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' Reply Brief

Oral Argument Requested

September 7, 2022

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INTRODUCTION

This is a simple case. Plaintiffs-Appellants ask that this Court acknowledge basic scientific reality—as basic as germ theory—that individuals who have recovered from infection with a live pathogen are, immunologically speaking, in the same *or better* position than those who have been exposed only to a laboratory-created version that mimics part of that pathogen. The entire field of immunology is keyed to this understanding. The Centers for Disease Control and Prevention ("CDC"), upon which Appellees purport to rely, is explicit: "The most effective immune responses are generally produced *in response to* antigens present in *a live organism*." A. Patricia Wodi, MD & Valerie Morelli, BA, CDC, *Principles of Vaccination*, *in* Epidemiology and Prevention of Vaccine-Preventable Diseases (Aug. 2021) ("The Pink Book") at 1, *available at* https://bit.ly/3zA9cBR (last visited Aug. 8, 2022). In the history of immunology and vaccinology, there has never been a case where a vaccine, standing alone, has resulted in better immune protection than exposure to and recovery from a live pathogen. And for good reason. Whereas vaccines (as valuable as they often are in preventing death and disease) work by inducing antibodies, live pathogens invoke both antibody *and* T-cell (cellular) responses. *See, e.g.*, Andrew J. Pollard & Else M. Bijker, *A Guide to Vaccinology: From Basic Principles to New Developments*, 21 Nature Revs. 83, 85 (2021); Todd Zywicki & Jeffrey Singer, M.D., Br. Amicus Curiae, 3-5, ECF 23 (filed July 12, 2022). Indeed, in clinical trials, the effectiveness of every vaccine is measured according to how closely the post-vaccination immune response

approximates the body's response to the actual disease. (*See* Joint Decl., RE 55-1, PageID.1254). Any policy predicated on ignoring or rejecting these basic scientific principles is, by definition, irrational.

Unable to dispute the irrefutable, Appellees attempt to distract with the irrelevant. For example, Appellees spend a significant amount of time and marshal multiple citations to show that Covid vaccines provide some minor additional protection even to those who have been infected with the live disease. This argument, however, is little more than a sleight of hand, because the relevant question is not whether vaccines provide some additional benefit *to the previously infected*, but whether vaccines provide an additional benefit to *third parties*. Appellees also cite studies concluding there is no way to know the antibody level at which a Covid-recovered person remains protected against reinfection. This is a red herring, because the same may be said of vaccine-induced immunity. And, as anyone who lived through the last year has surely observed, immunity from the vaccines is not particularly long lasting. Otherwise, we would not be in a phase where people are getting fourth boosters, and boosters specifically designed to protect against the Omicron variant.

Nor does Michigan State University ("MSU") compare correct groups. Plaintiffs-Appellants have argued since the beginning of this litigation that natural immunity is *at least as good* as vaccine-conferred immunity. In other words, Plaintiffs-Appellants have always compared vaccinated individuals whom MSU deemed "safe" to return to work with naturally immune individuals whom MSU deemed so "dangerous"

as to require termination. Knowing it cannot plausibly justify the distinction between the two groups (vaccinated and naturally immune), MSU instead attempts to compare individuals who have acquired natural immunity to other naturally immune individuals who, *in addition to* recovering from their infection, also obtained the vaccine.

The rest of Appellees' brief continues in much the same vein—irrelevant facts linked to imprecise legal arguments all leading to an incorrect overall conclusion. The Court should refuse to permit MSU's muddying of the waters to cloud its own judgment. Instead, it should reject MSU's argument and reverse the decision below.

ARGUMENT

I. NOTHING IN MSU'S SUBMISSION SHOWS THAT VACCINATING NATURALLY-IMMUNE INDIVIDUALS PROVIDES ADDED SAFETY TO OTHERS, SO ITS VACCINE MANDATE CANNOT SURVIVE RATIONAL BASIS REVIEW

"[A] competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment." *Cruzan ex rel. Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 278 (1990). And while the freedom to refuse medical treatment "is not absolute," *see, e.g.*, *Leath v. Webb*, 323 F. Supp. 3d 882, 893 (E.D. Ky. 2018) (internal quotations omitted), a State's ability to infringe on this right is limited to a narrow set of circumstances. As the Supreme Court explained in *Cruzan*, a State can override a person's decision to forgo medical treatment when advancing its own interests in "the protection … of innocent third parties, the prevention of suicide, and the maintenance of the ethical integrity of the medical profession." 497 U.S. at 271. It is important to emphasize that even assuming that refusing a particular treatment will have negative

effects on an individual (or even hasten death), this fact alone is insufficient for a State to disregard personal choice by a mentally competent person as to the medical intervention. *See, e.g.*, *In re Conroy*, 486 A.2d 1209, 1224 (N.J. 1985) ("[D]eclining life-sustaining medical treatment may not properly be viewed as an attempt to commit suicide. Refusing medical intervention merely allows the disease to take its natural course; if death were eventually to occur, it would be the result, primarily, of the underlying disease, and not the result of a self-inflicted injury."). When "there is no evidence in the record that would indicate that in forcing the unwanted medication on [an individual] the state was in any way protecting the interest of society or even any third party," *Winters v. Miller*, 446 F.2d 65, 70 (2d Cir. 1971), a State may not force such an individual to take even a life-saving medication, *see Conroy*, 486 A.2d at 1223 ("While … state interests in life are certainly strong, in themselves they will usually not foreclose a competent person from declining life-sustaining medical treatment for himself. This is because the life that the state is seeking to protect in such a situation is the life of the same person who has competently decided to forego the medical intervention; it is not some other actual or potential life that cannot adequately protect itself.").

In other words, if MSU's policy is to be sustained (under whatever level of scrutiny), it must be justified by something *other than* the concern for Appellants themselves. Rather, MSU must show that its intervention in the medical decision-making of competent adults either "protect[s] … innocent third parties," or

"maint[ains] … the ethical integrity of the medical profession." *Cruzan*, 497 U.S. at 271.[1] MSU's submissions do not come even remotely close to rising to the challenge.

From the very beginning, MSU's stated justification for its vaccine mandate was "keeping students, staff and faculty safe." Vaccine Mandate, RE 55-1, PageID.1327. In light of the legal strictures discussed above on the State's ability to mandate medical treatment against the wishes of a particular individual, *see Cruzan*, 497 U.S. at 271, this justification can only be understood as "keeping students, staff and faculty" *other than the individual being asked to get vaccinated* "safe," Dorit Rubinstein Reiss & Lois A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, 63 Buff. L. Rev. 881, 902 (2015) ("There is little question today that competent adults have an almost absolute right to refuse health care interventions, including lifesaving and life-sustaining treatment, unless their refusal has a *direct impact on the welfare of others*." (emphasis in original)). But what evidence has MSU put forth to justify its intrusion on the protected liberty interest? None at all, as it turns out.

For example, Appellees claim that "vaccination provides a strong boost in protection in people who have recovered from COVID-19." Appellees' Br. at 5. This is not an accurate portrayal the state of scientific knowledge to date, of which this Court

[1] There is no suggestion that medical ethics require (or even tolerate) administration of vaccines against a competent patient's wishes. *See* Code of Med. Ethics, Op. 1.1.3(d) (Am. Med. Ass'n 2016). Thus, in reality, the "protection … of innocent third parties" is the only way for MSU to justify its vaccination mandate.

may take judicial notice. Even the (latecoming) CDC has said that it makes no sense to discriminate against the unvaccinated, particularly the naturally immune, given what we now know.[2] *See Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems*, Ctrs. for Disease Control & Prevention (Aug. 19, 2022), *available at* https://bit.ly/3cNVvZ0 (last visited Sept. 5, 2022). Assuming *arguendo*, though, that vaccination provides a boost in antibodies, that fact is irrelevant to the question of whether the mandated Covid vaccines protect *others*. Similarly, MSU makes much of the fact that "Plaintiffs' allegations concede that vaccinating individuals who have recovered from COVID-19 'may raise their antibody levels' and that there is a possibility that this increase in antibody levels will translate into clinical benefits." Appellees' Br. at 7 (quoting RE 55, PageID.1224, ¶¶ 137-38). But again, such "clinical benefits," if any, will accrue only to the Plaintiffs themselves and not to third parties. So, as much as Plaintiffs appreciate MSU's concern for their health, at the end of the day, it is not for MSU to make personal healthcare decisions for them. Particularly when those healthcare decisions only "may" confer a benefit.

MSU next tries to marshal in support of its position the claim that "'those who have recovered from COVID could incrementally reduce the infection risk they pose to other [MSU] employees by also receiving the vaccine,' and that 'the combination of

[2] Indeed, as Plaintiffs have maintained for a year and substantiated with voluminous research, the science showed this just as clearly then, but for unclear reasons that data was obfuscated by CDC and other agencies.

a vaccination and a prior COVID [infection] reduces infection risk compared to either alone.'" *Id.* (quoting RE 55-1, PageID.1264, ¶ 37; *id.*, PageID.1306-07, ¶¶ 47-48). The problem with this argument though is that MSU, perhaps in hopes of confusing the Court, is comparing apples to oranges.

When it comes to exposure to Covid-19, the population generally, and MSU employees specifically, can be subdivided into four categories. The first group is one that has neither received the vaccine nor been exposed to Covid. This is the "no immunity" group. The second group is one that has received the vaccine but has not been exposed to Covid. This is the "vax immunity" group. The third group is one that has not received the vaccine but was infected with and survived Covid. This is the "natural immunity" group. All of the Plaintiffs belong to this group. And the final group is one that has both received the vaccine and survived native Covid. This is the "double immunity" group.

Appellants do not dispute that individuals falling into the first, "no immunity" category have the highest risk of both contracting Covid-19 and passing it along to others. Nor do Appellants dispute that individuals who agreed to be vaccinated and thus moved from the first group to the second (the "vax immunity" group) have a reduced risk of transmitting Covid to others. Whatever degree of reduction in risk exists, MSU has deemed it sufficient to permit employees in this group to remain employed and come to campus. The question then is whether Plaintiffs (and other similarly situated individuals) who fall into the third or "natural immunity" group have

reduced the risk of infecting others by the same or greater amount than individuals in the second group. If so, then there is no rational basis to discriminate between the second and third groups. That pairwise comparison is the *only* relevant one. Whether individuals in the fourth ("double immunity") group are *even better off* than individuals in the second or third groups is entirely irrelevant to the analysis, because MSU is allowing the second group on campus.

Appellants can concede, *arguendo*, that "the combination of a vaccination and a prior COVID [infection] reduces infection risk *compared to either alone*."[3] RE 55-1, PageID.1306-07, ¶¶ 47-48. But if that combination sets the floor level of risk that MSU is willing to tolerate, then it must insist that all of its vaccinated employees also contract and overcome Covid or lose their employment. If this sounds ludicrous, that is because it is. But Appellees are attempting to foist this absurdity on the Court. By comparing individuals with natural immunity to those who have had *both* the disease and the vaccine, the University appears to insist that the reduction in infection risk through

[3] In light of current data, even that assertion is at the very least questionable. Even the CDC has come to recognize the uselessness of vaccination mandates. The CDC Safer Federal Workforce Task Force has advised all federal agencies to no longer "require documentation of vaccination status from employees, [or] ask about the vaccination status of onsite contractor employees and visitors," explaining that "safety protocols *will not vary* based on vaccination status or otherwise depend on vaccination information." Safer Federal Workforce Task Force, *Initial Implementation Guidance for Federal Agencies on Updates to Federal Agency COVID-19 Workplace Safety Protocols* 2, Ctrs. for Disease Control & Prevention (Aug. 17, 2022), https://bit.ly/3QORQc5 (emphasis added).

either vaccination or overcoming live virus standing alone is insufficient. Yet, MSU is actually content to retain employees who have only had the vaccine. Given this posture, absent a showing that the vaccination *standing alone* protects others better than prior Covid infection *standing alone*, there is no rational reason to discriminate between individuals in the "vax immunity" and "natural immunity" groups. Indeed, as the CDC has recognized,

> A systematic review and meta-analysis including data from three vaccine efficacy trials and four observational studies from the US, Israel, and the United Kingdom, found *no significant difference in the overall level of protection provided by infection as compared with protection provided by vaccination*; this included studies from both prior to and during the period in which Delta was the predominant variant.

Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity, Ctrs. For Disease Control & Prevention (Oct. 29, 2021), *available at* https://bit.ly/3eklIhW (last visited Sept. 2, 2022) (emphasis added). Furthermore, "cohort studies including over 700,000 health system users in Israel and over 11,000 healthcare workers in India reported that history of prior infection provided greater protection from subsequent infection than vaccination alone." *Id.* This conclusion was in no way revelatory. The U.S. and Israeli studies referred to in the CDC's paper were published in April 2021, whereas the United Kingdom study was published a month before that, *i.e.*, almost as soon as vaccines became widely available and *months* before MSU promulgated its mandate. *See* Mahesh B. Shenai, *et al.*, *Equivalency of Protection from Natural Immunity in COVID-19 Recovered*

Versus Fully Vaccinated Persons: A Systematic Review and Pooled Analysis 21 nn.20-22 (citing studies), *available at* https://bit.ly/3QevLCH (last visited Sept. 2, 2022).

In short, MSU can point to no evidence whatever that even hints at the proposition that vaccinating naturally immune individuals provides *any* benefit to third parties. To the contrary, all evidence comparing naturally-immune individuals to vaccinated individuals indicates that the former group has at least as much (and likely more) protection from infection than the latter group. Yet, under MSU's policies, it is only the latter group that is viewed as sufficiently "safe" to be permitted to remain within MSU's employ. This classification defies reason and cannot be sustained even under deferential rational basis review.

Additionally, it is undisputed that vaccinations, safe and effective though they may be, like any other medical intervention carry a certain amount of risk. These are neither "conspiracy theories" nor unsupported worries about events that have almost no chance of occurring. These are medically documented, admittedly rare, but nevertheless quantifiable and serious side effects. For example, one of the documented risks posed by the Covid-19 vaccines is myopericarditis. And though it is not a very common complication, a Kaiser Permanente study concluded that "[t]he true incidence of myopericarditis [in individuals receiving a Covid vaccine] is markedly higher than the incidence reported to US advisory committees." *See* Katie A. Sharff, *et al.*, *Risk of Myopericarditis following COVID-19 mRNA vaccination*, MedRxiv (Dec. 27, 2021), bit.ly/3ncLwhN (last visited Sept. 2, 2022). In a similar vein, a recent study confirmed

that the Covid-19 vaccines may cause temporary changes to women's menstrual cycles. *See* Alison Edelman, *et al.*, *Association Between Menstrual Cycle Length and Coronavirus Disease 2019 Vaccination*, Obstetrics & Gynecology (Jan. 5, 2022), https://bit.ly/3pTAyyx (last visited Sept. 2, 2022). This finding may be indicative of long term, unknown effects. Joint Decl., RE 55-1, PageID.1258-59. As Dr. Anthony Fauci observed in 1999, a potential AIDS vaccine should not be administered widely for some time, because sometimes negative side effects take a decade or more to manifest themselves. *See* @jstylman, Twitter (Sept. 5, 2022, 1:50 PM), https://bit.ly/3D22JTS (last visited Sept. 6, 2022).

On this record, where MSU cannot establish any benefit to third parties from requiring naturally immune individuals to receive a Covid vaccine, while simultaneously being unable to dispute that these vaccines create some increased risk of medical complications in the putative recipients, the legal outcome follows ineluctably—the State cannot require employees to subject themselves to unwanted medical treatment. *See Cruzan*, 497 U.S. at 271; *Winters*, 446 F.2d at 70; *Conroy*, 486 A.2d at 1223.

II. *JACOBSON V. MASSACHUSETTS* OFFERS NO HELP TO APPELLEES

MSU spends a considerable portion of its brief attempting to convince the Court that the present case is both controlled and easily resolved by *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). In doing so, however, not only does MSU fail to convincingly rebut Appellants' arguments about the actual level of scrutiny that the *Jacobson* Court applied to the regulations at issue there, *see* Appellants' Op. Br. at 18-30, but it also fails to apply

the lesson that is drilled into every first-year law student—facts matter. Simply put, "*Jacobson*" is not a magic mantra the mere incantation of which allows the State to mandate upon its citizens whatever medical procedures it wishes.

Appellants will not needlessly repeat the arguments put forth in their opening brief about the appropriate level of scrutiny. However, it is worth reemphasizing that the *Jacobson* Court employed a quintessential intermediate scrutiny analysis when it required the government to 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. Unlike rational basis review, under which a court will uphold a statute so long as it can "find a reasonably conceivable state of facts that could provide a rational basis for the classification," *Minerva Dairy, Inc. v. Harsdorf*, 905 F.3d 1047, 1053 (7th Cir. 2018) (internal quotations omitted), the *Jacobson* Court cautioned that courts have a duty to intervene against a policy that has "no real or *substantial* relation" to public health ends, 197 U.S. at 31 (emphasis added).

In any event, on the facts before this Court, MSU's policy must fail review under *any* level of scrutiny. As the Seventh Circuit recently noted,

> *Jacobson*, although informative precedent, is factually distinguishable. The Massachusetts law and Cambridge mandate were challenged in the wake of the smallpox pandemic, which was of a different nature than the COVID-19 pandemic of the last few years. For example, … the smallpox fatality rate among

> the unvaccinated was about 26 percent; by contrast, the COVID-19 infection fatality rate was estimated in January 2021 to be somewhere between 0.0–1.63 percent.
>
> [Furthermore,] COVID-19 has "a low attack rate" in contrast to the smallpox pandemic. … [T]he vaccines for smallpox and COVID-19 are distinguishable—*the smallpox vaccine was a sterilizing vaccine, intended to kill the virus and prevent transmission, but many of the COVID-19 vaccines are, by design, non-sterilizing.*

Lukaszczyk v. Cook Cnty., ___ F.4th ___, ___, 2022 WL 3714639, at *7 (7th Cir. Aug. 29, 2022) (internal citations and footnotes omitted, emphasis added). Additionally, it is not disputed that in contrast to the present case, Rev. Henning Jacobson was unable to scientifically establish previous exposure to smallpox—indeed, testing to prove the existence of antibodies from a prior infection was not invented until the 1970s.[4]

Despite these key differences, the District Court concluded (and MSU argues here) that *Jacobson* unquestionably mandates this outcome. But if that were so, then any time there was an outbreak of *any* disease, the government could mandate *any* invasive procedure irrespective of the benefits it conferred on either the recipient or third parties. As bizarre and disturbing as it sounds, MSU is effectively urging this logic. *See*

[4] While it is true that neither the Massachusetts statute nor the Cambridge ordinance provided for any exceptions to the vaccination requirements for adults, *see* 197 U.S. at 12 (noting that the only exception was for "children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination"), it is equally true that the *Jacobson* Court was not presented with the question this Court is being asked to address. In other words, *Jacobson* may have rejected a *facial* challenge to the Massachusetts statute, but it had nothing to say about an *as applied* challenge of the type being pressed here.

Appellees' Br. at 35-36 (arguing that they could impose health care obligations on individuals on mere "speculation" and "unsupported by evidence or empirical data"). Taken to its logical conclusion, MSU's theory would permit the Government to require administration of any unproven and unapproved medication on the theory that it is "rational" to believe that "doing something" is better than "doing nothing." Under that reasoning, MSU could demand that every employee, for example, irradiate themselves on a daily basis with ultraviolet light, based on "speculation" that the light might kill the virus (even as it increases the irradiated person's chances of developing cancer).[5] If the Court recoils in horror (as it should) at endorsing the idea that the State can mandate its citizens (or a public university its employees or students) to become unwilling guinea pigs in its search for an effective therapeutic agent, it should recognize that the mandatory vaccination policy (especially for individuals who have acquired natural immunity to Covid-19) is equally problematic.

Even applying rational basis review, the Court should consider whether, in light of available scientific knowledge, MSU can establish a "conceivable basis' for [its] mandates." *Lukaszczyk*, ___ F.4th at ___, 2022 WL 3714639, at *8. In *Lukaszczyk*, the Seventh Circuit declined to preliminarily enjoin the mandate because "the plaintiffs did not provide any evidence—studies, expert reports, or otherwise—showing that the

[5] *See* John D'Orazio, *et al.*, *UV Radiation and the Skin*, 14 Int'l J. Molecular Scis. 12222 (2013).

benefits of vaccination on top of natural immunity eliminate a 'conceivable basis' for the mandates under rational basis review." *Id.* The same isn't true here. In the present case, Plaintiffs provided not only expert declarations and citations to a number of studies, but have also pointed out that the very authorities on which MSU seeks to rely recognize that natural immunity is *stronger* than the one provided by the vaccines and that no additional benefit *to others* is gained by vaccinating naturally immune individuals.[6] *See ante*, pp.5-10.

Jacobson thus offers no succor to MSU. That case merely upheld a democratically-adopted statute that required citizens to receive a vaccination or pay a *small* fine.[7] It

[6] It is also important to recall that unlike *Lukaszczyk*, which came up on an appeal from a denial of preliminary injunction, the procedural posture of this case is quite different—it is an appeal of a grant of a motion to dismiss Appellants' complaint. In seeking a preliminary injunction, it is the plaintiff that bears the burden of establishing a right to one. *See, e.g.*, *McNeilly v. Land*, 684 F.3d 611, 615 (6th Cir. 2012) ("The party seeking a preliminary injunction bears the burden of justifying such relief."). Thus, in the absence of "any evidence—studies, expert reports, or otherwise—showing that the benefits of vaccination on top of natural immunity eliminate a 'conceivable basis' for the mandates under rational basis review," *Lukaszczyk*, ___ F.4th at ___, 2022 WL 3714639, at *8, it is not surprising that requested relief would be denied. In contrast, on a motion to dismiss, the burden is on the movant (here Defendants-Appellees), *see Willman v. Att'y Gen. of United States*, 972 F.3d 819, 822 (6th Cir. 2020), and such motions are not to be granted "lightly because a dismissal denies the parties a full trial on the merits," *Holley v. Schreibeck*, 758 F. Supp. 283, 285 (E.D. Pa.), *aff'd*, 944 F.2d 897 (3d Cir. 1991). Here, where Plaintiffs-Appellants both brought forth substantial evidence of their own, and cast significant doubt on the claims made by Defendants-Appellees, dismissal was premature and improper.

[7] MSU makes much of the fact that Henning Jacobson was sentenced to jail for his refusal to pay the fine. In MSU's view, this is proof positive that the deprivation of liberty in *Jacobson* was even more significant than that visited upon Appellants. Once

does not provide governments of all levels with blanket authority to take over citizens' right to direct their own healthcare, nor does it abrogate centuries-old principles of common law that vest individuals with authority 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"). Instead, properly understood, *Jacobson* stands for a much narrower proposition, *viz.*, that whenever a particularly dangerous infectious disease is ravaging the community, the government may order its citizens to take precautions (including vaccines) that are universally recognized as having a "decided tendency to *prevent the spread of* [such] fearful disease." 197 U.S. at 34 (emphasis added). And lest there be any doubt about the scope of that decision, the Court itself cautioned 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.

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again, Appellees are playing fast and loose with the facts. The reason Rev. Jacobson was sent to jail has nothing to do with his refusal to get vaccinated, but everything to do with his refusal to obey a court order. Incarceration of someone who defies a court order (even if the order is eventually found to be unlawful) is entirely unremarkable and consistent with centuries of Anglo-American (if not worldwide) practice. *See, e.g.*, *Walker v. City of Birmingham*, 388 U.S. 307 (1967) (upholding incarceration of Dr. Martin Luther King, Jr. and other protestors for defying an injunction against marching in Birmingham, *even though* the underlying injunction was unlawful).

Appellees thus end where they began—facts matter. And the facts of the present case—including the inability of the vaccines in question to prevent the spread of Covid-19. *See, e.g.*, Eric Sykes, *CDC Director: Covid vaccines can't prevent transmission anymore*, MSN (Jan. 10, 2022), https://bit.ly/3cyqOH6 (last visited Sept. 2, 2022); Tim Hains, *CDC Director: Vaccines No Longer Prevent You From Spreading COVID*, REALCLEARPOLITICS (Aug. 6, 2021), https://bit.ly/3Rmj0Xo (last visited Sept. 2, 2022). The facts here are far too different from *Jacobson* to justify dismissal of Appellants' action by mere invocation of that precedent. Because the District Court succumbed to the temptation to do just that, its judgment must be reversed.

III. MSU CANNOT CLAIM RELIANCE ON CDC GUIDANCE BECAUSE EVIDENCE SHOWS *IT IS NOT—AND NEVER WAS*—ACTUALLY RELYING ON THE CDC

Realizing perhaps that this Court would not endorse its argument that it can require employees to undertake any medical procedure on the basis of mere "speculation," MSU also claims that its vaccine mandates "policy was aligned with the guidance from … subject-matter experts." Appellees' Br. at 36. Facts, however, show otherwise.

First, it is undisputed that no "subject-matter expert[]" in the United States approved the MSU-accepted Sinovac or Sinopharm vaccine. Indeed, the administration, sale, prescription, or distribution of those inferior vaccines is *illegal* in the United States. *See* 21 U.S.C. § 355(a). None of CDC's publications (or studies cited within those publications) discuss the efficacy of those two vaccines. Yet, under MSU's

policy, receiving an injection of these two *unapproved and illegal* vaccines satisfies the requirement. The lack of approval of the Sinovac and Sinopharm vaccines means, as a matter of law, that they are not "safe and effective." *See id.* Yet, MSU irrationally insists that an injection with a vaccine that is, by definition, "not effective" makes an individual so injected a lower risk than someone who is naturally immune as a result of a prior Covid infection.[8] MSU does not even bother defending including the Chinese vaccines in its policy and merely asserts *ipse dixit* that doing so is "rational" because these vaccines are approved by the World Health Organization.[9] The District Court did not credit this argument, R.E. 43, PageID.940-42, and neither should this Court.

MSU's recent behavior continues to show it does not rely on CDC's or anyone else's guidance in designing its policies. For example, as already discussed above, the CDC no longer advises agencies to "require documentation of vaccination status from

[8] MSU's argument, if adopted, would have far-reaching consequences. If it were the law in the 1950s, the University would have been able to require its pregnant female employees to take thalidomide, on the theory that the drug reduces pregnancy-related nausea (which it does). Under MSU's logic, in crafting such a mandate, it would have been "rational" to have relied on foreign "subject-matter experts," irrespective of the fact that at the time the drug was not adjudicated to have been "safe and effective." The mere possibility of such an outcome should strongly counsel this Court against adopting MSU's position.

[9] As explained in Appellants' Opening brief at 8 and n.8, the University's policy is driven by little more than administrative convenience and pursuit of tuition money from foreign students. MSU doesn't even bother to deny this. To the extent MSU relied on "subject-matter experts," the expertise was in finance and not public health. And while MSU's financial health is not unimportant, it cannot serve as a reason to override Appellants' abilities to make their own healthcare decisions.

employees" because "safety protocols *will not vary* based on vaccination status or otherwise depend on vaccination information." *COVID-19 Workplace Safety Protocols*, *supra* n.3. Yet, MSU continues to insist that all of its students, faculty, and staff receive one of the vaccines against Covid-19. *See Together We Will*, MSU https://bit.ly/3ebeKvF (last visited Sept. 4, 2022) ("All students, faculty and staff are required to be vaccinated against COVID-19 and boosted with an FDA-approved or -authorized or WHO-approved vaccine.").[10] Appellees once again are attempting to use a sleight of hand to justify their policy by pointing out that the CDC does continue to advise that "[p]eople who are up to date with their COVID-19 vaccines and get COVID-19 are less likely to develop serious illness than those who are unvaccinated and get COVID-19," Appellees' Br. at 37 n.14 (quoting *Omicron Variant: What You Need to Know*, CDC (updated July 29, 2022)). But while directing the Court's attention to that quote, MSU is palming the fact that the CDC's advice is directed to people (a) who seek to protect their *own* health, rather than safety of *others*, and (b) who have not acquired natural immunity through a prior infection. With respect to the latter point, as Appellants have shown time and again, the scientific consensus is uniform—"no significant difference in the overall level of protection provided by infection as

[10] Oddly enough, under MSU's policy, individuals who have been vaccinated with the Novovax vaccine are deemed to "meet the requirement as no booster has been authorized at this time." At the same time, even though neither Sinovac nor Sinopharm has been authorized, vaccination and boosters with those vaccines is required.

compared with protection provided by vaccination," and to the extent that there is a difference, the difference favors natural rather than vaccine-acquired immunity. *Infection-induced and Vaccine-induced Immunity*, *supra*.

MSU is playing a version of three-card monte here. Whenever any of MSU's policies happens to align with some CDC pronouncement, MSU uses the CDC's statement (no matter how out of context it might be) as proof that it is acting rationally. Yet, when it is pointed out that CDC's guidance does not actually support MSU's actions—for example, CDC never issued guidance advising universities to fire unvaccinated employees with natural immunity[11]—Appellees claim that their policies are nevertheless rational because they are promulgated in reliance on some other "subject-matter experts." Given the significant doubts that Plaintiffs-Appellants have cast on MSU's claims of reliance on the expertise of others, dismissal under Fed. R. Civ. P. 12(b)(6) is, at the very least, premature. *See Lawton v. Success Acad. Charter Sch., Inc.*, 323 F. Supp. 3d 353, 365 (E.D.N.Y. 2018) (holding that disputes about motivation underlying Defendants' actions going to the actions' legality "raises a factual dispute inappropriate for resolution on a Rule 12(b)(6) motion"); *see also Stratton v. Portfolio Recovery Assocs.*, 770 F.3d 443, 447 (6th Cir. 2014), as amended (Dec. 11, 2014) ("[O]f

[11] To the contrary, Dr. Fauci stated: "You don't want to mandate and try and force anyone to take a vaccine. We've never done that." Likewise, he has remarked, "You can mandate for certain groups of people like health workers, but for the general population you can't." *COVID-19 Vaccine Won't Be Mandatory in US, Says Fauci*, Med. Xpress (August 19, 2020), bit.ly/3x2sgHf (last visited Aug. 17, 2022). Addressing the prospect of such mandates, he has deemed them "unenforceable and not appropriate." *Id.*

course, a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely."(quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). The Court should, therefore, reverse the grant of MSU's motion to dismiss so that discovery can commence on the issue of what evidence (if any) MSU did rely on to craft its vaccination mandate.

IV. MSU'S VACCINE MANDATE IS AN UNCONSTITUTIONAL CONDITION

Little new needs to be said on this point, as this argument rises and falls with the argument that the vaccination requirement fails any level of scrutiny. *See ante*, §§ II-III. MSU does not dispute that the key question is not whether Appellants were tenured or at-will employees, but whether "MSU may constitutionally require its non-exempt faculty and staff to be vaccinated for COVID-19." Appellees' Br. at 42. Thus, the District Court's reliance on Appellants' employment status in resolving this issue was in error. Because MSU's vaccine mandate does not meet either intermediate or rational basis scrutiny, it necessarily follows that conditioning one's continued employment on submitting to the irrational mandate and thereby giving up one's constitutional rights to control one's one body and to refuse unwanted medical treatment is an unconstitutional condition. *See Nichols v. Dancer*, 657 F.3d 929, 932 (9th Cir. 2011); *McCabe v. Sharrett*, 12 F.3d 1558, 1562 (11th Cir. 1994).

V. MSU'S MANDATE IS IRRATIONAL BECAUSE IT VIOLATES FEDERAL LAW GOVERNING EMERGENCY USE AUTHORIZATION OF DRUGS

It is well settled that upon ratifying the Constitution, "the States implicitly agreed that their sovereignty 'would yield to that of the Federal Government so far as is necessary to the enjoyment of the powers conferred upon it by the Constitution.'" *Torres v. Tex. Dep't of Pub. Safety*, 142 S. Ct. 2455, 2463 (2022) (quoting *PennEast Pipeline Co. v. New Jersey*, 141 S. Ct. 2244, 2259 (2021)). In joining the Union, the States "commit[ted] not to 'thwart' or frustrate federal policy." *Id.* For that reason, "it has long been settled that state laws that conflict with federal law are 'without effect,'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479–80 (2013) (citing *McCulloch v. Maryland*, 17 U.S. 316, 317 (1819)), and therefore cannot survive any level of review.

It is also undisputed that the federal Food, Drug, and Cosmetic Act (FDCA) requires that with respect to drugs that are available only pursuant to the Emergency Use Authorization, 21 U.S.C. § 360bbb-3(a)(1), individuals who are offered such products must be "informed" "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks," *id.* § 360bbb-3(e)(1)(A)(ii)(III).[12] The choice, of course, must be freer than that usually offered by Vito Corleone. *See* The Godfather (Paramount 1972). Here, of course, such

[12] Appellees concede that at the very least, § 360bbb-3 requires medical providers to obtain informed consent prior to administering products authorized under that provision. *See* Appellees' Br. at 45.

a choice was absent. Instead, Plaintiffs were "put to a choice between their job(s) and their jab(s)." *BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021).

MSU does not deny that its mandate comes with a lack of any meaningful choice. Instead, it argues that Appellants have no private right of action to enforce FDCA's provisions and that, in any event, the provisions do not apply to MSU in its capacity as an employer. MSU, however, misunderstands Appellants' argument. Appellants are not seeking to enforce the FDCA as private attorneys general. Rather, Appellants are arguing that because MSU's policies frustrate rights granted them by a federal statute, such policies necessarily fail any level of scrutiny.

To understand the argument, consider the following hypothetical. Imagine that the State of Michigan decided to print its own money and then MSU demanded that its employees accept payments in this "Michigan currency." Undoubtedly, this would violate the U.S. Constitution's Article I, § 10. An individual aggrieved by the requirement to accept payment in the hypothetical "Michigan currency" would be able to bring suit to enjoin the requirement. A plaintiff in such a case would not be directly seeking to enforce a prohibition on Michigan coining its own money; rather, she would be seeking to enforce her own right not to take payment in such ersatz "currency."

The same logic applies here. Appellants are not challenging some specific protocol that MSU's doctors employ when administering a vaccine to willing recipients and seeking to change it to better align with the FDCA. Rather, Appellants are seeking

to ensure that their own right "to accept or refuse administration of the" vaccine, 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), is not undermined by MSU's conflicting policy.

CONCLUSION

Force-vaccinating naturally immune people is an irrational policy that does nothing to prevent the spread of Covid-19. Prevailing even on that narrow point suffices to defeat the Appellees' Motion to Dismiss, so the judgment of the District Court should be reversed and the matter remanded for further proceedings.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B)(ii) because it contains 6,470 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 serif typeface.

/s/ Jenin Younes

CERTIFICATE OF SERVICE

I hereby certify that on September 7, 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

RE	Description	PageID#'s
43	Transcript of Hearing on Motion for Preliminary Injunction	940-942
55	First Amended Complaint (November 5, 2021)	1190-1248
55-1	Attachments to First Amended Complaint (November 5, 2021)	1239-1340