail on their unconstitutional conditions argument, Plaintiffs must show that the decision whether or not to take the vaccine implicates *some* constitutional right. As Plaintiffs argue, the Supreme Court has long recognized that forcing people to take medication—and that includes vaccines—implicates the constitutional rights to bodily autonomy and to refuse unwanted treatment. (See FAC, RE 55, PageID #1220-1229; see also supra, Part I). If MSU does not have the power to compel Plaintiffs and other employees to receive a COVID-19 vaccine, then it also may not impose this requirement on Plaintiffs as a quid pro quo for their continued employment. See United States v. Whitten, 610 F.3d 168, 194 (2d Cir. 2010) ("Under the unconstitutional conditions doctrine, the government may not do indirectly what it cannot do directly.") (internal quotation omitted). See Sally Lynn Meloch, An Analysis of Public College Athlete Drug Testing Programs Through the Unconstitutional Condition Doctrine and the Fourth Amendment, 60 S. CAL. L. REV. 815, 832 (1987) ("[T]he unconstitutional condition doctrine reflects a balancing of the penalty against the justification."); see also Koontz, 570 U.S. at 604; cf. Jacobson, 197 U.S. 11 (penalty for non-compliance was a onetime fine of \$5, around \$150 today, as opposed to loss of employment and associated salary).

In short, MSU's vaccine mandate leveraged Plaintiffs' employment there to coerce them into surrendering their rights to bodily autonomy and to refuse medical

treatment. The mandate did so by threatening Plaintiffs' livelihoods even though—and in contrast to *Jacobson*—the vaccine in question does *not* stop transmission of the virus. And all of that was accomplished not through democratic means, but by an unelected, unaccountable administrator usurping legislative authority. In the face of these facts, the district court erred in concluding that the vaccine mandate was not an unconstitutional condition.

III. BECAUSE MSU'S VACCINE MANDATE DEPRIVES PLAINTIFFS OF THEIR RIGHTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, IT IS NECESSARILY IRRATIONAL

The Federal Food, Drug, And Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., governs the distribution and use of pharmaceuticals and medical devices in the United States. See, e.g., Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc., 552 F.3d 1033, 1036 (9th Cir. 2009). Under the Act, only FDA-approved pharmaceuticals can be marketed and prescribed in the United States. See United States v. Caronia, 703 F.3d 149, 153 (2d Cir. 2012) (citing 21 U.S.C. § 355(a)). Traditionally, the approval process includes yearslong testing first in non-human and then in human subjects. See Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 476-77 (2013). "A notable exception to this approval process, however, comes in the form of 'emergency use authorization." McCray v. Biden, No. CV 21-2882, 2021 WL 5823801, at *2 (D.D.C. Dec. 7, 2021). An EUA, once granted, permits a pharmaceutical "to be distributed to the public during a public health emergency, for the purpose of combatting that emergency, before the product has received final approval from the FDA." Id. (citing 21 U.S.C. § 360bbb-3). However,

emergency approval comes with significant caveats. As relevant here, when a product is granted an EUA, "individuals to whom the product is administered [must be] informed ... of the option to ... refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). On its face, the statute vests the decision of whether to take an unapproved drug with the person who is advised to take it and gives such a person an unfettered option to withhold informed consent and refuse the medication. MSU's mandate vitiates this statutory right.

MSU makes two arguments as to why its requirement does not violate the FDCA. Neither is convincing and both should be rejected.

First, MSU argues—and the court below agreed—that because Plaintiffs do "not have a constitutionally protected interest in" their employment, MSU was free to impose any condition on the continued employment it saw fit. That argument is without merit as outlined in the preceding section. *See supra*, Part II.

Second, MSU suggests that the informed consent provision "only applies to medical providers" administering the vaccine, and not to employers like itself. (Def. MTD, RE 60, PageID #1366-67 (quoting *Klaassen v. Trustees of Indiana Univ.*, 549 F. Supp. 3d 836, 870 (N.D. Ind. 2021), *vacated by* 24 F.4th 638 (7th Cir. 2022))). While the person responsible for explaining the pros and cons of the drug in question is the medical professional and not a university administrator, the doctrine of informed

Tribunal wrote, consent is only valid if given "without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion." *Brandt*, Judgment at 181(emphasis added); cf. 21 C.F.R. § 50.20 ("An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.").

Threats to one's livelihood are indubitably coercive. See, e.g., Spevack v. Klein, 385 U.S. 511, 516 (1967). In Spevack, the New York State Bar sought to discipline an attorney, essentially arguing that full cooperation with judicial inquiries is a condition of bar membership, regardless of his right against self-incrimination. Id. at 512-13. The Supreme Court rejected the State Bar's argument and held that "[t]he threat of disbarment and the loss of professional standing, professional reputation, and of livelihood" is coercive and impinges on a right not to self-incriminate in a different proceeding (even though that right was honored in the underlying case). Id. at 516. This case is no different. Here, Plaintiffs have a federal statutory right to decline administration of an experimental pharmaceutical approved only for emergency use. See 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). Federal law allows Plaintiffs (and others) to

make that choice based on their perception of the likely *medical* consequences alone,¹¹ but MSU seeks to use "[t]he threat of ... the loss of professional standing ... and of livelihood" to coerce Plaintiffs into surrendering their rights. The United States Constitution and federal laws are the "Supreme Law of the Land" and supersede the constitutions and laws of any state. U.S. Const. art. VI, cl. 2; *see English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) ("State law is pre-empted to the extent that it actually conflicts with federal law."). Much like in *Sperack*, this attempt should be viewed as coercive and irreconcilable with the federal right to decline an EUA product. *See Arizona v. United States*, 567 U.S. 387, 399-400 (2012) (holding that federal law preempts any state law that creates "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.").

If there is any doctrine well settled in our Constitutional law it is that "the states have no power ... to retard, impede, burden, or in any manner control the operations of the constitutional laws enacted by Congress to carry into effect the powers vested in the national government." *McCulloch v. Maryland*, 17 U.S. 316, 317 (1819). MSU's vaccine mandate does just that: it impedes and burdens a law passed by Congress which

To the extent that MSU argues that loss of employment is merely one of the consequences of which Plaintiffs were advised and which they voluntarily chose, such an argument runs contrary to the natural meaning of the word "consequences" in the context of a statute designed to regulate *medical* safety and efficacy of pharmaceuticals and devices. See NFIB v. Dep't of Lab., Occupational Safety & Health Admin., 142 S. Ct. 661, 665 (2022); Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs., 141 S. Ct. 2485, 2488 (2021).

bestows certain rights on citizens. Because it does so, it is inherently unlawful and fails any level of scrutiny. Even assuming that the mandate is subject only to rational basis review, a state law that deprives citizens of their federal statutory rights is necessarily irrational. See Nation v. San Juan Cnty., 150 F. Supp. 3d 1253, 1269 (D. Utah 2015), aff'd sub nom. Navajo Nation v. San Juan Cnty., 929 F.3d 1270 (10th Cir. 2019) ("A county or other local governing body cannot have a legitimate governmental interest in violating state law.").

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed and remanded to the district court so that Plaintiffs may prosecute their claims.

July 5, 2022 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 29(a)(5) because it contains 12,975 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in 14-point Garamond, a proportionally spaced typeface.

/s/ Jenin Younes

CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2022, an electronic copy of the foregoing brief was filed with the Clerk of Court for the United States Court of Appeals for the Sixth Circuit using the CM/ECF filing system and that service upon counsel for the parties will be accomplished using the CM/ECF system.

/s/ Jenin Younes

DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

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