

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN**

JEANNA NORRIS, KRAIG EHM,)
and D’ANN ROHRER,)
)
Plaintiffs,)

Case No. 1:21-cv-00756

vs.)

SAMUEL L. STANLEY, JR.,)
in his official capacity as President of)
Michigan State University; DIANNE)
BYRUM, In her official capacity as Chair)
of the Board of Trustees, DAN KELLY,)
in his official capacity as Vice Chair)
of the Board of Trustees; and RENEE)
JEFFERSON, PAT O’KEEFE,)
BRIANNA T. SCOTT, KELLY TEBAY,)
and REMA VASSAR in their official)
capacities as Members of the Board of)
Trustees of Michigan State University,)
and JOHN and JANE DOES 1-10,)
)
Defendants.)

DEFENDANTS’ BRIEF IN SUPPORT OF MOTION TO DISMISS

Michigan State University’s requirement that its staff be vaccinated for COVID-19 is unquestionably constitutional and violates no other laws. Plaintiffs’ Amended Complaint contains three claims to the contrary under the Fourteenth Amendment and the Supremacy Clause. None survives the Rule 12(b)(6) standard. Plaintiffs’ “right to refuse unwanted and medically unnecessary care” is neither fundamental nor implicated by MSU’s policy, which also does not constitute an unconstitutional condition or violate any procedural due process right that Plaintiffs possess. The Emergency Use Authorization statute is similarly inapplicable to MSU’s policy and thus does not give rise to a claim under the Supremacy Clause. The Amended Complaint should be dismissed.

I. Relevant Facts¹

A. The COVID-19 Pandemic

“The virus causing COVID-19 arrived in Michigan and began to spread rapidly.” *GRO Holdco, LLC v. Hartford Fire Ins. Co.*, No. 1:20-CV-1093, 2021 WL 1827076, at *3 (W.D. Mich. May 7, 2021). According to the Michigan Department of Health and Human Services (MDHHS), Michigan’s first presumed-positive cases of COVID-19 were identified on March 10, 2020. *See* Executive Order No. 2020-4, Declaration of State of Emergency (last visited Nov. 15, 2021), *available at*: https://www.michigan.gov/whitmer/0,9309,7-387-90499_90705-521576--,00.html. Between March 10, 2020 and November 15, 2021, Michigan has had 1,209,715 confirmed cases of COVID-19, with 22,862 deaths. MDHHS, *Where We Stand With COVID-19* (last visited Nov. 15, 2021), *available at*: <https://michigan.gov/coronavirus>; *see also* Michigan COVID-19 Cases by County (last visited Nov. 15, 2021), *available at*: https://www.michigan.gov/coronavirus/0,9753,7-406-98163_98173---,00.html (estimating 1,370,035 total cases).

Michigan currently leads the nation in new COVID-19 cases, with a seven-day new case rate of 504 per 100,000 residents. United States COVID-19 Deaths, and Laboratory Testing

¹ For purposes of this motion, MSU accepts the facts in the Amended Complaint as true and supplements them only with publicly available information of which the Court may take judicial notice. *See, e.g., U.S. ex rel. Dingle v. BioPort Corp.*, 270 F. Supp. 2d 968, 972 (W.D. Mich. 2003), *aff’d sub nom.*, 388 F.3d 209 (6th Cir. 2004) (taking judicial notice of “public records and government documents available from reliable sources on the Internet” in granting motion to dismiss); *Weaver v. Palmer*, No. 1:09-CV-232, 2009 WL 1212817, at *2 n.2 (W.D. Mich. Apr. 30, 2009) (same). However, neither MSU nor the Court are required to accept the legal conclusions in the Amended Complaint as true. *Bright v. Gallia Cty., Ohio*, 753 F.3d 639, 652 (6th Cir. 2014) (instructing that in evaluating a motion to dismiss, “[c]onclusory allegations or legal conclusions masquerading as factual allegations will not suffice”).

(NAATs) by State, Territory, and Jurisdiction (last updated Nov. 16, 2021), *available at:* https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days. Accordingly, the CDC advises that the risk of community transmission of COVID-19 in Michigan is “high.” CDC, COVID-19 Integrated County View, Michigan, Nov. 8, 2021 – Nov. 14, 2021 (last visited Nov. 15, 2021), *available at:* https://covid.cdc.gov/covid-data-tracker/#county-view|Michigan|Risk|community_transmission_level. As of Michigan’s November 5, 2021 State Profile Report for the CDC, the rate of new COVID-19 cases per 100,000 people in Michigan had increased 17% over the previous week, and the rate of new confirmed COVID-19 hospital admissions per 100 beds had increased 7% over the previous week. HHS, *Michigan State Synopsis* (dated Nov. 5, 2021), *available at:* <https://healthdata.gov/Community/COVID-19-State-Profile-Report-Michigan/s8hn-gz3c>. By August 2021, over 96% of the samples tested in Michigan are positive for a variant, and the Delta variant and Mu variant are both confirmed to be present in Michigan. HHS, *Michigan State Synopsis* (dated Aug. 27, 2021), *available at:* <https://healthdata.gov/Community/COVID-19-State-Profile-Report-Michigan/s8hn-gz3c>; MDHHS *identifies first Michigan case of new COVID-19 variant, B.1.1.7 in Washtenaw County* (last visited Nov. 15, 2021), *available at:* <https://www.michigan.gov/coronavirus/0,9753,7-406-98158-549766--,00.html#:~:text=19%20variant%2C%20B.-.1.1.,Kingdom%2C%20where%20this%20variant%20originated.>²

² Variants are different forms of the COVID-19 virus that arise as the virus mutates. *See* CDC, *What You Need to Know about Variants* (updated Nov. 1, 2021), *available at:* <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html>. The Delta variant “is currently the predominant variant of the virus in the United States” and “causes more infections and spreads faster than early forms of SARS-CoV-2, the virus that causes COVID-19.” CDC, *Delta Variant: What We Know About the Science* (last visited Nov. 15, 2021), *available at:* https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html?s_cid=11621:cdc%20delta%20variant%20vaccine:sem.ga:p:RG:GM:gen:PTN.Grants:FY22. The World Health Organization has designated the Mu variant as a recently

Since August 2, 2021, MSU has reported 794 cases of COVID-19. MSU, *Testing and Reporting* (last visited Nov. 15, 2021), available at: <https://msu.edu/together-we-will/testing-reporting/>. As of November 15, 2021, Ingham County, Michigan (where MSU’s primary campus is located) had reported 32,663 cases, approximating that 54% of those cases are in individuals ages 20 to 49. *COVID-19 Dashboard Ingham County, Michigan* (last updated Nov. 10, 2021), available at: <https://ichd.maps.arcgis.com/apps/dashboards/d9fd5db6d01348fdb1b9f8d1516bb825>.

B. COVID-19 Vaccinations

Vaccinating individuals against COVID-19 currently is the leading prevention strategy to protect individuals from the virus and end the pandemic. CDC, *Guidance for [IHEs]* (last updated July 23, 2021), available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/considerations.html>. Three COVID-19 vaccinations are available in the United States: the Pfizer-BioNTech vaccine (recently FDA approved as “Comirnaty”), the Moderna vaccine, and the Johnson & Johnson vaccine (collectively, “COVID-19 Vaccines”). ECF No. 55, PageID.1190-1191 ¶¶ a-b.

All three of the vaccines were initially authorized for use under an Emergency Use Authorization (“EUA”) granted by the FDA. ECF No. 55, PageID.1190-1191, 1198. The FDA’s ability to grant EUAs for medical inventions to combat the pandemic arose from a United States Department of Health and Human Services declaration issued at the outset of the pandemic. 85 Fed. Reg. 18250, 18250-51. An EUA is not issued unless certain showings are made. Interim

emerging fifth variant of interest because of its potential for high transmissibility and infectiousness. See WHO, *Weekly epidemiological update on COVID-19 - 31 August 2021* (last visited Nov. 15, 2021), available at: <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---31-august-2021>.

clinical trial data must demonstrate that the product “may be effective” and that the “known and potential benefits outweigh the known and potential risks.” 21 U.S.C. § 360bbb-3(c)(2)(A); FDA, *Emergency Use Authorization for Vaccines Explained* (last visited Nov. 15, 2021), available at: <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>. The EUA process for the COVID-19 Vaccines was “EUA on proverbial steroids.” *Klaassen v. Trs. of Ind. Univ.*, No. 1:21-cv-238, 2021 WL 3073926, at *36 (N.D. Ind. July 18, 2021). Manufacturers were required to provide the “same level of endpoint efficacy data as required for full [FDA] approval” and sufficient safety data to demonstrate safety by clear and compelling evidence. *Id.* at *8. As a result, the COVID-19 Vaccines are “proven safe and effective.” *Benefits of Getting a COVID-19 Vaccine* (updated Nov. 5, 2021), available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html>.

The Pfizer vaccine now has received full FDA approval for use in individuals at least 16 years old. FDA Biologics License Application Approval for BioNTech Manufacturing GmbH (dated Aug. 23, 2021), available at: <https://www.fda.gov/media/151710/download>. There is no difference in the formulation of the EUA-approved (BioNTech) or fully approved (Comirnaty) vaccine. Plaintiffs allege that the BioNTech and Comirnaty vaccines may be factually distinguishable. ECF No. 55, PageID.1191; *contra* Q&A for Comirnaty (COVID-19 Vaccine mRNA) (last visited Nov. 15, 2021), available at: <https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna> (confirming the vaccines “have the *same formulation* and *can be used interchangeably* for provide the COVID-19 vaccination series;” the “licensed vaccine has the *same formulation* as the EUA-authorized vaccine and the products *can be used interchangeably* to provide the vaccination series *without presenting any safety or effectiveness concerns*” (emphasis added)); *see also* Pfizer-BioNTech COVID-19 Vaccine

Overview and Safety (also known as COMIRNATY) (last updated Oct. 28, 2021), *available at*: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html> (“Now that the FDA-authorized Pfizer-BioNTech COVID-19 vaccine has been approved by the FDA for individuals 16 years of age and older, it will be marketed as COMIRNATY. . . . There has **been no change** in the formulation of the vaccine since the name change.” (emphasis in original)).

C. COVID-19 Risks to and Caused by Unvaccinated Individuals

“COVID-19 is still a threat to people who are unvaccinated.” *Benefits of Getting a COVID-19 Vaccine* (last updated Nov. 5, 2021), *available at*: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html>. According to the MDHHS, from January to July 2021, unvaccinated Michiganders accounted for 98% of COVID cases, 95% of hospitalizations and 96% of deaths. MDHHS, *MDHHS renews call for Michiganders to get vaccinated following Pfizer COVID-19 vaccine recommendation by CDC’s Advisory Committee on Immunization Practices* (dated Sept. 1, 2021), *available at*: <https://www.michigan.gov/coronavirus/0,9753,7-406-98158-567102--,00.html>.

The FDA currently does not recommend the use of antibody tests to measure an individual’s natural immunity after a COVID-19 infection because “[c]urrently authorized antibody tests have not been evaluated to assess the level of protection provided by an immune response to COVID-19 vaccination,” and “[i]f antibody test results are interpreted incorrectly, there is a potential risk that people may take fewer precautions against [COVID-19] exposure.” FDA Safety Communication, *Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination* (issued May 19, 2021), *available at*: <https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety>.

Immunization after natural infection with COVID-19 is recommended by the vast majority of experts, including every major medical society, the NIH, and the CDC, including the Advisory Committee on Immunization Practices (ACIP) which is an authoritative agency that makes recommendations for immunization to clinicians in the United States. CDC, *Frequently Asked Questions about COVID-19 Vaccination* (last updated Nov. 5, 2021), available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html?s_cid=11572:vaccine%20after%20covid%20infection:sem.ga:p:RG:GM:gen:PTN.Grants:FY21; American Medical Association Press Release, *AMA in support of COVID-19 vaccine mandates for health care workers* (dated July 26, 2021), available at: <https://www.ama-assn.org/press-center/press-releases/ama-support-covid-19-vaccine-mandates-health-care-workers>; American Medical Association, *COVID-19 vaccines patients' frequently asked questions* (last visited Nov. 15, 2021), available at: <https://www.ama-assn.org/delivering-care/public-health/covid-19-vaccines-patients-frequently-asked-questions>; Infectious Diseases Society of America, *Vaccines FAQ*, (last updated Nov. 8, 2021), available at: <https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/#>.

Notwithstanding the weight of this public health guidance, Plaintiffs allege that vaccination is unnecessary and unsafe for individuals previously infected with COVID-19. *See, e.g.*, ECF No. 55, PageID.1201-1210, ¶¶ 33-68. However, they also admit that “the CDC recommends COVID vaccines for all adults” and “the CDC does not list prior immunity as a contraindication to vaccination.” ECF No. 55-1, PageID.1297 ¶ 30-31.

D. MSU

MSU is a public research university located in East Lansing, Michigan. MSU has seven campuses, at which it serves more than 49,000 undergraduate and graduate students. MSU, *Community Campuses & Clinical Sites* (last visited Nov. 15, 2021), available at:

<https://mdadmissions.msu.edu/resources/campuses.html>; MSU, *MSU Facts, Campus Profile* (last visited Nov. 15, 2021), available at: <https://msu.edu/about/facts>. MSU has over 12,000 employees. *MSU Facts, Campus Profile* (last visited Nov. 15, 2021), available at: <https://msu.edu/about/facts>.

Plaintiffs have sued MSU's President and each member of its Board of Trustees in their official capacities. ECF No. 55, PageID.1195-1196.

E. MSU's COVID-19 Policy

MSU's COVID-19 policy for the Fall 2021 semester was first announced on July 30, 2021 by MSU's President, Dr. Samuel L. Stanley Jr., M.D. ECF No. 55-1, PageID.1327. MSU's policy requires vaccination for all faculty, staff, and students who do not qualify for a medical or religious exemption. ECF No. 55-1, PageID.1329-1335. MSU also requires face coverings indoors (regardless of vaccination status). *Id.* at 1335; <https://msu.edu/together-we-will/directives.html> (last updated Nov. 4, 2021). Employees who do not receive a vaccination or exemption face potential disciplinary action, including termination of employment. ECF No. 55, PageID.1192 ¶ g.

F. Plaintiffs

Plaintiff Jeanna Norris is a supervisory Administrative Associate and Fiscal Officer at MSU. ECF No. 55-1, PageID.1316. She previously contracted and recovered from COVID-19. *Id.* An immunologist has advised her that she currently has antibodies that are protecting her from COVID-19. *Id.* at 1317.

Plaintiff Kraig Ehm is a former video producer for MSU. ECF No. 55-1, PageID.1320. He recently was terminated from his employment. ECF No. 55, PageID.1212; ECF No. 55-1, PageID.1322. He previously contracted COVID-19. ECF No. 55-1, PageID.1320. A physician

has opined that based on “antibody lab results . . . there is no good reason that [he] should be vaccinated.” ECF No. 55-1, PageID.1294.

Plaintiff D’Ann Rohrer is an Extension Educator at MSU. ECF No. 55-1, PageID.1324. She has been placed on unpaid leave. *Id.* She previously contracted COVID-19. *Id.* A physician has opined that based on “antibody lab results . . . there is no good reason that [she] should be vaccinated.” ECF No. 55-1, PageID.1294.

II. Legal Standard

The Court may dismiss a complaint under Rule 12(b)(6) when “it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.” *Morgan v. Church’s Fried Chicken*, 829 F.2d 10, 12 (6th Cir. 1987) (citation omitted). While the Court construes all well-plead facts in Plaintiffs’ favor, it “need not accept any legal conclusions or unwarranted factual inferences.” *Berrington v. Wal-Mart Stores, Inc.*, 696 F.3d 604, 607 (6th Cir. 2012). Moreover, when any amendment to a defective complaint still would not permit it to survive this standard, the complaint may be dismissed with prejudice. *See, e.g., Layer-Rosario v. Allied Mortg. Cap. Corp.*, No. 17-5468, 2018 WL 1989636, at *3 (6th Cir. Jan. 9, 2018).

III. Argument

All of Plaintiffs’ claims fail as a matter of law. MSU’s policy does not violate their substantive or procedural due process rights or the Supremacy Clause. Because Plaintiffs can plead no set of facts that will support claims sufficient to survive Rule 12(b)(6), their complaint should be dismissed with prejudice.

A. Plaintiffs’ Fourteenth Amendment Substantive Due Process Claim (Count I) fails as a matter of law.

Plaintiffs’ substantive due process challenge to MSU’s vaccination policy fails because MSU’s policy is reasonably related to legitimate government interests as a matter of law. While

Plaintiffs premise their substantive due process challenge to MSU’s policy on their “liberty and privacy interests that the Ninth and Fourteenth Amendments protect” and cite authority discussing individuals’ Fourteenth Amendment rights to bodily integrity and to refuse unwanted medical treatment, the Court need not accept these legal allegations for purposes of this motion. ECF No. 55, PageID.1222, ¶¶ 121-129.³ And it should not.

For over 100 years, the Supreme Court and lower courts have repeatedly recognized that mandatory vaccination requirements like MSU’s do not implicate an individual’s fundamental rights and thus are constitutional so long as they satisfy rational basis scrutiny. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11 (1905); *Zucht v. King*, 260 U.S. 174, 175-177 (1922) (upholding dismissal of constitutional challenge to public school mandatory vaccination requirement); *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) (reiterating *Jacobson*’s premise that mandatory vaccination requirements are constitutional); *Phillips v. City of New York*, 775 F.3d 538, 542 (2nd Cir. 2015) (upholding dismissal of substantive due process challenge to public school mandatory vaccination requirement); *Klaassen v. Trs. of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021) (confirming *Jacobson* and rational basis scrutiny apply to university’s COVID-19 vaccination requirement);⁴ *Workman v. Mingo Cty. Bd. of Educ.*, 419 F. App’x 348, 353-354 (4th Cir. 2011) (affirming dismissal of facial substantive due process challenge to mandatory student-immunization requirement because “the Supreme Court has consistently

³ Despite referencing the Ninth Amendment, Plaintiffs state no claim under it. MSU therefore addresses their claims under the Fourteenth Amendment. *See CH Royal Oak, LLC v. Whitmer*, 472 F. Supp. 3d 410, 414 (W.D. Mich. 2020) (instructing that “[w]here a particular Amendment provides an explicit textual source of constitutional protection against a particular sort of government behavior, that Amendment . . . must be the guide for analyzing these claims” (quoting *Albright v. Oliver*, 510 U.S. 266, 273 (1994))).

⁴ Although Plaintiffs contend that “none” of the district decisions denying preliminary injunctions against COVID-19 vaccine requirements have “made it to Courts of Appeals,” this Seventh Circuit decision denying an injunction pending appeal demonstrates otherwise.

recognized that a state may constitutionally require [students] to be immunized”); *George v. Kankakee Cmty. Coll.*, No. 14-cv-2160, 2014 WL 6434152 (C.D. Ill. Nov. 17, 2014) (dismissing under *Jacobson* substantive due process challenge to mandatory student-vaccination requirement); *Middleton v. Pan*, No. CV 16-5224-SVW (AGR), 2016 WL 11518596, at *7 (C.D. Cal. Dec. 15, 2016) (dismissing substantive due process challenge to mandatory student vaccination requirement); *Whitlow v. California*; 203 F. Supp. 3d 1079, 1089 (S.D. Cal. 2016) (declining to enjoin elimination of exemption to mandatory student vaccination requirement because “[u]nquestionably, imposing a mandatory vaccine requirement . . . as a condition of enrollment does not violate substantive due process,” and “the State is well within its powers to condition school enrollment on vaccination”); *Viemeister v. White*, 72 N.E. 97, 98 (N.Y. 1904) (upholding mandatory public school vaccination requirement); *see also, e.g.*, ECF No. 42, PageID.821-823 (finding Norris’s constitutional claim implicates no fundamental right and is subject to rational basis scrutiny).

No court has distinguished *Jacobson* to apply a different level of scrutiny to vaccine requirements, as Plaintiffs’ counsel urged at the hearing on Norris’s motion for preliminary injunction and Plaintiffs urge in their Amended Complaint. ECF No. 43, PageID.952-953 (125:22-127:5); ECF No. 55, PageID.1221-1222, ¶¶ 126-128. And none of Plaintiffs’ attempts to undercut this controlling authority are persuasive. First, contrary to Plaintiffs’ suggestion, *Jacobson* has frequently been applied to decisions that were not “the product of legislative action.” ECF No. 55, PageID.1221, ¶ 126; *see, e.g. George*, 2014 WL 6434152, at *3 (C.D. Ill. Nov. 17, 2014) (applying *Jacobson* to challenge to hospital policy vaccination requirement); *League of Indep. Fitness Facilities & Trainers, Inc. v. Whitmer*, 814 F. App’x 125, 127, 129 (6th Cir. 2020) (applying *Jacobson* to challenge to governor’s executive order). Second, *Jacobson* also has been applied to

vaccination requirements for a wide range of infectious diseases – not just smallpox and COVID-19. *See, e.g. Kiel, J.D. v. The Regents of the Univ. of Cal.*, No. HG20-072843, 2020 WL 9396579, at *5 (Cal. Super. Dec. 04, 2020) (applying *Jacobson* to challenge to mandatory flu vaccination). There is no support for Plaintiffs’ suggestion that *Jacobson* applies to only vaccination for diseases meeting some threshold level of deadliness—and COVID-19 has indeed proven itself to be deadly in any event. ECF No. 55, PageID.1221, ¶ 127. Finally, Plaintiffs insist that *Jacobson* should be ignored essentially because it was decided during a different “era.” ECF No. 55, PageID.1221-1222, ¶ 128. Not only is this position inconsistent with our entire system of precedential authority, the Supreme Court also has expressly rejected it. *Rodriguez de Quijas v. Shearson/Am. Exp., Inc.*, 490 U.S. 477, 484 (1989) (instructing that “[i]f a precedent of [the Supreme] Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, [courts] should follow the case which directly controls, leaving to [the Supreme] Court the prerogative of overruling its own decisions”).

Because *Jacobson*’s rational basis scrutiny applies, MSU’s policy is “accorded a strong presumption of validity” and must be upheld so long as there is “any plausible justification offered by [MSU], or even hypothesized by the court,” including “rational speculation unsupported by evidence or empirical data” and without “a foundation in the record.” *ARJN #3 v. Cooper*, 517 F. Supp. 3d 732, 745 (M.D. Tenn. 2021) (citation omitted); *Ashki v. I.N.S.*, 233 F.3d 913, 920 (6th Cir. 2000) (citation omitted); *Midkiff v. Adams Cty. Reg’l Water Dist.*, 409 F.3d 758, 770 (6th Cir. 2005). Conversely, to prevail, Plaintiffs “must negate every conceivable basis which might support” MSU’s policy. *ARJN #3*, 517 F. Supp. 3d at 745 (quotations and citation omitted). The facts before the Court confirm that MSU’s policy meets this standard. Plaintiffs do not appear to contest the significant, even fatal, risks that COVID-19 poses to members of

MSU's community, *see, e.g.*, ECF No. 55, PageID.1198, ¶¶ 15-16, that as many as 30% of individuals "who recover from COVID infection will experience lingering symptoms . . . [that] pose a real burden on [them]," ECF No. 55-1,⁵ PageID.1262-1263, ¶¶ 34-35, that new COVID-19 variants continue to emerge, *see, e.g.*, ECF No. 55, PageID.1205, ¶ 49, and that COVID-19 "will continue to mutate as it continues to spread," ECF No. 55-1, PageID.1307, ¶ 49. These admissions support the Supreme Court's guidance that stemming the spread of COVID-19 is a legitimate (indeed, compelling) state interest. *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020).

Plaintiffs also admit that "vaccines are an excellent tool for protecting the vulnerable," ECF No. 55, PageID.1210, ¶ 68 (citation omitted), that "[v]accinated people . . . rarely have severe symptoms in response to [COVID-19] infection," ECF No. 55-1, PageID.1262, ¶ 33, that "the COVID-19 vaccines appear to be relatively safe at a population level," ECF No. 55, PageID.1210, ¶ 69, that the CDC "recommends the vaccines for children 12 years old and up," ECF No. 55-1, PageID.1296, ¶ 28, and that MSU implemented its policy "after careful consideration of the scientific data" "to keep[its] students, faculty and staff safe" and "slow the spread of COVID-19" because "the COVID-19 vaccine [is] the best defense against the spread of the disease and the clearest path to the resumption of [MSU's] on-campus living and learning." ECF No. 55-1, PageID.1327, 1335.

Plaintiffs' objection to MSU's policy relates specifically to the policy's lack of exemption for individuals who were previously infected with COVID-19 and still have some measure of antibodies. *See, e.g.*, ECF No.55, PageID 1226, ¶¶ 144-145. Though Plaintiffs cite

⁵ The declaration from Drs. Bhattacharya and Kulldorff that Plaintiffs filed in support of their complaint are unverified (ECF No. 55-1, PageID.1269), but, consistent with Rule 12(b)(6)'s standard, MSU accepts the factual assertions in it as true for purposes of this motion.

scientific studies for the proposition that “natural immunity” is at least as robust as vaccine-induced immunity, *see, e.g.*, ECF No. 55, PageID.1202, ¶¶ 36-37, they also admit that at least one scientific study concludes otherwise, *see, e.g.*, ECF No. 55, PageID.1205,1224, ¶¶ 51, 136,⁶ Even as to their own alleged natural immunity, Plaintiffs concede that they lack certainty that they will not transmit the virus to others, *see* ECF No. 55, PageID.1222, ¶ 129. And, as Plaintiffs admit and the Court has already recognized, guidance from “federal and state agencies that have extensively studied the COVID-19 vaccine” advises that previously infected individuals should be vaccinated for COVID-19. ECF No. 42, PageID.824-825; ECF No. 55-1, PageID.1264, ¶ 36.

Thus, in addition to conceding that MSU’s policy serves, at minimum, legitimate interests, Plaintiffs also have failed to “negate every conceivable basis which might support” MSU’s policy. *ARJN #3*, 517 F. Supp. 3d at 745 (quotations and citation omitted); *see also, e.g.*, *TJM 64, Inc. v. Harris*, 475 F. Supp. 3d 828, 834 (W.D. Tenn. 2020) (“A law involving public health emergencies will only be struck down if it has “no real or substantial relation to those objects, or is beyond all question, a plain, palpable invasion of rights secured by the fundamental law.”).

Finally, Plaintiffs’ invitation for the Court to referee a battle of scientific experts is precisely the type of request rational basis scrutiny requires the Court to decline. *See, e.g.*, *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020) (Roberts, C.J., concurring) (instructing that where “broad limits” of policymaking “are not exceeded, they should not subject to second-guessing” by judiciary, which “lacks expertise to access public health”); *League of Indep. Fitness Facilities & Trainers*, 814 Fed. App’x at 129 (“Shaping the

⁶ Plaintiffs contest the legitimacy of this study, but admit that the CDC and others have cited it to support their recommendation that previously infected individuals receive the COVID-19 vaccine. *See, e.g.*, ECF No. 55, PageID.1205-1206, ¶ 51-53.

precise contours of public health measures entails some difficult line-drawing. Our Constitution wisely leaves that task to officials directly accountable to the people.”); *Reinoehl v. Whitmer*, No. 1:21-cv-00061, 2021 WL 320727, at *4 (W.D. Mich. Jan. 22, 2021) (“It is not in the public interest for this Court to override and/or modify the decisions and judgments rendered by public officials concerning the current pandemic.”); *Klaassen*, 2021 WL 3073926 at *43 (collecting Supreme Court cases, including *Roman Cath. Diocese*, 141 S. Ct. at 68 (“Members of this Court are not public health experts[.]”). Even accepting Plaintiffs’ premise that at least some scientists believe previously infected individuals should not be vaccinated for COVID-19, the Court need not wade into the scientific debate so long as MSU’s position is rationally supported, and even Plaintiffs’ allegations establish that it is.

Because MSU’s policy satisfies rational basis scrutiny as a matter of law, Count I should be dismissed.

B. Plaintiffs’ Unconstitutional Conditions/Procedural Due Process Claim (Count II) Fails as a Matter of Law.

The bulk of the allegations in Count II contain legal arguments that are entitled to no deference at the motion to dismiss stage. ECF No. 55, PageID.1229-1234. To state an unconstitutional conditions claim, Plaintiffs “would first have to identify an enumerated right that the vaccine policy coerces [them] into giving up.” ECF No. 42, PageID.824 (citing *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013)). Plaintiffs have not alleged violation of any right that the law deems fundamental. ECF No. 42, PageID.822 (“[T]here is no fundamental right to decline a vaccination.”). They also fail to allege any facts giving rise to an inference of coercion. And their legal conclusion that they are not required to demonstrate coercion to state an unconstitutional conditions claim is inconsistent with settled law. ECF No. 42, PageID.824 (citing *Koontz*).

Plaintiffs also have failed to even state a *prima facie* case for a procedural due process claim. To do so, they must establish “(1) a life, liberty or property interest requiring constitutional protection, (2) a deprivation of that interest, [and] (3) that the deprivation occurred without adequate process.” *Reinoehl*, 2021 WL 320727, at *3. Here, Plaintiffs assert a liberty interest in their bodily integrity, a property interest in their careers, and a statutory interest in informed consent. ECF No. 55, PageID.1229 ¶ 160. Again, these allegations are legal conclusions that the Court need not accept as true.⁷ For all of the reasons explained above, MSU’s policy does not implicate Plaintiffs’ right to bodily integrity. And Plaintiffs can have no “statutory interest in informed consent” arising from the EUA Statute because it gives them no rights. *See infra* at 18-19.

But, even if the Court were to accept Plaintiffs’ alleged interests as true for purposes of this motion, they cannot state a procedural due process claim as a matter of law. They can establish no deprivation of their interest in bodily integrity because MSU’s policy “does not force [them] to forego” that right. ECF No. 42, PageID.42. Their claim premised on any alleged “deprivation” related to their employment fails, at minimum, the “adequate process” element because MSU’s policy, which is a “[g]overnmental determination[] of a general nature” that affects all MSU students, faculty, and staff “equally,” “do[es] not give rise to a due process right to be heard.” *Nasierowski Bros. Inv. Co. v. City of Sterling Heights*, 949 F.2d 890, 896 (6th Cir. 1991); *see also, e.g., Pickney Bros. Inc. v. Robinson*, 194 F.3d 1313 (6th Cir. 1999); *Smith v. Jefferson Cty. Bd. of School Com’rs*, 641 F.3d 197 at 216-17 (6th Cir. 2011); *Reinoehl*, 2021 WL 320727 at *3 (confirming no pre- or post-deprivation hearing is required “in those circumstances

⁷ Indeed, Plaintiffs’ counsel has conceded in this matter that Norris has no constitutionally protected interest in protecting her job at MSU. ECF No. 42, PageID.822; ECF No. 43, PageID.889. Plaintiffs Ehm and Rohrer do not allege otherwise.

where the State has issued a generally applicable law or order” (quoting *Hartman v. Acton*, No. 2:20-CV-1952, 2020 WL 1932896, at *7 (S.D. Ohio Apr. 21, 2020))). And Plaintiffs have suffered no deprivation of any purported right under the EUA Statute because “MSU’s policy does not preclude [them] from receiving informed consent” ECF No. 42, PageID.825 n.2.

Plaintiffs alternatively argue that they are being denied adequate process because MSU’s policy is “in essence” a conclusive presumption that vaccination is required “unless the risks to a particular recipient warrant a special exception.” ECF No. 55, PageID.1233 ¶ 176.⁸ This simply underscores the general applicability of MSU’s policy. The Sixth Circuit has held that when such a uniform rule is rationally related to legitimate state objectives, it cannot be attacked on due process grounds “merely by labeling the rule [as] an irrebuttable presumption.” *Darks v. City of Cincinnati*, 745 F.2d 1040, 1044 (6th Cir. 1984); *see also e.g., Metro. Detroit Plumbing & Mech. Contractors Ass’n v. H.E.W.*, 418 F. Supp. 585, 589-90 (E.D. Mich. 1976) (holding plaintiffs demonstrated no likelihood of success on their due process claim where the alleged irrebuttable presumption was wholly rational and promoted the purpose of the resolution at issue).

⁸ Plaintiffs allege in Count II that they possess “equal or higher levels of protection than those who took one or more of the various inferior vaccines that MSU accepts and equivalent levels to those who took” FDA authorized or approved vaccines. ECF No. 55, PageID.1233 ¶ 177. This allegation is inconsistent with public health guidance cautioning against equating immunity with antibody levels alone. FDA Safety Communication, *Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination* (issued May 19, 2021), available at: <https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety> (“[M]ore research is needed to understand the meaning of a positive or negative antibody test, beyond the presence or absence of antibodies, including in people who received a COVID-19 vaccination, in people who have been exposed and have SARS-CoV-2 antibodies, and in people who are not fully vaccinated.”). At any rate, even accepting the allegation as true does nothing to strengthen Plaintiffs’ unconstitutional conditions or procedural due process claim. MSU may constitutionally require those previously infected with COVID-19 to be vaccinated. ECF No. 42, PageID.824-825.

Plaintiffs rely heavily on *Speiser v. Randall*, 357 U.S. 513 (1958), to support their unconstitutional conditions and procedural due process claims. ECF No. 55, PageID.1230-1232. But *Speiser* supports neither. There, the Supreme Court’s analysis centered on the fact that California’s tax exemption regime required subjective judgments about whether veterans had engaged in speech that would violate an affirmation that they had not advocated for overthrow of the government—effectively chilling what might be otherwise protected speech. *Speiser*, 357 U.S. at 526 (“The vice of the present procedure is that, where particular speech falls close to the line separating the lawful and the unlawful, the possibility of mistaken factfinding . . . will create the danger that the legitimate utterance will be penalized.”). MSU’s policy, conversely, involves no line drawing around protected activity. Moreover, *Speiser* does not stand for the proposition that the burden of proof may never be shifted toward the interest holder, as Plaintiffs allege, ECF No. 55, PageID.1231, ¶ 166, and, in fact, observed that such an allocation is appropriate “in most circumstances,” *Speiser*, 357 U.S. at 524-25. Thus, even Plaintiffs’ legal allegations do not support their claim. And because Plaintiffs allege no facts that could give rise to any inference that MSU’s policy effects an unconstitutional condition or deprives them of procedural due process, Count II should be dismissed.

C. Plaintiffs’ Supremacy Clause Claim (Count III) Fails as a Matter of Law.

Plaintiffs’ third claim also fails for at least two reasons: they have no statutory right to assert it, and MSU’s policy is not preempted by the EUA Statute.

1. Plaintiffs have no private right of action under the EUA Statute.

The EUA Statute that Plaintiffs contend preempts MSU’s policy addresses powers and responsibilities of the Secretary of the Department of Health and Human Services. *See, e.g.*, 21 U.S.C. § 360bbb-3(e) (“the Secretary . . . shall . . .”); *see also, e.g., Ass’n of Am. Physicians & Surgeons v. Food & Drug Admin.*, 479 F. Supp. 3d 570, 575 (W.D. Mich. 2020), *aff’d sub nom.*,

13 F.4th 531 (6th Cir. 2021) (providing overview of EUA statute). It requires *the Secretary* to ensure that medical providers that administer EUA-approved drugs, like certain of the COVID-19 vaccines, obtain informed consent (including advising patients of their right to refuse the treatment) and provide patients with the risks and benefits of the vaccination. *See Klaassen*, 2021 WL 3073926 at *25; *see also, e.g., Valdez v. Grisham*, No. 21-CV-783 MV/JHR, 2021 WL 4145746, at *4 (D.N.M. Sept. 13, 2021) (explaining that EUA Statute directs the Secretary to establish conditions facilitating informed consent and does not “prevent the state, or any other entity, from requiring certain individuals to be vaccinated against COVID-19”).

This directive to the HHS Secretary in the EUA Statute, which is housed within the Food, Drug, and Cosmetic Act (“FDCA”), is consistent with Congress’s decision to vest the Food and Drug Administration with exclusive authority to enforce or restrain purported violations of the FDCA. *See* 21 U.S.C. § 337(a) (“[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter [*i.e.*, the FDCA] shall be by and in the name of the United States.”). Accordingly, Plaintiffs have no private right of action to pursue a claim under the EUA Statute, so, to the extent they are invoking any statutory right to do so, their claim necessarily fails. *See also, e.g., Buckman Co. v. Pls.’ Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (“The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . .”).

2. The EUA Statute does not preempt MSU’s policy.

Plaintiffs also have no constitutional claim associated with the EUA Statute. Plaintiffs concede that state law is only preempted “to the extent that it actually conflicts with federal law.” ECF No. 55, PageID.1235 ¶ 185. No actual conflict is present here. As noted, the EUA Statute addresses powers and responsibilities of the HHS Secretary, not employers like MSU. *Bridges v. Houston Methodist Hosp.*, No. H-21-1774, 2021 WL 2399994, at *2 (S.D. Tex. June 12, 2021)

(observing EUA statute “neither expands nor restricts” employers’ responsibility); *Klaassen*, 2021 WL 3073926 at *25 (confirming “the informed consent requirement under the EUA statute only applies to medical providers”). This alone is fatal to Plaintiffs’ preemption claim.

Plaintiffs’ alternative formulation that MSU’s policy amounts to “invalid” “conflicting state action” because it creates an “obstacle” to their ability to give informed and voluntary consent for the COVID-19 vaccination, which “frustrates the objectives of the EUA process” fares no better. ECF No. 55, PageID.1235 ¶¶ 186-192. The EUA Statute requires medical providers to obtain informed consent from those receiving an EUA vaccination (including advising them of their right to refuse) and to provide those individuals with the risks and benefits of the vaccination. ECF No. 55, PageID. 1235 ¶¶ 188-189. MSU’s policy neither requires nor results in any violation of these requirements. Indeed, as the facts in and attached to the Amended Complaint confirm, MSU’s policy does not govern the administration of COVID-19 vaccines at all. *See, e.g.*, ECF No. 55-1, PageID.1327 (requiring “[a]ll students, faculty and staff . . . to be fully vaccinated” and directing them to resources to “find a vaccination provider”). As a matter of law, “MSU’s policy does not preclude [Plaintiffs] from receiving informed consent, nor does it prevent [them] from accepting or refusing administration of the vaccine.” ECF No. 42, PageID.825 n.2.

Finally, Plaintiffs admit that the Pfizer vaccination has obtained full approval by the FDA. ECF No. 55, PageID.1198 ¶ 20(d). They further admit that the EUA-authorized and FDA-approved Pfizer vaccines have “the same formulation.” ECF No. 55, PageID.21 ¶21.⁹ Thus, Plaintiffs can comply with MSU’s policy without receiving an EUA-authorized vaccine.

⁹ Even were this not the case, for the reasons stated, Plaintiffs would have no claim related to the EUA statute.

For all of these reasons, Count III should be dismissed.

D. Plaintiffs' Remaining Claims also Fail as a Matter of Law.

Plaintiffs allege that MSU's policy violates the 1947 Nuremburg Code and Helsinki Declaration. ECF No. 55, PageID.1244 ¶ 223-224. These claims fails because "[t]here is no private right of action for an alleged violation of international law for the protection of human research subjects based upon the Declaration of Helsinki and the Nuremberg Code." *Ammend v. BioPort, Inc.*, 322 F. Supp. 2d 848, 872 (W.D. Mich. 2004); *see also Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985, 1000 (E.D. Mo. 2006), *aff'd*, 490 F.3d 667 (8th Cir. 2007).

Plaintiffs also mention in passing that the HHS Policy for Protection of Human Research Subjects "is to similar effect." ECF No. 55, PageID.1244 ¶ 225. Plaintiffs can have no claim under Title 45 of the Code of Federal Regulations part 46 because it applies only to "research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal Department or agency" 45 C.F.R. § 46.101. Plaintiffs have not, and cannot allege, that provision is implicated by MSU's policy. Consequently, these claims, too, must be dismissed.

E. The Amended Complaint Should Be Dismissed with Prejudice.

The Amended Complaint represents Norris's single opportunity to amend her complaint as a "matter of course." Fed. R. Civ. Proc. 15(a)(1). At this point, the Amended Complaint should be dismissed with prejudice with no further leave to amend because Plaintiffs can allege no facts that would permit their claims to meet Rule 12(b)(6)'s standard. *See, e.g., Layer-Rosario v. Allied Mortg. Cap. Corp.*, No. 17-5468, 2018 WL 1989636, at *3 (6th Cir. Jan. 9, 2018) (affirming dismissal of complaint with prejudice because "[a]ppellants have not pointed to any assertions that they could have added to their complaint that would have allowed the complaint to survive a motion to dismiss"). MSU's policy, which is undisputed, does not implicate any

legal rights that Plaintiffs have to procedural due process or under the EUA Statute. And Plaintiffs cannot prevail on their substantive due process challenge because even the factual allegations in their amended complaint in the Amended Complaint and those facts of which the Court may take judicial notice unequivocally confirm that MSU's policy satisfies the rational basis standard that applies as a matter of law. Because any amendment to the Amended Complaint would be futile, the Amended Complaint should be dismissed with prejudice. *See, e.g., Solarek v. Oshtemo Charter Twp.*, No. 1:18-CV-204, 2019 WL 7582818, at *5 (W.D. Mich. Apr. 26, 2019) (dismissing complaint with prejudice when "any motion for leave to amend would be futile").

IV. Conclusion

Defendants respectfully request that the Amended Complaint be dismissed with prejudice.

Date: November 19, 2021

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CERTIFICATE OF COMPLIANCE

As required by LCivR 7.2(b)(ii), I certify that this document complies with the word limit contained within LCivR 7.2(b)(i) because, excluding the parts of the document exempted by that rule, this document contains 6292 words, according to the word count function of Microsoft Word for Office 365.

Date: November 19, 2021

/s/ Anne K. Ricchiuto _____
Anne K. Ricchiuto

CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2021, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel of record by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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