UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

RYAN KLAASSEN *et al.*,

Plaintiffs,

v.

THE TRUSTEES OF INDIANA UNIVERSITY,

Defendant.

CAUSE NO. 1:21-CV-238 DRL

OPINION & ORDER

Under guiding principles of federalism, our Constitution preserves the power of the States, within constitutional limits, to adopt laws to provide for public health and safety. Twice the United States Supreme Court has upheld state authority to compel reasonable vaccinations. The States don't have arbitrary power, but they have discretion to act reasonably in protecting the public's health.

Students at Indiana University have a significant liberty protected by the Constitution—refusing unwanted medical treatment based on bodily autonomy. The Fourteenth Amendment says no state may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV § 1. Given this due process protection of liberty, longstanding constitutional law prevents a public university—an arm of the State—from mandating a vaccine for its students unless it has rationally pursued a legitimate interest in public health for its campus community.

This case presents that question: whether Indiana University has acted constitutionally in mandating the COVID-19 vaccine for its students, as announced on

May 21, 2021. Albeit, and this should not be overlooked, this case does so only in the context of a preliminary injunction motion, not for a final decision on the merits.

Indiana University's policy has real implications. Students may be deprived of attending the university without being vaccinated or qualifying for an exemption. Still they have real options—taking the vaccine, applying for a religious exemption, applying for a medical exemption, applying for a medical deferral, taking a semester off, or attending another university or online. The policy applies for the fall 2021 semester only.

Eight students sued Indiana University because of its vaccination mandate and because of the extra requirements of masking, testing, and social distancing that apply to those who receive an exemption. They ask the court to enter a preliminary injunction—an extraordinary remedy that requires a strong showing that they will likely succeed on the merits of their claims, that they will sustain irreparable harm, and that the balance of harms and the public interest favor such a remedy.

The court now denies their motion. The Constitution and longstanding precedent should endure. Recognizing the students' significant liberty to refuse unwanted medical treatment, the Fourteenth Amendment permits Indiana University to pursue a reasonable and due process of vaccination in the legitimate interest of public health for its students, faculty, and staff. Today, on this preliminary record, the university has done so for its campus communities. The students haven't established a likelihood of success on the merits of their Fourteenth Amendment claim or the many requirements that must precede the extraordinary remedy of a preliminary injunction.

FACTS

A. *Parties*.

Indiana University is a world-renowned public research university, with seven campuses, two regional centers, and three medical centers across the State of Indiana, providing education to over 90,000 undergraduate and graduate students and employment for over 40,000 employees [Ex. 116 ¶ 4]. The university, with its flagship campus in Bloomington, Indiana home to over 40,000 students, continually ranks as one of the top 100 universities in the country, and one of the top 150 universities in the world.

The eight students here have varied backgrounds. Jaime Carini (age 39) is a graduate student pursuing two doctorates in music, with but her examinations and dissertation to complete [Ex. 121 at 10, 19-20, 23]. She has received an exemption from the university's vaccination requirement already [*id.* 57-58].

Ashlee Morris (age 26) is an incoming first year law student at the McKinney School of Law who has worked hard for six years to get there to pursue her J.D. [Ex. 123 at 10, 66-67]. She too has received a religious exemption from the university's vaccination requirement [*id.* 44]. She testifies that she will not attend the law school if she must wear a mask or undergo surveillance testing [*id.* 66-67].

Seth Crowder (age unknown) is pursuing his MBA at the Kelley School of Business [Ex. 124 at 13]. He too has received a religious exemption from the university's vaccination requirement already [*id.* 9, 20-21]. He has not decided if he will return to school if he must wear a mask or undergo surveillance testing this fall semester [*id.* 42].

Macey Policka (age 22) is a senior at Indiana University studying English (medieval studies) [Ex. 125 at 8-9]. She also has received a religious exemption from the university's vaccination requirement [*id.* 22]. She plans to return to Indiana University regardless of the outcome of this case [*id.* 36-37]

Ryan Klaassen (age 19) is an incoming sophomore at Indiana University studying biochemistry [Ex. 120 at 5, 15-17]. He has received a religious exemption to the university's vaccination requirement [*id.* 33]. He says he hasn't decided if he will return to Indiana University if the injunction is not granted. [*id.* 41-43].

Daniel Baumgartner (age 18) is an incoming freshman at Indiana University who plans to study business [Ex. 122 at 8, 12-13]. He has received a religious exemption to the university's vaccination requirement [*id.* 8]. He has not decided if he will go to Indiana University this fall if he must wear a mask or undergo surveillance testing [*id.* 41].

Margaret Roth (age unknown) is an incoming freshman at Indiana University and has already registered for classes [Ex. 126 at 9, 20]. She has a religious objection to the vaccine but has not requested an exemption, though she would qualify, because she prefers not to wear a mask or undergo testing [*id.* 45-47]. She says she will most likely not attend Indiana University if the injunction isn't granted [*id.* 9].

Natalie Sperazza (age unknown) is an incoming sophomore who will be taking five classes this fall [Ex. 127 at 11]. She has not applied for an exemption and believes she wouldn't qualify [*id.* 15-16]. She says she will not attend Indiana University this fall if the policy remains in place [*id.* 42]. She appears to be the only student without an exemption or basis for an exemption.

B. *COVID-19.*

COVID-19 is an infectious disease caused by the novel coronavirus. It primarily spreads through respiratory droplets, viral particles suspended in the air, and touching mucosal membranes with contaminated hands [Ex. 115 ¶ 6].[1] The initial presentation of an infection ranges from no symptoms at all (asymptomatic) to severe illness and death; and even after recovery, various long-term health problems may linger [*id.* ¶ 8].[2]

Individuals with longstanding systemic health inequities or preexisting or immunocompromising conditions, and elderly individuals prove at greater risk of severe illness or hospitalization following an infection [*id.* ¶ 9].[3] Children and young adults are less likely to experience serious illness or death from infection [Ex. 115 ¶ 10; Ex. 117 ¶ 21]. Though data from the Centers for Disease Control and Prevention (CDC) suggest that more young adults are becoming infected with the virus than other age groups [Ex. 115 ¶ 16],[4] these individuals are less likely to require hospitalization or die [*id.* ¶ 10].[5]

---

[1] *See also* Ctrs. for Disease Control & Prevention (CDC), *Scientific Brief: SARS-CoV2 Transmission*, https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html.

[2] *See also* CDC, *People with Certain Medical Conditions*, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last visited July 18, 2021); Neal M. Dixit *et al.*, *Post-Acute COVID-19 Syndrome and the Cardiovascular System: What is Known?*, 5 Am. Heart. J. Plus. 100025 (May 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223036/.

[3] *See also* CDC, *People with Certain Medical Conditions*, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last visited July 18, 2021).

[4] Of the total reported cases, those reported from the 18-29 age group account for 22.5 percent of all infections—the highest proportion of any age group—despite accounting for only 16.4 percent of the United States population. *See* CDC, *Demographic Trends of COVID-19 Cases and Deaths in the U.S. Reported to CDC,* https://covid.cdc.gov/covid-data-tracker/#demographics (last visited July 18, 2021).

[5] *See also* CDC, *Risk for COVID-19 Infection, Hospitalization and Death by Age (Updated June 24, 2021)*, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html (last visited July 18, 2021) (individuals aged 30-49 twice as likely to be hospitalized, individuals 50-64 four times as likely to be hospitalized, individuals aged 30-39 four times as likely to die, individuals 40-49 ten times as likely to die, individuals 50-64 thirty-five times as likely to die). The most

Worldwide COVID-19 has infected almost 189 million people and caused 4 million deaths, with these numbers still changing daily.[6] In the United States, the novel coronavirus has infected over 33.5 million citizens, losing to death over 600,000 [Ex. 115 ¶ 15]. Since March 6, 2020, Indiana has had over 750,000 confirmed COVID-19 cases and over 13,000 deaths [*id.* ¶ 14]. The COVID winter of 2020-2021 was particularly rough, until vaccines became options first in December 2020 and then in the early months of 2021.

As vaccination now increases, data gathered by the CDC point toward the waning of new COVID infections across the country—down from a peak of 312,325 new cases reported on January 8, 2021, with a seven-day average positive test rate of 13.85 percent, to 39,719 new cases reported on July 16, 2021, with a seven-day average positive test rate of 5.01 percent.[7] The rate of new cases today is akin, if not greater, to the rate of new cases reported during the peak of the pandemic's first wave in the spring 2020, through the relative rate of positive tests thankfully remains much lower.[8]

Our nation has come a long way since the darker days of 2020 that tested many people, though some uncertainty persists even now in this 2021 summer. The current

---

recent CDC figures suggest that only 0.04 percent of cases from this age group result in death, and this group represents only 0.5 percent of all COVID deaths. CDC, *Demographic Trends of COVID-19 Cases and Deaths in the U.S. Reported to CDC*, https://covid.cdc.gov/covid-data-tracker/#demographics (last visited July 18, 2021) (6,174,415 individuals aged 18-29 contracted the virus, and 2,732 individuals died).

[6] *See* CDC, *Global Cumulative Cases of COVID-19 Reported* (July 18, 2021), https://covid.cdc.gov/covid-data-tracker/#global-counts-rates (citing World Health Organization (WHO), *WHO Coronavirus (COVID-19) Dashboard* (July 16, 2021), https://covid19.who.int/).

[7] CDC, *COVID Data Tracker*, https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (last visited July 18, 2021).

[8] *Id.* (35,080 new cases reported on April 9, 2020, with a seven-day average positive test rate of 20.43 percent).

seven-day moving averages of new COVID-19 cases has increased by 69.3 percent in the past week alone; the positive test rate has increased by 40.7 percent; and new hospital admissions have increased by 35.8 percent.[9] Recalling the bell curves we all have become accustomed to seeing, the trend still proves sharply down from the worse days of COVID-19, but virulent and highly transmissible variants of this coronavirus present new challenges [Ex. 115 ¶ 36]. As of July 3, 2021, the CDC estimates that 57.6 percent of new cases come from the Delta variant.[10] New COVID-19 cases often originate in unvaccinated individuals [Ex. 115 ¶ 38-39].

In Indiana, 561 new cases were reported on July 15, 2021; and the most recent data suggest a seven-day average positive test rate of 4.3 percent for unique individuals from July 3, 2021 to July 9, 2021, lower than the national average.[11] Of all positive cases, 18.4 percent, the highest proportion of all age populations, comes from young adults aged 20-29.[11] In Indiana, approximately 67.3 percent of all cases came from the Delta variant.[12] Our country and our state have vastly improved, but challenges remain.

C. *Indiana University Board of Trustees.*

The Indiana General Assembly endows the Indiana University Board of Trustees with the responsibility to fulfill its powers and duties under the law. Ind. Code § 21-27-

[9] CDC, *COVID Data Tracker Weekly Review* (July 16, 2021) https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.

[10] *Id.*; *see also* CDC, *COVID Data Tracker*, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (last visited July 18, 2021).

[11] Indiana State Department of Health, *COVID Dashboard*, https://www.coronavirus.in.gov/2393.htm (last visited July 18, 2021).

[12] Indiana State Department of Health, *COVID Dashboard*, https://www.coronavirus.in.gov/2393.htm (last visited July 18, 2021).

2-1. The Trustees may pass all bylaws necessary to put into effect its powers. Ind. Code. § 21-27-4-3. The Trustees may set conditions and standards for admission that are in the "best interests of the state and the state educational institution." Ind. Code § 21-40-3-1(b).

Among these powers, the Trustees may govern "the conduct of the state educational institution's students, faculty, and employees, wherever the conduct might occur, to prevent unlawful or objectionable acts that . . . violate the reasonable rules and standards of the [university] designed to protect the academic community from . . . a serious threat to person or property of the academic community." Ind. Code § 21-39-2-3(b). The university remains answerable to the legislature, particularly its funding.

D. *State Law on Vaccines*.

Indiana requires all public university students to be vaccinated for diphtheria, tetanus, measles, mumps, rubella, and meningococcal disease before attending school. Ind. Code § 21-40-5-2. All but one of these vaccinations have been required since 1993. Outside these state-mandated vaccines, Indiana University has had a policy for managing infectious and communicable diseases since at least 2015 designed to take "reasonable measures to ensure the safety of members of the university community during global and local infectious disease events" [Ex. 229]. Students must report vaccination status, save for religious and medical exemptions, including any "contraindication to a vaccine" [*id.*]. This reporting occurs according to state law and recommendations from the CDC's Advisory Committee on Immunization Practices. *See* Ind. Code. § 21-40-5-2.

Since this pandemic's advent, many states have considered bills that would prohibit either vaccine "mandates" or vaccine "passports." For instance, just last week

the State of Ohio passed a law banning public vaccine mandates. *See* 2021 Bill Text OH H.B. 244, Sec. 3792.04(B)(1) (signed July 14, 2021). Other states have more reservedly passed laws that would prohibit just having to show proof of COVID-19 vaccination—hence the term COVID-19 passport. Indiana's General Assembly recently enacted law that prohibits a vaccine passport, not a vaccine requirement.[13] Ind. Code § 16-39-11-5.

E. *Vaccine Guidance for Institutions of Higher Education*.

Governmental agencies and collegiate associations have with one chorus promoted vaccination to address the COVID-19 pandemic, though they typically have remained silent on whether universities should mandate a vaccine. Today more than 500 colleges and universities have mandated vaccination, though many are private institutions of higher learning, not public universities.[14]

The CDC recommends that institutions of higher learning (IHEs) "can return to full capacity in-person learning, without requiring or recommending masking or physical distancing" only when "all students, faculty, and staff are fully vaccinated prior to the start of the semester."[15] The Indiana State Department of Health aligns with the CDC.[16]

---

[13] This statute applies to "the state or a local unit." Ind. Code § 16-39-11-5(a). The students withdrew their claim under this law because the statute omits a private right of action, leaving enforcement to the Indiana State Department of Health. *See, e.g.*, Ind. Code § 16-19-3-18. For sake of clarity, the court never reaches the point whether this anti-passport law applies to a public university or not.

[14] *See* Andy Thomason & Brian O'Leary, *Here's a List of Colleges That Will Require Students or Employees to Be Vaccinated Against Covid-19*, The Chronicle of Higher Education (July 15, 2021), https://www.chronicle.com/blogs/live-coronavirus-updates/heres-a-list-of-colleges-that-will-require-students-to-be-vaccinated-against-covid-19?cid2=gen_login_refresh ("The Chronicle has so far identified 583 such campuses.").

[15] CDC, *Guidance for Institutions of Higher Education (IHEs)* (June 4, 2021), https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/considerations.html.

[16] ISDH, *Public Resources: Back to School Resources (Universities)* (July 18, 2021), https://www.coronavirus.in.gov/2400.htm.

Likewise citing the CDC, the United States Department of Education has said "IHEs where everyone is fully vaccinated can return to full capacity in-person learning without requiring or recommending masking, physical distancing, or screening testing."[17] The American College Health Association has recommended that institutions require COVID-19 vaccinations for all on-campus students for the fall semester.[18]

F. *Indiana University's Vaccine Mandate.*

Acting under state authority, *see* Ind. Code § 21-38-3-4, and with the vision of promoting public health and restoring the educational and social environment of the university's campuses, President Michael McRobbie created a university restart committee during the spring of 2021 to make recommendations to the Board of Trustees for the fall semester [Ex. 104 at 5; Ex. 116 ¶ 22]. The restart committee's charge was to advise and recommend requirements necessary to resume "normal face-to-face" operations [Ex. 116 ¶ 22].

Indiana University's Executive Vice President for University Clinical Affairs and the School of Medicine's Dean spearheaded the restart committee [*id.* ¶ 23]. It included fifteen members with expertise in public health, epidemiology, virology, data modeling and monitoring, risk mitigation, health equity, health sciences, and law [*id.*; Ex. 300 at 4-

[17] U.S. Dept. of Educ., *ED COVID-19 Handbook, Volume 3: Strategies for Safe Operation and Addressing the Impact of COVID-19 on Higher Education Students, Faculty, and Staff* 9 (June 2021), https://www2.ed.gov/documents/coronavirus/reopening-3.pdf.

[18] Am. College Health Ass'n, *American College Health Association Recommends COVID-19 Vaccination Requirements for All On-Campus College Students in Fall 2021* (April 29, 2021), https://www.acha.org/ACHA/About/ACHA_News/ACHA_Recommends_COVID-19_Vaccination_Requirements_for_Fall_2021.aspx.

5]. The committee consisted of seven MDs, some with additional degrees in public health or other PhDs, and others with graduate degrees in public health, risk mitigation, law, and ethics [Ex. 300 at 5].

The restart committee met regularly to review the university's campus population and experiences from the 2020-2021 year, as well as "guidelines from the CDC, IU Health, the ISDH, the Indiana Governor's Office, and the Central Indiana Corporate Partnership, among others," "scientific literature and data, including COVID-19 case and hospitalization rates for Indiana," and "input from other Indiana and out-of-state IHEs" [Ex. 116 ¶¶ 24-26]. The data considered by the restart committee were vast [Exs. 302-317, PowerPoint presentations from December 8, 2020 to April 6, 2021); *see also* Ex. 301 ¶ 2].

Four MDs from this committee presented near-weekly from December 2020 to June 2021 to Indiana University's Executive Academic Leadership Council, including the President and Executive Vice Presidents as part of the medical response team's ongoing COVID-19 evaluation efforts [Ex. 301 ¶ 4]. The Board of Trustees adopted the restart committee's recommendations for the 2021 fall semester [Ex. 116 ¶ 29].

The aim was short and strategic—vaccinate everyone, subject to certain exemptions [*id.* ¶ 31; Exs. 101, 300]. Initially, the policy required all students, faculty, and staff to submit proof of vaccination before returning to campus, but the university revised this requirement after Indiana passed its anti-passport law [Ex. 101]. The policy today requires all students, faculty, and staff to be fully vaccinated, which the university defines as being two weeks post the second dose of the Pfizer and Moderna vaccines, or two weeks post the single dose of the Johnson & Johnson vaccine, before returning to campus

between August 1 to August 15 for the fall 2021 semester [Ex. 118 at 3, 5; *see also* Exs. 102-104].

The choice of foregoing vaccination is not inconsequential. If not vaccinated, students are not permitted on campus, their emails and university accounts are suspended, and their access cards are deactivated [Ex. 118 at 7]. Although it seems from argument that the university will not create an informant culture, it reserves the right to pursue disciplinary action should a student deceive the process. Faculty and staff who refuse vaccination face termination. The faculty councils from Indiana University—Bloomington and Indiana University-Purdue University Indianapolis and the staff council from Indiana University—Bloomington, have endorsed the policy, as has the graduate and professional student government [Ex. 116 ¶ 45-60].

The university's COVID-19 vaccine policy has exemptions. A student may request an exemption for religious reasons; provide proof from a physician of an allergy to the vaccine or one of its component parts (a medical exemption); provide proof from a physician of active pregnancy or breastfeeding, receiving a hematopoietic or solid organ transplant, receiving treatment with Rituximab within the past 3-6 months, or COVID-specific monoclonal antibodies[19] in the past 90 days (a medical deferral) [Ex. 210 at 3]. Students who are enrolled in an online program, with no on-campus component, don't need to receive the vaccine [*id.*].

[19] Monoclonal antibody therapy involves the injection of laboratory-made proteins that mimic the immune system's ability to fight off various pathogens. FDA, *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab* (April 16, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab.

For those who receive exemption from vaccination, the policy imposes additional safety requirements. These requirements apply to six of the eight students here who have received exemptions and potentially a seventh who qualifies for an exemption. Such students must participate in more frequent mitigation testing, quarantine if exposed to someone who has tested positive for COVID-19, wear a mask in public spaces, and return to their permanent address or quarantine if there is a serious outbreak of COVID-19 [Ex. 118 at 6].

G. *Experts.*

The parties have tendered declarations, supplemental declarations, and testimony from several experts, leaving to the court the task of deciding what weight to give to their opinions. Among the more than 100 exhibits admitted for this preliminary injunction motion, the experts and other materials refer to numerous medical studies and industry guidance on the risks of COVID-19 and the risks of the vaccines—where the parties in part have drawn the battle lines. The court has endeavored to be studious in reviewing at times a daunting record on this emergent timetable.

The university offers Dr. Cole Beeler, MD,[20] and Dr. Aaron Carroll, MD, MS,[21] and the students tender Dr. Peter McCullough, MD, MPH.[22] All have credentials and opinions that exceed restatement here. Much of that treatment occurs later in this opinion as the court makes additional findings of fact and discusses its legal analysis. Though points of agreement occur at times, these experts largely disagree about the urgency of vaccination, particularly for often younger university students, the effects from natural COVID-19 infection, and the risks of the three emergency use approved vaccinations.

For the students, Dr. McCullough says the risks of COVID-19 to college age students in 2021 proves significantly lower than in 2020 because of the rapidly declining infection rate, increasing likelihood of herd immunity in Indiana, low risk of serious complications or death from COVID-19 in college-aged students, low risk of asymptomatic spread, and other posited COVID-19 treatments [Ex. 117 ¶ 73; *see also* Exs. 221-22, 233-34, 240-41, 246-47, 251]. He views a mandate as unwise and a violation of the medical ethics principle of autonomy translated to the university setting [Ex. 117 ¶ 73]. He opines that the risks associated with the COVID-19 vaccines "are not minor or

[20] Dr. Beeler is an assistant professor of clinical medicine at Indiana University Medical School. He earned his BS and MD from Indiana University and is board certified in infectious disease and internal medicine [Ex. 115 ¶ 1-5; Ex. 128 at 5, 7-11, 13-17, 21-22, 31, 147-150].

[21] Dr. Carroll is the chief health officer for Indiana University and associate dean for research mentoring at Indiana University Medical School who holds various professorial positions. He earned his BA from Amherst College, his MD from the University of Pennsylvania, and his MS from the University of Washington. He is board certified in preventative medicine-clinical informatics, pediatrics, and by the National Board of Medical Examiners [Ex. 116 ¶ 1-6; Ex. 206 at 7-8].

[22] Dr. McCullough is a professor of medicine at Texas A & M University School of Medicine and practices medicine at various Texas hospitals. He received his BA from Baylor University, MD from University of Texas Southwestern Medical School, and his MPH in epidemiology from the University of Michigan. He is board certified in internal medicine and cardiovascular disease [Ex. 117 ¶ 1-12].

unserious and can include hospitalization and death," however "unpredictable" and "impossible to calculate" [*id.*]. His opening declaration largely isn't stated to any reasonable degree of medical certainty [*id.*; *but cf.* Ex. 222 at 11].

For the university, Dr. Beeler says the COVID-19 vaccine mandate facilitates a "safe and reliable way to assure lack of spread of COVID" within the university's campus communities and "prevents morbidity and mortality" [Ex. 115 ¶ 87; *see also* Ex. 319]. He appreciates that, though COVID-19 often will not pose "disproportionate bad outcomes" in the university's constituency, "any bad outcome from COVID is potentially avoidable with the vaccines where the benefit dwarfs the potential rare risks," and risks that "may not be causally linked" [Ex. 115 ¶ 87]. He recalls that "the vaccines used for COVID are based on technology that has been developed over decades and have repeatedly been shown to be safe when given to millions of patients" [*id.*]. He calls the vaccines "known science" applied to a "novel pathogen" with often "uncertain and threatening immediate and long-term consequences to [the university's] students, faculty, staff, and communities at large" [*id.*]. He says the risk of asymptomatic hosts puts others at risk [*id.*]. In support, Dr. Carroll marshals relevant industry, governmental, and university guidance and the relevant scrutiny the restart committee gave to it [Exs. 116, 301]. Dr. Beeler states his opinions to a reasonable degree of medical or professional certainty [Ex. 115 at 25; Ex. 319 at 8].

H. *Emergency Use Authorization of Vaccines.*

COVID-19 caught the world unaware. Initially, there were no vaccines or treatments, and testing was expensive and difficult to secure. Four days after the United

States Department of Health and Human Services (HHS) declared a public health emergency, it issued a second declaration allowing the United States Food and Drug Administration (FDA) to grant emergency use authorizations (EUAs) for medical devices and interventions to combat the pandemic. 85 Fed. Reg. 7316, 7316-7317; 85 Fed. Reg. 18250, 18250-18251.

Despite creating an expedited pathway to distribute new medical products during emergencies, products that receive EUA approval still must adhere to specified safety, efficacy, and manufacturing criteria, and HHS must ensure medical providers and individuals are informed of the product's EUA status, the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown;" and for individuals, of the option to refuse and the consequences of such a decision. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)-(III). An EUA generally allows a manufacturer to apply for EUA approval using interim clinical trial data, and the data need only demonstrate the product "may be effective" and that the known and potential benefits outweigh the known and potential risks.[23] The statute anticipates the FDA will impose additional obligations beyond those enumerated. 21 U.S.C. § 360bbb-3(e)(1)(B).

There have been six significant public health emergencies for which the FDA has authorized EUAs: anthrax, swine flu (H1N1), MERS (Middle East respiratory syndrome

[23] 21 U.S.C. § 360bbb-3(c)(2)(A); FDA, *Emergency Use Authorization for Vaccines Explained*, https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (last visited July 13, 2021).

coronavirus), Ebola, Zika, and now COVID-19.[24] During these events, EUAs were issued for diagnostic tests (swine flu, MERS, Ebola, Zika, and COVID-19), off-label use of previously approved and use of unapproved pharmaceuticals (anthrax, swine flu, and COVID-19), novel vaccines (anthrax and COVID-19), and medical devices (swine flu and COVID-19).[24] FDA authorization for EUA vaccinations began in 2005 during the anthrax scare, particularly for use in the armed forces. *See* 70 Fed. Reg. 5452, 5453 (Feb. 2, 2005).[25] Later in 2009, based on a CDC request, the FDA issued the first EUA that was geared towards civilians, including infants, for Tamiflu, an antiviral otherwise approved for use in adults. 74 Fed. Reg. 56644 (Nov. 2, 2009).[26]

Not all EUAs are created equally. Because of the widespread use of a COVID-19 vaccine, the FDA informed manufacturers that it expected the same level of endpoint efficacy data as required for full approval, enough safety data to justify by clear and compelling evidence the vaccine's safety, and confirmation of the technical procedures and verification steps necessary to support full approval.[27] In short, and as described in more detail below in this opinion's analysis, the FDA promulgated guidance that

---

[24] FDA, *Emergency Use Authorization – Archived Information*, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#H1N1 (last visited July 16, 2021).

[25] *See also* Stuart L. Nightingale *et al.*, *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States*, 13(7) Emerging Infectious Diseases 1047 (July 2007), https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article.

[26] CDC, *Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season* (Dec. 7, 2009), available at https://www.cdc.gov/h1n1flu/recommendations.htm#d.

[27] FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (May 2021), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid.

enhanced the basis on which any COVID-19 vaccine would meet EUA approval. In setting these more stringent standards, the FDA invited EUA applications only for vaccines positioned well to receive full approval.[28]

I. *COVID-19 Vaccines*.

In the United States, three vaccines rushed to the front: two using mRNA technology and one using a viral vector [Ex. 115 ¶ 23-26]. Johnson & Johnson's vaccine is a viral vector vaccine (implementing technology since the 1970s) that uses a modified version of a virus to teach the immune system to respond [Ex. 115 ¶ 87].[29] Pfizer and Moderna's vaccines use mRNA, a novel type of vaccine, but one based on decades of research using easily accessible materials found already in many laboratories [*id.*].[30]

[28] The industry guidance has since been superseded twice, once in February 2021 and once in May 2021. FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (May 2021). Pfizer, Moderna, and Johnson & Johnson's applications were submitted in accordance with the October 2020 enhanced guidance, *see* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer-BioNTech)* (2020) https://www.fda.gov/media/144416/download; (application submitted November 20, 2020); FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Moderna)* (2020) https://www.fda.gov/media/144673/download (application submitted November 30, 2020); FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Janssen)* (2021) https://www.fda.gov/media/146338/download (application submitted February 4, 2021).

[29] *See* CDC, *Understanding Viral Vector COVID-19 Vaccines*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html (last visited July 16, 2021).

[30] *See* CDC, *Understanding mRNA COVID-19 Vaccines*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html (last visited July 16, 2021).

Having quickly adapted the existing technology, Moderna started testing the vaccine in humans in March 2020.[31] Pfizer began clinical trials in late April 2020.[32]

By the time Pfizer applied for an EUA on November 20, 2020, their application included safety, immunogenicity, and efficacy data from over 40,000 study participants in ongoing phase I, II, and III, randomized, placebo-controlled, observer-blind, clinical trials conducted in the U.S., Argentina, Brazil, Germany, South Africa, and Turkey.[33] A team of representatives from across the FDA, including experts in clinical review, toxicology, biostatistics, products, production facilities, pharmacovigilance, data integrity, bioresearch monitoring, and labeling reviewed the data submitted by Pfizer, and independently assessed the risks and benefits of the vaccine.[34] The agency granted the EUA on December 11, 2020, noting that Pfizer "met the FDA's expectations as conveyed in [the agency's] June and October guidance documents."[35]

---

[31] Nat'l Insts. Health (NIH), *Experimental Coronavirus Vaccine is Safe and Produces Immune Response (Moderna)*, NIH Research Matters (July 21, 2020) https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-safe-produces-immune-response.

[32] NIH, *Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates against COVID-19 in Healthy Individuals*, https://clinicaltrials.gov/ct2/show/NCT04368728 (last visited July 16, 2021).

[33] FDA, *Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum*, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.

[34] *Id.* at 1, 49-54.

[35] FDA, *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020) https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

Moderna applied for an EUA on November 30, 2020.[36] Their application included safety, immunogenicity, and efficacy data from over 30,000 study participants in ongoing phase I, II, and III, randomized, stratified, observer-blind, placebo-controlled clinical trials conducted at 99 locations in the United States.[37] A team of representatives from across the FDA, including experts in clinical review, toxicology, biostatistics, products, production facilities, pharmacovigilance, data integrity, bioresearch monitoring, and labeling, reviewed the data submitted by Moderna, and independently assessed the risks and benefits of the vaccine.[38] The agency granted the EUA on December 18, 2020, noting that "the FDA's expectations described in [the agency's] June and October guidance documents have been met."[39]

Janssen, a Johnson & Johnson company, applied for an EUA on February 4, 2021.[40] Their application included safety, immunogenicity, and efficacy data from five studies, including two randomized, double-blind, placebo-controlled phase III trials, enrolling over 70,000 participants.[41] A team of representatives from across the FDA, including experts in clinical review, toxicology, biostatistics, products, production facilities,

---

[36] FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Moderna),* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.

[37] *Id.* at 12-13.

[38] *Id.* at 1, 55-60.

[39] FDA, F*DA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020) https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

[40] FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Janssen),* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.

[41] *Id.* at 13.

pharmacovigilance, data integrity, bioresearch monitoring, and labeling, reviewed the data submitted by Johnson & Johnson, and independently assessed the risks and benefits of the vaccine.[42] The FDA granted the EUA on February 27, 2021, noting that "the vaccine meets the FDA's expectations for safety and effectiveness appropriate for authorization of a vaccine for emergency use."[43]

With these vaccines, an emerging light appeared at the end of the tunnel. As of July 17, 2021, 337,239,448 doses of vaccine have been administered, and 161 million Americans, or 48.5 percent of the total population, is fully vaccinated.[44] Of adults over the age of eighteen, 59.4 percent are fully vaccinated.[44] In Indiana, 5,749,173 doses have been administered, and 2,888,239 Hoosiers, or 49.6 percent of those over the age of twelve, are fully vaccinated.[45] Of ages 18-24, who account for 9.2 percent of the U.S. population, 11,720,847, or 42.2 percent, are fully vaccinated.[46] In Indiana, 164,098 individuals aged 20-24, or 34.7 percent, are fully vaccinated.[47]

---

[42] *Id.* at 1, 59-61.

[43] FDA, F*DA Issues Emergency Use Authorization for Third COVID-19 Vaccine* (February 27, 2021) https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[44] CDC, *COVID-19 Vaccinations in the United States*, https://covid.cdc.gov/covid-data-tracker/#vaccinations (last visited July 17, 2021).

[45] *ISDH*, *Indiana COVID-19 Vaccination Dashboard*, https://www.coronavirus.in.gov/vaccine/2680.htm (last visited July 18, 2021).

[46] CDC, *COVID-19 Vaccinations in the United States*, https://covid.cdc.gov/covid-data-tracker/#vaccinations (last visited July 17, 2021).

[47] *ISDH*, *Indiana COVID-19 Vaccination Dashboard*, https://www.coronavirus.in.gov/vaccine/2680.htm (last visited July 18, 2021).

J. *Risks of Vaccines*.

Though the vaccines show remarkable effectiveness against infection and severe cases of COVID-19, and "have undergone and will continue to undergo the most intensive safety monitoring in U.S. history," they are not without risks, heretofore rare for serious risks [Ex. 115 ¶ 33].[48] Many recipients experience mild local and systemic reactions, including fever, headache, muscle pain, chills, and tiredness.[48] In very rare cases, more serious side effects seem to emerge such as allergic reactions or blood clots with low platelets [Ex. 115 ¶ 66; Ex. 117 ¶ 38].[48] For young men specifically, experts are studying a temporal correlation between vaccines and myocarditis, an inflammation of the heart muscle, or pericarditis, inflammation of tissue around the heart [Ex 117 ¶ 37].[49] However, the risk of myocarditis appears to be exceptionally small [Ex. 115 ¶ 67].[50]

The medical community closely tracks adverse events from the vaccine in a national database called VAERS, or the Vaccine Adverse Event Reporting System.[51] This database is used to track adverse events temporally related to all vaccine administration, including for the COVID-19 vaccines, but it is not a definitive or final resource to

---

[48] CDC, *Safety of COVID-19 Vaccines*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (last visited July 13, 2021).

[49] *See also* Han W. Kim *et al.*, *Patients with Acute Myocarditis Following mRNA COVID-19 Vaccination*, JAMA Cardiol doi:10.1001/jamacardio.2021.2828 (June 29, 2021) https://jamanetwork.com/journals/jamacardiology/fullarticle/2781602 (finding handful of patients out of 561,197, and all recovered after a few days).

[50] *See, e.g.*, Israeli Ministry of Health, *Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021*, https://www.gov.il/en/departments/news/01062021-03 (last visited July 18, 2021) (121 cases out of a total of 5,049,424 vaccinated individuals).

[51] HHS, *VAERS*, https://vaers.hhs.gov/.

conclusively prove contraindications.[52] "While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness."[53] Nevertheless, the FDA considers VAERS data when assessing whether to make changes to any approval or to apply any additional warnings to vaccines.[54] Based on this surveillance, reports of anaphylaxis appears to be rare, blood clotting concerns are rare but higher in women under the age of 50, myocarditis is rare but more common in young people, and reports of death are rare.[55]

The FDA has issued revisions to the patient and provider fact sheets about the risk of myocarditis and pericarditis acknowledging data about this risk.[56] Furthermore, the FDA and CDC recommended a pause on the use of Johnson & Johnson's vaccine in light of reports of clotting in young women (a pause subsequently lifted).[57] Recent changes last week occurred because of reported neurological impacts of the Johnson & Johnson

---

[52] CDC, *Selected Adverse Events Reported after COVID-19 Vaccination*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (last visited July 13, 2021).

[53] CDC, *The Vaccine Adverse Event Reporting System (VAERS) Results* (July 17, 2021), https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=DBF4A737A762F523202A55E30B57.

[54] *See, e.g.*, FDA, *Coronavirus (COVID-19) Update: July 13, 2021* (July 13, 2021) (discussing concerns over VAERS reports of Guillain-Barré Syndrome following vaccination) (available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-july-13-2021).

[55] *Id.*; *see also* CDC, *The Vaccine Adverse Event Reporting System*, https://wonder.cdc.gov/vaers.html (last visited July 14, 2021); CDC, *COVID-19 Vaccination Demographics in the United States, National*, https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Demographics-in-the-United-St/km4m-vcsb (last visited July 18, 2021) (more than 24 million doses of a vaccine have been administered to this age group as of July 14, 2021)

[56] FDA, *Coronavirus (COVID-19) Update: June 25, 2021*, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021 (last visited July 13, 2021).

[57] CDC, *CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html (last visited July 13, 2021).

vaccine, based on VAERS data.[58] These refinements indicate that the ongoing safety of these vaccines are rigorously monitored by agency professionals.

K. *Herd Immunity.*

Much has been said of herd immunity at the national and state levels. The university too wants to achieve herd immunity. Herd immunity occurs when a virus cannot spread because so many of the individuals it encounters are protected against infection [Ex. 117 ¶ 14-17; Ex. 115 ¶ 43-44].[59] The students say we are there [Ex. 117 ¶ 14-17]. The university disagrees [Ex. 116 ¶ 43]. As more infectious variants emerge, some suggest the percent immunized must also increase to reach herd immunity [Ex. 115 ¶ 19-22].[60] Like many aspects of the pandemic, the point at which society is able to conclude enough people have protection from the virus is still undetermined.

The character of immunity is also uncertain. As COVID-19 is a new disease, and the vaccines are even newer, the long-term efficacy of immunity derived from vaccination and infection is not proven [Ex. 117 ¶ 68-72; Ex. 115 ¶ 70].[61] Immune responses appear to exist for at least several months following a COVID-19 infection [Ex. 117 ¶ 68-72; Ex. 319

[58] FDA, *Coronavirus (COVID-19) Update: July 13, 2021* (July 13, 2021) (discussing concerns over VAERS reports of Guillain-Barre syndrome following vaccination) (available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-july-13-2021).

[59] Christie Aschwanden, *The False Promise of Herd Immunity for COVID-19*, Nature, https://www.nature.com/articles/d41586-020-02948-4 (Last visited July 13, 2021).

[60] *See* Kamran Kadknoda, *Herd Immunity to COVID-19*, Am. J. Clin Gypsyamber D'Souza & David Dowdy, *What is Herd Immunity and How Can We Achieve It With COVID-19?*, https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html (last visited July 13, 2021).

[61] *See* Jennifer M. Dan, *Immunological Memory to SARS-CoV-2 Assessed for Up to 8 Months after Infection*, 371(6529) Science eab4063 (Feb. 5, 2021); *See* Chris Baraniuk, *How Long Does Covid-19 Immunity Last?*, 373 BMJ n1605 (June 30, 2021) https://www.bmj.com/content/373/bmj.n1605.short?rss=1.

¶ 1].[61] Dr. Beeler explains a recent study that suggests that vaccination after COVID-19 exposure secures more protection than just antibodies from prior contraction of the virus—in terms of duration and strength against the prevailing variants [Ex. 128 at 82].[62]

The parties disagree over the relative risk of college students spreading the virus to the community, with the students contending the risk is very low [*see* Ex. 117 ¶ 29-31], and the university contending the risk is real [*see* Ex. 115 ¶ 51-52]. There is no consensus on this issue, and some research has not been peer-reviewed.[63] Nevertheless, peer-reviewed research suggests that outbreaks on college campuses pose a risk of spreading to neighboring communities.[64] Data suggest that as of May 26, 2021, 260,000 infections have been linked to universities and colleges in 2021, including 3,062 reported cases across the Indiana University system—though this data appears limited to students, faculty members, staff members, and other college workers, and thus does not provide insight on greater community spread [*see* Ex. 115 ¶ 52].[65] Universities are unique

---

[62] *See* Delphine Planas *et al.*, *Reduced Sensitivity of SARS-CoV-2 Variant Delta to Antibody Neutralization*, Nature doi: 10.1038/s41586-021-03777-9, 3 (July 8, 2021) (online ahead of print), https://www.nature.com/articles/s41586-021-03777-9_reference.pdf.

[63] *See* Callum R.K. Arnold *et al.*, *SARS-CoV-2 Seroprevalence in a University Community*: *A Longitudinal Study of the Impact of Student Return to Campus on Infection Risk Among Community Members*, medRxiv Preprint (Feb 19, 2021) https://pubmed.ncbi.nlm.nih.gov/33619497/ (minimum impact on community); *but see* Gabriel T. Bosslet *et al.*, *The Effect of In-Person Primary and Secondary School Instruction on County-Level SARS-CoV-2 Spread in Indiana*, Clinical Infectious Diseases (manuscript accepted) https://doi.org/10.1093/cid/ciab306 (Apr. 13, 2021) (finding that a 10 percent increase in K-12 students attending school in-person corresponded to a daily increase of 0.336 cases per 100,000 residents in the community).

[64] *See* Hannah Lu *et al.*, *Are College Campuses Superspreaders? A Data-Driven Modeling Study*, Computer Methods in Biomechanics & Biomedical Eng'g, https://doi.org/10.1080/10255842.2020.1869221 (Jan. 13, 2021) (Stanford researchers looked at county spikes following outbreaks at 30 universities and concluded that outbreaks at 17 campuses translated directly into respective community spikes).

[65] N.Y. Times, *Tracking Coronavirus Cases at U.S. Colleges and Universities (May 26, 2021)*, https://www.nytimes.com/interactive/2021/us/college-covid-tracker.html (last visited July 13, 2021). The New York Times appears to be the most comprehensive database for tracking COVID-19 cases across U.S. colleges and universities, collecting and compiling data from individual universities, local health

environments, with students, faculty, and staff often in close contact, particularly given the number that call Indiana University home.

L. *The Student's Objections.*

The eight plaintiffs in this case, all students of Indiana University, don't want the vaccine. Six of the eight have received exemptions already. One would qualify if she applied. The other appears not to qualify for an exemption.

Ryan Klaassen is concerned that the vaccine is too new to be safe [Ex. 120 at 18]. He objects to the masking and testing requirements because of their unreasonableness and the potential for discrimination [*id.* 36]. He complied with the university's mask policy during his freshman year, including wearing a mask in most places, and has undergone many COVID-19 tests [*id.* 27].

Jaime Carini has up to seven more years to finish her joint dissertation after she finishes her exams [Ex. 121 at 23]. Her physician provided a letter saying she should not take the vaccine, though the letter has not been presented to the university or to the court [Ex. 121 at 52-53]. She applied for a religious exemption and received one [*id.* 57]. She did not apply for a medical exemption [Ex. 100 ¶ 187 (never applied for one); Ex. 121 at 60]. Despite wearing a mask in public spaces when required and previously taking several COVID-19 tests, she objects to the mask policy because it makes it difficult for her to breathe, she gets bad acne from the mask, and she struggles deadlifting with a mask [Ex.

departments, counties, states, and through open record requests at universities who would not otherwise provide data.

121 at 44, 47-51]. She also doesn't like surrendering her biological information for testing [*id.* 55]. In total, she views the university's policy as a cultural harm [*id.* 55-56].

Daniel Baumgartner says he has a deeply held religious objection to wearing a mask and being tested. He wore a mask while attending religious services, in school, and at stores in the past [Ex. 122 at 8, 18-20]. He previously contracted COVID-19 and says he has "natural" COVID antibodies, though for how long he doesn't know [*id.* 21-22].

Ashlee Morris believes she previously contracted COVID-19 [Ex. 123 at 27-28]. She has been tested before and acknowledges that she did not suffer any lasting harm from the test [*id.* 35]. She wore a mask to work, on a plane, and when she went to a casino, but not to stores even if signs were posted [*id.* 35-37]. She testifies she has a religious objection to wearing a mask and being tested [*id.* 45-48]. She admits that she has never experienced discrimination because she did not wear a mask [*id.* 56].

Seth Crowder has a deeply held religious objection to wearing a mask and being tested [Ex. 124 at 29-30]. He has worn a mask once or twice a week since March 2020, including to stores and restaurants [*id.* 22].

Macey Policka objects generally to the extra requirements of masks and tests because of the minimal risk to those in her age group, also stating that vegans and pescatarians are less likely to experience serious illness [Ex. 125 at 28]. She lived on the Bloomington campus for the 2020 school year, complied with the university's masking policy, and underwent weekly mitigation testing from which she states she did not suffer any harm [*id.* 14-18]. She has never experienced judgment or alienation due to wearing a

mask at the university but is concerned about having to wear a mask while pursuing her theatre degree [*id.* 25, 42].

Margaret Roth objects to the mask and testing requirements because she thinks masks are silly and she claims nasal swabs cause cancer [Ex. 126 at 12, 29, 35-36]. She has worn a mask while at school, shopping, and working [*id.* 31-33]. She has a religious objection to the vaccine but did not file for an exemption because she doesn't want to be subject to testing or wear a mask [*id.* 45-47].

Natalie Sperazza complied with the university testing and masking requirement during the 2020 school year [Ex. 127 at 30-32]. She has been tested for COVID-19 many times, including while working at Amazon, where she would occasionally go to get tested just to have a break [*id.* 25-26, 30].

M. *Procedure.*

The students filed a preliminary injunction motion. The court expedited briefing and discovery. The court held oral argument on July 13, 2021, after receiving the record the day before. The parties stipulated to the admissibility of all exhibits. The parties stipulated not to present additional testimony at the preliminary injunction hearing because it would duplicate what they had presented already.

Further evidentiary hearing is generally required for a preliminary injunction motion when there are "genuine issues of material fact" and either side "intends to introduce evidence [at the hearing] that if believed will so weaken [the other's] case as to affect the judge's decision on whether to issue the injunction." *Ty, Inc. v. GMA Accessories, Inc.*, 132 F.3d 1167, 1171 (7th Cir. 1997). That said, such a hearing isn't necessary when the

evidence would essentially duplicate the declarations, depositions, and other documents the parties have already submitted. *See Goodman v. Ill. Dep't of Fin. & Pro. Regul.*, 430 F.3d 432, 439 (7th Cir. 2005) (summarizing *Ty, Inc.*, 132 F.3d at 1171); *Ty, Inc.*, 132 F.3d at 1171. No additional hearing was necessary here. The court has considered over a hundred written exhibits, including sworn depositions and declarations, and heard three hours of argument. This motion is ripe for immediate ruling.

STANDING

Before considering the preliminary injunction motion, the court must ensure its jurisdiction. *See Common Cause Ind. v. Lawson*, 937 F.3d 944, 949 (7th Cir. 2019); *Simic v. City of Chicago*, 851 F.3d 734, 738 (7th Cir. 2017). The United States Constitution confines the federal judiciary's power to "Cases" and "Controversies." U.S. Const. Art. III § 2. For a case or controversy to exist, a plaintiff must have standing—an injury, fairly traceable to the defendant's conduct, that the court's decision will likely redress. *Uzuegbunam v. Preczewski*, 141 S. Ct. 792, 797 (2021); *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

Indiana University raises the issue of standing. Of the eight students here, six have received an exemption under the university's policy and one (Margaret Roth) qualifies so long as she pursues it. This leaves one student (Natalie Sperazza) who yet faces an unexemptible choice this semester: either she gets vaccinated or she cannot attend Indiana University this fall. She doesn't qualify for an exemption. At minimum, she has standing—an injury fairly traced to Indiana University's decision to mandate the vaccine and one the court can redress. *See Uzuegbunam*, 141 S. Ct. at 797; *Taylor v. McCament*, 875 F.3d 849, 853 (7th Cir. 2017).

The court has subject matter jurisdiction under Article III so long as one plaintiff has standing. *See Horne v. Flores*, 557 U.S. 433, 446 (2009); *Massachusetts v. E.P.A.*, 549 U.S. 497, 518 (2007). Even when the standing of others may prove doubtful, *see*, *e.g.*, *Chi. Joe's Tea Room, LLC v. Vill. of Broadview*, 894 F.3d 807, 813 (7th Cir. 2018), the court's jurisdiction remains intact so long as one plaintiff has demonstrated standing to assert her rights, *Horne*, 557 U.S. at 446. The court thus may proceed to this preliminary injunction motion without addressing the standing of the other students. *See id.*

That said, the court remains mindful (and the reader should too) that it cannot issue a mere advisory opinion. Article III's "case or controversy" requirement prohibits "advisory opinions that do not affect the rights of the parties before the court." *Matlin v. Spin Master Corp.*, 979 F.3d 1177, 1181 (7th Cir. 2020) (citation omitted). The court isn't a law office established for legal advice—the federal judiciary decides cases, not hypothetical outcomes. If the court's decision doesn't affect a litigant's rights, "the aggrieved party [is] unable to illustrate the redressability component of standing, rendering any judicial decision in the case an impermissible advisory opinion." *United States v. Brixen*, 908 F.3d 276, 280 (7th Cir. 2018). In short, the court won't decide today issues that would not redress the injuries these particular students allege.

PRELIMINARY INJUNCTION STANDARD

A preliminary injunction is a "very far-reaching power, never to be indulged [] except in a case clearly demanding it." *Cassell v. Snyders*, 990 F.3d 539, 544 (7th Cir. 2021) (quoting *Orr v. Shicker*, 953 F.3d 490, 501 (7th Cir. 2020)). To obtain an injunction, the students "must make a threshold showing that: (1) absent preliminary injunctive relief,

[they] will suffer irreparable harm in the interim prior to a final resolution; (2) there is no adequate remedy at law; and (3) [they have] a reasonable likelihood of success on the merits." *Tully v. Okeson*, 977 F.3d 608, 612-13 (7th Cir. 2020) (quoting *Turnell v. CentiMark Corp.*, 796 F.3d 656, 662 (7th Cir. 2015)); *see also Winter v. Nat. Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). If they make these threshold showings, the court "consider[s] the balance of harms between the parties and the effect of granting or denying a preliminary injunction on the public interest." *Tully*, 977 F.3d at 613 (quotation omitted).

ANALYSIS

A. *These Students Aren't Likely to Succeed on the Merits.*

No case to date has decided the constitutionality of whether a public university, such as Indiana University, may mandate that its students receive a COVID-19 vaccine.[66] Given the unique constitutional nature of this case, the court assesses the students' likelihood of success first, ever mindful that this determination proves preliminary only.

The students must show a likelihood of success on the merits. This is their burden. This showing must be "strong," which "normally includes a demonstration of how the applicant proposes to prove the key elements of [the] case." *Tully*, 977 F.3d at 613 (quoting *Ill. Republican Party v. Pritzker*, 973 F.3d 760, 762-63 (7th Cir. 2020)). Though an "applicant need not show that [she] definitely will win the case," a "mere possibility of success is not enough." *Pritzker*, 973 F.3d at 762-63.

[66] A district court recently upheld a COVID-19 vaccine mandate, albeit by a private employer (hospital). *See Bridges v. Houston Methodist Hosp.*, 2021 U.S. Dist. LEXIS 110382, 7-8 (S.D. Tex. June 12, 2021).

1. *The Fourteenth Amendment.*

The students pursue a Fourteenth Amendment claim. The Bill of Rights—the first ten amendments to the United States Constitution—originally applied only to the federal government. *See McDonald v. City of Chicago*, 561 U.S. 742, 754 (2010). Individual states weren't obligated to respect its protections against citizens. *See Livingston's Lessee v. Moore*, 32 U.S. 469, 551-52 (1833); *see also McDonald*, 561 U.S. at 754 (citing *Moore*, 32 U.S. at 551-52). This changed with the Fourteenth Amendment in 1868.

The Fourteenth Amendment "furnishe[d] an additional guaranty against any encroachment by the States upon the fundamental rights [that] belong to every citizen as a member of society." *United States v. Cruikshank*, 92 U.S. 542, 554 (1875); *accord United States v. Morrison*, 529 U.S. 598, 622 (2000); *see also* 42 U.S.C. § 1983; *Albright v. Oliver*, 510 U.S. 266, 271 (1994); *Power v. Summers*, 226 F.3d 815, 819 (7th Cir. 2000). For today's dispute, the Fourteenth Amendment says no "State [may] deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV § 1. This due process clause applies to the States and protects, absent a deprivation with due process, certain rights to life, liberty, and property. Indiana University is a state actor, *Medlock v. Trustees of Ind. Univ.*, 738 F.3d 867, 871 (7th Cir. 2013), so the Fourteenth Amendment also applies to it.

As interpreted, the Fourteenth Amendment has both substantive and procedural dimensions. *See Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985). This case concerns substantive due process—"a substantive limitation on the power of government to legislate." *Durigan v. Sanitary Dist. No. 4*, 5 F. Appx. 492, 494 (7th Cir. 2001); *see Campos*

v. Cook Cnty., 932 F.3d 972, 975 (7th Cir. 2019). The Fourteenth Amendment protects a person's substantive rights in life, liberty, and property. U.S. Const. amend. XIV § 1. Certain rights or liberties have been deemed "fundamental," so they receive greater protection. *See Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997).

Bearing that in mind, the court initially approaches this case in a two-fold manner. First, the law requires a "careful description" of the asserted right or liberty. *See id.* at 721; *see*, *e.g.*, *Doe v. City of Lafayette*, 377 F.3d 757, 768 (7th Cir. 2004). Second, the court must determine whether the so-defined right or liberty is fundamental under the Constitution. *See Glucksberg*, 521 U.S. at 721; *Doe*, 377 F.3d at 768. The Fourteenth Amendment's due process clause specially protects fundamental rights and liberties—those that objectively are "deeply rooted in this Nation's history and tradition" and so "implicit in the concept of ordered liberty" that "neither liberty nor justice would exist if they were sacrificed." *Glucksberg*, 521 U.S. at 721 (citations omitted); *accord Khan v. Bland*, 630 F.3d 519, 535 (7th Cir. 2010). These guideposts direct and restrain due process decisionmaking. *Glucksberg*, 521 U.S. at 721.

Many rights explicitly secured in the Bill of Rights are considered fundamental, having been gradually incorporated as substantive guarantees under the Fourteenth Amendment. These fundamental rights include, as examples, freedom of speech, *Gitlow v. New York*, 268 U.S. 652 (1925); freedom of the press, *Near v. Minnesota*, 283 U.S. 697 (1931); the right against cruel and unusual punishment, *Robinson v. California*, 370 U.S. 660 (1962); and the right to keep and bear arms, *McDonald*, 561 U.S. at 742. There are others.

Fundamental rights aren't limited to those specifically enumerated in the Bill of Rights. Beginning with *Griswold v. Connecticut*, 381 U.S. 479, 483 (1965), the Supreme Court recognized a right to privacy within the "penumbra" of other constitutional protections and called it fundamental. This right to privacy has included the right for both married and unmarried couples to purchase contraceptives, *see Griswold*, 381 U.S. at 484-86; *Eisenstadt v. Baird*, 405 U.S. 438, 454-55 (1972), to abortion, *see Roe v. Wade*, 410 U.S. 113, 153 (1973), to sexual privacy, *Lawrence v. Texas*, 539 U.S. 558, 578 (2003), and to marital privacy, *Obergefell v. Hodges*, 576 U.S. 644, 664-65 (2015). As these cases illustrate, privacy rights largely have been confined to "to sexual and reproductive rights, such as the right to use contraceptives or have an abortion or engage in homosexual acts." *Wolfe v. Schaefer*, 619 F.3d 782, 784 (7th Cir. 2010).

The students and university disagree on the constitutional analysis. Declaring a right or liberty fundamental has important implications. Modern constitutional jurisprudence employs a different analysis when a person's fundamental right is at stake. If the government infringes on a fundamental right, the court often applies strict scrutiny. *Glucksberg*, 521 U.S. at 721. In such circumstances, the Fourteenth Amendment "forbids the government to infringe . . . fundamental liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Id.* (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993)); *see*, *e.g.*, *Siefert v. Alexander*, 608 F.3d 974, 981 (7th Cir. 2010); *Ent. Software Ass'n v. Blagojevich*, 469 F.3d 641, 646 (7th Cir. 2006). This is the most rigorous form of constitutional scrutiny of government action.

Whereas infringements on other rights or liberties, though still constitutionally scrutinized, must meet what courts call rational basis review. *Glucksberg*, 521 U.S. at 722, *Sweeney v. Pence*, 767 F.3d 654, 668 (7th Cir. 2014). The law normally applies this standard to Fourteenth Amendment challenges to infringed liberties, if not fundamental or based on a suspect classification. *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring); *see, e.g.*, *Glucksberg*, 521 U.S. at 721. It is less stringent than strict scrutiny. Under rational basis review, "legislation is presumed to be valid and will be sustained if the classification drawn by the statute is rationally related to a legitimate state interest." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985). The students argue for strict scrutiny, and the university argues for rational basis review.

2. *The Constitution in a Public Health Crisis.*

We live in the era of the COVID-19 virus—worldwide seeing to nearly 189 million cases and 4 million deaths, with these numbers changing daily. The United States hasn't been immune. Our citizens have recovered or struggled to recover from over 33 million cases of this novel coronavirus when over 606,000 tragically have passed.[67] A public health crisis of this magnitude begs the question: how should the law respond to state action that infringes on the People's liberties during such times?

To be sure, the Constitution isn't put on the shelf. Indeed, in times of crisis, perhaps constitutional adherence proves the very anchor we all need against irrational and overweening government intrusion that would otherwise scuttle the ship. As the

[67] CDC, *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory* (July 16, 2021), https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases.

arbiters of the Constitution's checks and balances, *see Marbury v. Madison*, 5 U.S. 137, 176-78 (1803); *accord Morrison*, 529 U.S. at 616, the courts play an important role in ensuring that the government doesn't simply declare a never-ending public emergency and expand its powers *ad libitum* to the People's detriment.

Under our country's federalist system, state and federal governments share regulatory authority over public health matters. States traditionally exercise most authority under their inherent police power—and reasonably so when public health may flux and evolve by locale. States thus have the power, within constitutional limits, to pass laws that "provide for the public health, safety, and morals[.]" *Barnes v. Glen Theatre*, 501 U.S. 560, 569 (1991); *accord Glucksberg*, 521 U.S. at 729-31; *Zucht v. King*, 260 U.S. 174, 176-77 (1922), *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 24-25 (1905).

To answer the question today, the court travels back in time to 1905: a time before the modern tiers of constitutional analysis (strict scrutiny and rational basis) and one rampaged by the smallpox epidemic. In that year, the United States Supreme Court issued a leading decision in answer to this question.

In *Jacobson*, 197 U.S. at 12, Massachusetts passed a law that allowed a city, if "necessary for the public health or safety," to enforce vaccination of its citizens. If a person refused, he could be fined $5.00 (about $140.00 today). *Id.*; *Cuomo*, 141 S. Ct. at 70 (Gorsuch, J., concurring). The law allowed an exception for children who had physician-signed certificates saying they weren't fit for vaccination, but no such exemption existed for adults. *Jacobson*, 197 U.S. at 12.

The City of Cambridge, relying on this statute and acting through its board of health, ordered its citizens vaccinated for smallpox. *Id.* at 12-13. Smallpox was devastating, claiming almost 300 million lives in the 20th century before being eradicated.[68] In the early 1900s, and closer to the time that Massachusetts wrestled with the disease, there were 1,596 cases of smallpox in Boston, with 270 deaths, in a city with a population close to 561,000.[69] Massachusetts, particularly Boston, was an epicenter of one of two major smallpox outbreaks. Opponents of vaccination questioned its safety and efficacy; though generally safe, it could cause ulceration, lobar pneumonia, cellulitis, parotitis, sepsis, and tetanus, to name a few conditions.[70] Side effects ostensibly posed a greater problem than mild smallpox.[71] The smallpox vaccine wasn't risk-free in the early 1900s. That said, vaccinations had been used for some considerable time—begun by state-supported facilities in England in 1808 and mandated by many other countries throughout the 1800s before the Massachusetts mandate in 1902. *Id.* at 31, n.1. This all transpired before the FDA came into being.

Henning Jacobson refused the vaccine in Massachusetts. After a trial, a jury found him guilty of refusing the vaccine. The court sentenced him to jail until he paid the $5.00

---

[68] *See D L Heymann et al., Successful Smallpox Eradication: What Can We Learn to Control COVID-19?*, 27 J. Travel Med. 1 (2020).

[69] Michael R. Albert *et al.*, *The Last Smallpox Epidemic in Boston and the Vaccination Controversy, 1901-1903*, 344 New Eng. J. Med. 375 (2001).

[70] *Id*. at 375-76.

[71] Bernard Brabin, *An Analysis of the United States and United Kingdom Epidemics (1901-5) – The Special Relationship that Tested Public Health Strategies for Disease Control*, 64 Med. Hist. 1, 26 (2020).

criminal fine. On appeal, he argued that the Massachusetts law authorizing the vaccine mandate violated his Fourteenth Amendment rights. *Id.* at 13.

The United States Supreme Court rejected his challenge. A state's police power "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." *Id.* at 25. This power included the "authority of a state to enact quarantine laws and health laws of every description;" and such power extended to "all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states." *Id.* The Constitution gave Massachusetts broad deference: a court should only intervene "if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, 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." *Id.* at 31.

Of note, *Jacobson* upheld only the constitutionality of the state statute, *id.* at 39 ("We now decide 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."); and phrased its holding in terms of a reasonable regulation established "directly by legislative enactment," *id.* at 25, but the case contemplated the action of local state bodies when vested legislatively with the power to act to safeguard public health and safety, *see*, *e.g.*, *id.* at 25, 38. A State's power, "whether exercised directly by the legislature, or by a local body acting under its authority, may be exerted in such circumstances," and only "regulations so arbitrary and oppressive in

particular cases [would] justify the interference of the courts to prevent wrong and oppression." *Id.* at 38.

The students want *Jacobson* confined to its time, whereas the university believes it applies with full force. In the years since, the high court has leaned on *Jacobson* to uphold government measures intended for the public welfare under effectively rational basis review, finding the measures reasonably advancing a legitimate state interest. For example, *Zucht*, 260 U.S. at 175-77, relied on *Jacobson* to uphold a city ordinance excluding from its public schools children not having a certificate of vaccination, holding that it was within the state's police powers reasonably to so act. According to *Zucht*, *Jacobson* settled the state's power "to provide for compulsory vaccination" and, "consistently with the federal Constitution, delegate to a municipality authority to determine under what conditions health regulations shall become operative." *Id.* at 176. This was not authorization of "arbitrary power," but only that broad discretion required for the protection of the public health." *Id.* at 177. In doing so, "state and federal legislatures [enjoy] wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007) (citing *Jacobson*, 197 U.S. at 30-31).

Based on this power, states and their authorized arms have historically adopted vaccination mandates. For instance, all fifty states and the District of Columbia have laws

requiring students to receive certain vaccines before they may attend school.[72] Many align their vaccine requirements with CDC's immunization recommendations, and all laws provide exemptions for medical reasons and nearly all religious exemptions.[72] Adult vaccination mandates often have been limited to the private employment sector,[73] though not always. For instance, the State of Indiana requires all public university students to receive vaccinations for diphtheria, tetanus, measles, mumps, rubella, and meningococcal disease, save for religious and medical exemptions. *See* Ind. Code § 21-40-5-2.

Similarly, but outside the vaccination context, *Hamilton v. Regents of the University of California*, 293 U.S. 245, 264 (1934), relied on *Jacobson* to uphold a state university's decision to compel military training for its students (five years before World War II). Certain minors (not adults) were required to take a course in military science and tactics, part of training prescribed by the country's war department at the time. The students objected on religious grounds through the Fourteenth Amendment—"no more than an assertion that the due process clause of the Fourteenth Amendment as a safeguard of 'liberty' confers the right to be students in the State University free from obligation to take military training as one of the conditions of attendance." *Id.* at 262. *Hamilton* held this view "untenable," recognizing the government's duty to the people to maintain

[72] Nat'l Conf. of State Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements* (April 30, 2021), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx.

[73] Michael J. Vernick, Molly E. Whitman & McKenzie F. Miller, *The Mandate Maze*, Inside Higher Ed (May 25, 2021), https://www.insidehighered.com/views/2021/05/25/advice-legal-issues-related-vaccine-mandates-opinion.

peace and order and every citizen's "reciprocal duty, according to his capacity, to support and defend government against all enemies." *Id.* at 262-63. Justice Cardozo eloquently concurred: "The right of private judgment has never yet been so exalted above the powers and the compulsion of the agencies of government. One who is a martyr to a principle—which may turn out in the end to be a delusion or an error—does not prove by his martyrdom that he has kept within the law." *Id.* at 268.

Repose the thought whether we face just such a common enemy today in COVID-19. In this century, other than the Supreme Court's reliance on *Jacobson* in 2007, *see Gonzales*, 550 U.S. at 163, courts have returned again to its guidance during the COVID-19 pandemic. Just last year, this circuit endorsed *Jacobson*. *See Pritzker*, 973 F.3d at 763 ("The district court appropriately looked to *Jacobson* for guidance, and so do we."). The circuit held that "*Jacobson* t[ook] off the table any general challenge" to an executive order that subjected religious gatherings to recommended limits on gatherings, rather than mandatory ones. *Id.* at 763-64. The Illinois governor implemented "an order designed to address a serious public-health crisis," and *Jacobson* afforded broad deference "[a]t least at this stage of the pandemic." *Id.*

That decision was almost ten months ago—in terms of the law very recent, but in terms of this ever-evolving health crisis before the proverbial rinderpest. We are no longer at the same stage of the COVID-19 pandemic; indeed, some—like the students—argue that the pandemic is effectively over. And since this circuit's *Pritzker* decision, more cases bearing on the subject of public health in the COVID-19 pandemic have arrived.

One such decision—and one heavily briefed by the parties—is *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63 (2020). In *Cuomo*, the State of New York adopted capacity restrictions on religious institutions that treated them less favorably than so-called "essential" businesses, *id.* at 66, including liquor and hardware stores, *id.* at 69 (Gorsuch, J., concurring). *Cuomo* applied strict scrutiny because the law targeted religious practice contrary to the First Amendment, as incorporated against the states by the Fourteenth Amendment, and enjoined the limitations, saying they were not narrowly tailored to fulfill the state's compelling interest in controlling the spread of COVID-19. *Id.* at 67 (majority opinion).

Cuomo enhanced the law's focus under the First Amendment. *See Cassell*, 990 F.3d at 543 (citing *Cuomo* for the proposition that "[i]ntervening authority from the Supreme Court offers plaintiffs a greater prospect for success on the merits of their First Amendment claim than either the district court or we had expected"). So this begs another question: to what extent has *Cuomo*—if any—impacted the broad deference the court would seemingly afford a state during a pandemic under *Jacobson* to act in the interest of public health? *Cuomo*'s majority opinion never referenced *Jacobson*.

The students read *Cuomo* as implicitly overruling *Jacobson*, or at least as abrogating it. Though the Supreme Court may overrule a case without explicitly saying so, *see Levine v. Heffernan*, 864 F.2d 457, 461 (7th Cir. 1988), this is a tall task. Before a federal court concludes that the Supreme Court has implicitly overruled a prior decision, it must be "certain or almost certain that the decision or doctrine would be rejected by the higher court if a case presenting the issue came before it." *Olson v. Paine, Webber, Jackson & Curtis,*

Inc., 806 F.2d 731, 741 (7th Cir. 1986). This high bar is rarely met. *Id.* It isn't met here. *Cuomo* and *Jacobson* involved entirely different modes of analysis, entirely different rights, and entirely different kinds of restriction. *See Cuomo*, 141 S. Ct. at 70 (Gorusch, J., concurring) (saying the same). "*Jacobson* applied what would become the traditional legal test associated with the right at issue"—exactly what *Cuomo* did. *Id.* The cases walk hand-in-hand.

This history isn't all rosy. Unsuccessful thus far, the students turn to *Buck v. Bell*, 274 U.S. 200 (1927). In a rather infamous case, an eight-member majority, save for one dissenting justice, upheld the involuntary sterilization of a woman based on a Virginia law that rested on faulty science and public support for "eugenics"—the repulsive notion that the human race could be improved by controlling reproduction from those with developmental challenges, mental illness, or criminal histories. Citing *Jacobson* for the principle that "compulsory vaccination is broad enough to cover cutting the Fallopian tubes," and offering the chilling justification that "[t]hree generations of imbeciles are enough," the majority upheld the law against a Fourteenth Amendment challenge. *Id.* at 207. This case isn't *Buck*; and one over-extension of *Jacobson* merely counsels once more that the Constitution cannot be cut loose even now, in a pandemic's seeming twilight. *Cuomo*, 141 S. Ct. at 68.

Jacobson was written before the modern tiers of constitutional scrutiny, so a legitimate question is the extent to which *Jacobson* applies with full force today. This is a topic of some debate. *See, e.g.*, *id.* at 70 (Gorsuch, J., concurring) ("*Jacobson* didn't seek to depart from normal legal rules during a pandemic, and it supplies no precedent for doing

so."); *Calvary Chapel Dayton Valley v. Sisolak*, 140 S. Ct. 2603, 2608 (2020) (Alito, J., dissenting) ("it is a mistake to take language in *Jacobson* as the last word on what the constitution allows public officials to do during the COVID-19 pandemic"); *Big Tyme Inv., LLC v. Edwards*, 985 F.3d 456, 470-71 and n.3 (5th Cir. 2021) (Willett, J., concurring) ("I am not the first to express doubts about *Jacobson*"); *S. Bay United Pentecostal Church v. Newsom*, 959 F.3d 938, 943 n.2 (9th Cir. 2020) (Collins, J., dissenting) ("I am unable to agree with the Fifth Circuit's conclusion that *Jacobson* instructs that all constitutional rights may be reasonably restricted to combat a public health emergency.") (quotations omitted), *cert. denied*, 140 S. Ct. 1613 (2020). No Supreme Court opinion has overruled or abrogated *Jacobson*.

Considering the modern tiers of constitutional scrutiny, the court reads *Jacobson* and *Cuomo* harmoniously, appreciating their respective spheres. Though *Jacobson* was decided before tiers of scrutiny, it effectively endorsed—as a considered precursor—rational basis review of a government's mandate during a health crisis. *See Jacobson*, 197 U.S. at 31; *see also Cuomo*, 141 S. Ct. at 70 (Gorusch, J., concurring). In its words, if a law purporting to be enacted to protect public health "has no real or substantial relation to [that legitimate aim]" or if the law proves "a plain, palpable invasion of rights secured by the fundamental law," the court's job is to give effect to the Constitution. *Jacobson*, 197 U.S. at 31. Should the court have this melding of history and modernity wrong in faithfully adhering to the Fourteenth Amendment's plain original meaning of "life" and "liberty," comfort should come in knowing that *Jacobson*, whether rational basis review by any other name, leads to the same result today.

This view remains consistent with the right at stake in *Jacobson*: though a true "liberty" proved at stake—the right to refuse a vaccine during a smallpox epidemic—this interest in bodily autonomy, though protected by the Constitution, wasn't fundamental under the Constitution to require greater scrutiny than rational basis review. *See Sweeney*, 767 F.3d at 668 (rational basis review for infringements on non-fundamental rights). At the same time, *Jacobson* didn't hold that the government's authority in a pandemic balloons for it do whatever it wants in the name of public safety.

Jacobson instead counseled that federal courts should require a rational relation to a legitimate interest in public health. *See Jacobson*, 197 U.S. at 31; *Cuomo*, 141 S. Ct. at 70 (Gorsuch, J., concurring). That *Cuomo* imposed heightened scrutiny of the government's interference with the free exercise of religion—a fundamental right under the First Amendment—was presciently contemplated a century beforehand by *Jacobson*: a court should intervene if a state imposes a regulation that is "beyond all question, a plain, palpable invasion of rights secured by the *fundamental* law." *Jacobson*, 197 U.S. at 31 (emphasis added). Because *Cuomo* involved a fundamental right, a "right[] secured by the fundamental law" under today's jurisprudence, the court intervened. *See Cuomo*, 141 S. Ct. at 67; *see also Glucksberg*, 521 U.S. at 721 (Fourteenth Amendment forbids the government to infringe "fundamental" liberty interests at all, unless it has narrowly tailored its law to serve a compelling state interest). The Constitution's original meaning should be so enduring.

The university seems to argue that *Jacobson* gave even more deference than rational basis review during a public health crisis, but not fairly so; and, even then, *Jacobson* cannot

be taken once more too far. *See, e.g.*, *Big Tyme*, 985 F.3d at 467; *ARJN #3 v. Cooper*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 22286, 19 (M.D. Tenn. Feb. 5, 2021); *Let Them Play MN v. Walz*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 23485, 15 (D. Minn. Feb. 8, 2021); *Culinary Studios, Inc. v. Newsom*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 23775, 38-39 (E.D. Cal. Feb. 8, 2021); *Oakes v. Collier Cnty.*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 15174, 4 n.4 (M.D. Fla. Jan. 27, 2021); *M. Rae, Inc. v. Wolf*, __ F. Supp.3d __, 2020 U.S Dist. LEXIS 241961, 16 n.25 (M.D. Pa. Dec. 23, 2020); *Denver Bible Church v. Azar*, 494 F. Supp.3d 816, 829 (D. Colo. 2020); *AJE Enterprise LLC v. Justice*, 2020 U.S. Dist. LEXIS 222186, 12 (N.D. W. Va. Oct. 7, 2020).

Jacobson doesn't justify blind deference to the government when it acts in the name of public health or in a pandemic. For instance, the decision left the door open for people with legitimate medical concerns to challenge the vaccine mandate. *See Jacobson*, 197 U.S. at 38-39. And the deference owed to the States during a pandemic or public health crisis under *Jacobson* doesn't extend indefinitely. *See Pritzker*, 973 F.3d at 763.

> [A]t the outset of an emergency, it may be appropriate for courts to tolerate very blunt rules. . . . [B]ut a public health emergency does not give . . . public officials *carte blanche* to disregard the Constitution for as long as the medical problem persists. As more medical and scientific evidence becomes available, and as States have time to craft policies in light of that evidence, courts should expect policies that more carefully account for constitutional rights.

Calvary Chapel, 140 S. Ct. at 2605 (Alito, J., dissenting); *accord Cassell*, 458 F. Supp.3d at 993-94 ("courts must remain vigilant, mindful that government claims of emergency have served in the past as excuses to curtail constitutional freedoms.").

In short, the Constitution doesn't permit the government to declare a never-ending public emergency and expand its powers arbitrarily. *See Belcher v. Norton*, 497 F.3d 742, 753 (7th Cir. 2007) ("substantive due process . . . affords protection of the individual against arbitrary action of government"). Instead, as our country and communities progress through a pandemic, the government must continually update its practices in light of the most recent medical and scientific developments. And a law or policy should be written with a mindset that medicine and science, and the circumstances that they create, will evolve, and so must the law or policy evolve or be revisited in amendment.

In sum, the law today recognizes *Jacobson* as a precursor to rational basis review. This is consistent with statements of many justices who continue to acknowledge *Jacobson* as good law, albeit with constitutional restraint.[74] Government action that infringes on the liberty interest here, as in *Jacobson*, is subject to rational basis review. *See Sweeney*, 767 F.3d at 668.

[74] *See, e.g., Democratic Nat'l Comm. v. Wisconsin State Legislature*, 141 S. Ct. 28, 43 (2020) (Kagan, J., dissenting). ("To be sure, deference is usually due to a legislature's decisions about how best to manage the COVID pandemic.") (citing *South Bay*, 140 S. Ct. at 1613-14) (Roberts, C.J., concurring in denial of an injunction seeking to prevent a COVID-19 executive order); *South Bay*, 140 S. Ct. at 1613 (Roberts, C.J., concurring); *Calvary Chapel*, 140 S. Ct. at 2608 (Alito, J., dissenting) ("Language in *Jacobson* must be read in context"); *id.* at 2614 (Kavanaugh, J., dissenting); *Cuomo*, 141 S. Ct. at 71 (Gorsuch, J., concurring); *Cuomo*, 141 S. Ct. at 79 (Sotomayor, J., dissenting) (courts "play a deadly game in second guessing the expert judgment of health officials about the environments in which a contagious virus, now infecting a million Americans each week, spreads most easily"); *Glucksberg*, 521 U.S. at 742 (Stevens, J., concurring) ("As Justice Brennan pointed out in his *Cruzan* dissent, we have upheld legislation imposing punishment on persons refusing to be vaccinated . . . . In most cases, the individual's constitutionally protected interest in his or her own physical autonomy, including the right to refuse unwanted medical treatment, will give way to the State's interest in preserving human life.").

3. *Defining the Right & Constitutional Analysis.*

The students assert a right to refuse the vaccine, saying the mandate infringes on their bodily autonomy and medical privacy. Indiana University throws a challenge flag here. To it, these students are merely saying they have a right to refuse a vaccine *so that* they may attend college. The university says the right being infringed then isn't the right to refuse a vaccine, but the right to attend college. Indeed, if they choose to forego college at Indiana University, there is no vaccine requirement. To the university, the students aren't being forced to take the vaccination against their will; they can go to college elsewhere or forego college altogether. If this case were merely that, merely the right to attend university, this state action wouldn't trample on their rights. There is no fundamental or constitutional right to a college education, *see, e.g.*, *Charleston v. Bd. of Trustees*, 741 F.3d 769, 774 (7th Cir. 2013); *Bissessur v. Ind. Univ. Bd. of Trustees*, 581 F.3d 599, 601 (7th Cir. 2009); *Williams v. Wendler*, 530 F.3d 584, 589 (7th Cir. 2008), much less one at a particular institution.

But that's not what this case concerns, and that's not the liberty at stake. The "unconstitutional conditions doctrine" forbids the university from pulling the rug out from under the students in a roundabout way. Under this doctrine, argued by the students as "coercion," "the government may not deny a benefit to a person because he exercises a constitutional right." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (citations omitted); *Regan v. Taxation with Representation of Wash.*, 461 U.S. 540, 545 (1983). This doctrine protects constitutional rights "by preventing the government from coercing people into giving them up." *Koontz*, 570 U.S. at 604. It "aims to prevent

the government from achieving indirectly what the Constitution prevents it from achieving directly." *Planned Parenthood of Ind. v. Comm'r*, 699 F.3d 962, 986 (7th Cir. 2012). The students say this state actor is denying a benefit—a public university education—because they are exercising a constitutional right to refuse a vaccine.

The first step in an unconstitutional condition claim "is to identify the nature and scope of the constitutional right arguably imperiled by the denial of a public benefit." *Id.* Here, the Fourteenth Amendment "liberty" at stake is a college student's right to refuse a vaccine, today at this stage of the pandemic [Tr. 26, 30-31]. The Supreme Court has assumed (using its word) and strongly suggested that individuals have a constitutional right to refuse unwanted medical treatment, *see, e.g., Cruzan v. Director, Missouri Dept. of Health* 497 U.S. 261, 279 (1990); *Glucksberg*, 521 U.S. at 720. *Cruzan* held that a competent individual had a constitutional right to refuse unwanted lifesaving hydration and nutrition; and *Glucksberg* recognized that an individual had a liberty interest in refusing unwanted lifesaving medical treatment, though not any fundamental right to assisted suicide. *See Cruzan*, 497 U.S. at 279; *Glucksberg*, 521 U.S. at 728.

But in these, and in other cases, this liberty interest has remained confined either by duly enacted and constitutional state laws or the state's legitimate interests that it had rationally pursued in regulation. *See also Washington v. Harper*, 494 U.S. 210, 221-22 (1990) (prisoner has a "significant liberty interest in avoiding the unwanted administration of antipsychotics drugs under the Due Process Clause . . . [but] no greater right than that recognized under state law"); *Vitek v. Jones*, 445 U.S. 480, 492 (1980) ("Compelled treatment in the form of mandatory behavior modification programs . . . was a proper

factor to be weighed by the District Court. . . . Were an ordinary citizen to be subjected involuntarily to these consequences, it is undeniable that protected liberty interests would be unconstitutionally infringed absent compliance with the procedures required by the Due Process Clause."); *Ingraham v. Wright*, 430 U.S. 651, 673, 683 (1977) ("Among the historic liberties so protected was a right to be free from, and to obtain judicial relief for, unjustified intrusions on personal security. . . . The Eighth Amendment's prohibition against cruel and unusual punishment is inapplicable to school paddlings, and the Fourteenth Amendment's requirement of procedural due process is satisfied by Florida's preservation of common-law constraints and remedies.")

The rights recognized (or assumed) in these cases weren't "simply deduced from abstract concepts of personal autonomy." *Glucksberg*, 521 U.S. at 725. They were rooted in longstanding common law rules or legal traditions consistent with this Nation's history. *See id.* The students, quite skillfully represented in this emergency setting, offer no preliminary record of such historic rules, laws, or traditions that would facilitate the court's announcement, now in mere days from receiving this case, that a right to refuse a vaccine is anything more than a significant liberty under the Fourteenth Amendment.

The dearth of this record isn't a passing point. Indeed, both *Cruzan* and *Glucksberg* were limited to an individual's choice related to the refusal of lifesaving subsistence or medical treatment—with no ramifications to the physical health of others. Vaccines address a collective enemy, not just an individual one. Indeed, "the elimination of communicable diseases through vaccination [is] one of the greatest achievements of public health in the 20th century," *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 226 (2011) (Scalia,

J.) (citation and quotations omitted), and it continues to be so now in this century. A vaccine is implemented as a matter of public health, and historically hasn't been constitutionally deterred from state mandate. *See, e.g.*, *Zucht*, 260 U.S. at 176-77; *Jacobson*, 197 U.S. at 30-31.

In the backdrop of the Fourteenth Amendment's ratification in 1868, for instance, England had already passed its first compulsory vaccination act for smallpox in 1853 (and so had many countries). *See Jacobson*, 197 U.S. at 31, n.1. Science wasn't absolute or infallible at that time—nor is it today. But the "possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases." *Id.* at 35. Appreciating the relative risks of vaccines, they nonetheless "are effective in preventing outbreaks of disease only if a large percentage of the population is vaccinated." *Wyeth*, 562 U.S. at 227.

Added comfort comes from the consistent use of rational basis review to assess mandatory vaccination measures. *See, e.g.*, *Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944) (parent "cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds" and "[t]he right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death"); *Zucht*, 260 U.S. at 176-77; *Jacobson*, 197 U.S. at 30-31; *Phillips v. City of New York*, 775 F.3d 538, 542-43 (2d Cir. 2015); *Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. Appx. 348, 355-56 (4th Cir. 2011); *W.D. v. Rockland Cnty.*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 33515, 74 (S.D.N.Y. Feb. 22, 2021); *Doe v. Zucker*, __ F. Supp.3d __, 2021 U.S.

Dist. LEXIS 28937, 111 (N.D.N.Y. Feb. 17, 2021); *Connecticut Citizens Defense League, Inc. v. Lamont*, 465 F. Supp.3d 56, 72 (D. Conn. 2020); *Middleton v. Pan*, 2016 U.S. Dist. LEXIS 197627, 20 (C.D. Cal. Dec. 15, 2016); *George v. Kankakee Cmty. Coll.*, 2014 U.S. Dist. LEXIS 161379, 8-9 (C.D. Ill. Oct. 27, 2014), *recommendation adopted*, 2014 U.S. Dist. LEXIS 160737, 1-2; *Boone v. Boozman*, 217 F. Supp.2d 938, 954 (E.D. Ark. 2002).

Given over a century's worth of rulings saying there is no greater right to refuse a vaccination than what the Constitution recognizes as a significant liberty, the court declines the students' invitation to extend substantive due process to recognize more than what already and historically exists. *See Glucksberg*, 521 U.S. at 721; *Harper*, 494 U.S. at 221-22; *Prince*, 321 U.S. at 166-67; *Zucht*, 260 U.S. at 176-77; *Jacobson*, 197 U.S. at 30-31.

Quite separately from this, the Constitution never provides a fundamental right to a collegiate education. Nor does it secure as a fundamental liberty a student's right to attend a public university no matter his or her vaccinated status. The court isn't saying a student doesn't have the right to choose. Of course every individual does—subject to the state's reasonable measures designed to pursue legitimate ends of disease control or eradication.

The students argue that the university's vaccine mandate doesn't provide for informed consent. "The notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Cruzan*, 497 U.S. at 269. Informed consent "entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each." *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972). The students acknowledge that, for medical products under an EUA like the

three COVID-19 vaccines, HHS must establish conditions to facilitate informed consent. *See* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). HHS must ensure that individuals taking the vaccine are informed "that the Secretary has authorized the emergency use of the product," "of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown," and "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.*

The students admit that the informed consent requirement under the EUA statute only applies to medical providers. The university isn't directly administering the vaccine to its students; instead, it is requiring students to obtain the vaccine from a medical provider and to attest that they have been vaccinated, save for certain exemptions. The students will be informed of the risks and benefits of the vaccine and of the option to accept or refuse the vaccine by their medical providers. *See id.* The university isn't forcing the students to undergo injections. The situation here is a far cry from past blunders in medical ethics like the Tuskegee Study.[75]

The university is presenting the students with a difficult choice—get the vaccine or else apply for an exemption or deferral, transfer to a different school, or forego school for the semester or altogether. But this hard choice doesn't amount to coercion. The

[75] *See* CDC, *The U.S. Public Health Service Syphilis Study at Tuskegee* (as part of a study on the history of untreated syphilis, "researchers did not collect informed consent from participants and they did not offer treatment, even after it was widely available"), https://www.cdc.gov/tuskegee/index.html (last visited July 16, 2021).

students taking the vaccine are choosing it among other options, and before the shot reaches their arms, they are made aware of the risks and the option to refuse.

One last point before moving on. As a final push, the students argue that the vaccination requirement violates their free exercise of religion. The First Amendment says "Congress shall make no law . . . prohibiting the free exercise" of religion. U.S. Const. amend. I. The Supreme Court has declared this right to exercise religion as fundamental and subject to strict scrutiny. *See Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940). But the Constitution also permits general regulations that incidentally burden religious practices: the "right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)." *Employment Division v. Smith*, 494 U.S. 872, 879 (1992) (quotations omitted). Neutral and generally applicable regulations need only be supported by a rational basis. *Ill. Bible Colleges Ass'n v. Anderson*, 870 F.3d 631, 639 (7th Cir. 2017).

The vaccine mandate is a neutral rule of general applicability. It applies to all students, whether religious or not. It doesn't discriminate among religions. Indeed, the university has chosen to *enable* the practice of religion by providing a religious exemption to this vaccination requirement—one that the university, on this record, has freely granted to students if they request it, no questions asked. This is consistent with the Constitution. *See Nikolao v. Lyon*, 875 F.3d 310, 316 (6th Cir. 2017) (religious plaintiff had no constitutional right to an exemption from mandatory vaccination law for public school students, though state provided one); *Phillips*, 775 F.3d at 543 (state "could

constitutionally require that all children be vaccinated in order to attend public school. . . . [but the State went] beyond what the Constitution requires by allowing an exemption for parents with genuine and sincere religious beliefs"); *see also Workman*, 419 F. Appx. at 356; *Whitlow v. California*, 203 F. Supp.3d 1079, 1084 (S.D. Cal. 2016); *Boone*, 217 F. Supp.2d at 954. Indiana University adopted a religious exemption, despite a religious-neutral vaccine mandate, which the law views as a matter of grace. Indeed, six of the eight students here applied for just such a religious exemption and obtained one.

In short, based on this analysis, all roads effectively lead to rational basis review: *Jacobson* as a precursor to or stand-alone iteration of it, the modern tiers of constitutional scrutiny, the unconstitutional conditions doctrine, and the First Amendment as applied through the Fourteenth Amendment to this state actor. And to this road once traveled the court now turns.

4. *On This Preliminary Record, Non-Exempt Students Haven't Shown a Likelihood of Success on their Claim that Indiana University Lacks a Rational Basis for Its Vaccine Mandate.*

Determining that the students have a liberty interest under the Fourteenth Amendment's due process clause doesn't end the analysis. *See Cruzan*, 497 U.S. at 278. To decide whether the students' constitutional rights have been violated, or more appropriately whether they are likely to succeed on such a claim, the court must balance their liberty against the relevant state interests in accord with the Constitution. *See id.* Two students aren't exempt from the COVID-19 vaccine mandate: Natalie Sperazza and Margaret Roth. They assert a right to refuse the vaccine, saying the mandate infringes on their bodily autonomy and medical privacy.

"Stemming the spread of COVID-19 is unquestionably a compelling interest." *Cuomo*, 141 S. Ct. at 67 (majority opinion). According to the federal government and the State of Indiana, a state of emergency persists related to COVID-19, all the while restrictions are being scaled back gradually. Recognizing today's status of this pandemic, neither health professionals, government representatives, nor this court may say public health *vis-à-vis* COVID-19 has waned from being a legitimate state interest. Improved it undoubtedly has—today seems a world altogether different from last year—but public health remains a legitimate interest of the state to pursue. Indiana University too has a legitimate interest in promoting the health of its campus communities—students, and not least the faculty and staff who come daily in contact with them.

The students argue that the pandemic is basically over, but this goes against current proclamations from the Secretary of Health and Human Services, the Indiana State Department of Health, Governor Eric Holcomb, and the CDC, all then supported for institutions of higher learning by the U.S. Department of Education and the American College Health Association.[76] In Indiana (and nationally), the trend line remains sharply down (since winter) in terms of both new cases and deaths, though the recent snapshot of seven-day lookbacks proves nearly triple what it was just when this case commenced.

[76] *See, e.g.*, U.S. Dep't of Educ., *ED COVID-19 Handbook, Volume 3: Strategies for Safe Operation and Addressing the Impact of COVID-19 on Higher Education Students, Faculty, and Staff* 9 (June 2021), available at [Ex. 116 at 7], https://www2.ed.gov/documents/coronavirus/reopening-3.pdf ("COVID-19 vaccination is the leading prevention strategy [institutions of higher learning] can use to return to normal operations."); Am. College Health Ass'n, *ACHA Guidelines: American College Health Association Recommends COVID-19 Vaccination Requirements for All On-Campus College Students in Fall 2021* (Apr. 29, 2021), https://www.acha.org/ACHA/About/ACHA_News/ACHA_Recommends_COVID-19_Vaccination_Requirements_for_Fall_2021.aspx. Though it appears many public universities, including those in the State of Indiana, are ACHA members, Indiana University is not. The guidance is nonetheless pertinent here.

It isn't unreasonable to believe that, absent concerted vaccination, the fall and winter months will prove more arduous than these summer months for the university [Ex. 129 at 32]. Vastly improved, yes; out of the woods we aren't, not on this preliminary record.

The students argue that the bell curve that depicts ongoing cases and deaths from this pandemic's outset mirrors the CDC's continuum of pandemic phases that directs more conservative measures, not more draconian ones [*see*, *e.g.*, Exs. 212, 222, 230-231]. The students call this pandemic in the "deceleration" or "preparation" intervals—terms of art that define its waning stages. Deceleration occurs when state or local health officials rescind community mitigation measures because no new cases are occurring or are occurring infrequently; and preparation occurs when the pandemic is declared ended because evidence indicates that the disease is transitioning to seasonal patterns of transmission [Ex. 231]. The overall trend line may well support a seeming deceleration [*cf.* Exs. 222, 319]; but Indiana University insisting on vaccinations for its campus communities is rationally related to ensuring the public health of students, faculty, and staff this fall. Even under the university's pandemic and infectious disease action levels [Ex. 212], the university must continue to consult CDC and Indiana State Department of Health standards; and those today favor vaccination.

Let's not forget why we are here at this more promising stage of the pandemic, July 18, 2021. Antibody resistance developed naturally from prior cases has been a contributor to be sure; but, materially, improvement has come because of vaccinations—nationally over 161 million complete (over 337 million doses) and statewide nearly 3 million complete (and over 5.7 million doses). The vaccination campaign has markedly

curbed the pandemic. In fact, certain age-stratified, agent-based modeling of COVID-19 has concluded that another 279,000 deaths and nearly 1.25 million more hospitalizations would have occurred by the end of June 2021 but for the vaccines.[77] Stemming illness, hospitalizations, or deaths at the university level hardly proves irrational.

It isn't a foregone conclusion that this is overkill. This pandemic continues to evolve, and medicine and science with it. Science is a process in search of fact. One such moving target is the Delta variant (B.1.617.2). A mere four days ago Indiana reported 612 COVID cases—the highest count in more than six weeks (since May 27, 2021)—that health officials attributed largely to the Delta variant and the unvaccinated population. Though this daily case count is much lower than at the pandemic's height, the CDC, Indiana's State Department of Health, and epidemiologists have identified the Delta variant of particular lingering concern.[78] The CDC labeled Delta a "variant of concern" in mid-June.[79] Current science shows it more virulent and transmissible. A peer-reviewed study from scientists (issued July 8, 2021) found that the Delta variant has mutations that allow it to evade certain natural antibodies, with vaccination proving the best protection [Ex.

[77] *See* Alison Galvani *et al.*, *Deaths and Hospitalizations Averted by Rapid U.S. Vaccination Rollout* (Commonwealth Fund, July 2021), https://doi.org/10.26099/wm2j-mz32.

[78] *See* Shari Rudavsky, *Delta Variant on the Rise in Indiana, State Health Officials Say*, IndyStar (July 9, 2021, 12:58 PM), https://www.indystar.com/story/news/health/2021/07/09/covid-delta-variant-rise-indiana-state-health-officials-say/7908502002/ ("Not only is the Delta variant more readily transmitted from person to person, there's some indication it may cause more severe disease, said Indiana State Health Commissioner Dr. Kris Box.").

[79] *See See* CDC, *SARS-CoV-2 Variant Classifications and Definitions* (July 13, 2021), https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html.

319].[80] Reports of surges of Delta cases among the 12-29 age group have occurred.[81] For now, Indiana University has reasonably concluded that the safety and public health of its campus communities can be augmented by the vaccines [*id.*]. *See Gonzales*, 550 U.S. at 163 (citing *Jacobson*, 197 U.S. at 30-31) (the law gives "wide discretion to pass legislation in areas where there is medical and scientific uncertainty").

Indiana University reasonably believes the vaccine promotes the safety of not only its students, but that of its entire community. This wasn't (and still isn't) a decision taken lightly. It wasn't a decision reached overnight. It wasn't a decision taken by some fly-by-night committee undetached from the current science, the current progress of the fight

---

[80] *See* Delphine Planas *et al.*, *Reduced Sensitivity of SARS-CoV-2 Variant Delta to Antibody Neutralization*, Nature doi: 10.1038/s41586-021-03777-9, 3 (July 8, 2021) (online ahead of print), https://www.nature.com/articles/s41586-021-03777-9_reference.pdf ("[A] single dose of Pfizer or AstraZeneca was either poorly or not at all efficient against Beta and Delta variants. Both vaccines generated a neutralizing response that efficiently targeted variant Delta only after the second dose.") According to Dr. Beeler, the data show that 50 percent of individuals had antibodies to the Beta variant and 47 percent had antibodies to the Delta variant one year after natural infection, whereas those who had vaccination after natural infection maintained 100 percent antibodies to both variants a year later [Ex. 319 ¶ 1]. According to Yale Medicine, the Delta variant is 50 percent more transmissible. *See also* Venkata-Viswanadh Edara *et al.*, *Infection and Vaccine-Induced Neutralizing-Antibody Responses to the SARS-CoV-2 B.1.617 Variants*, N. Eng. J. Med. DOI: 10.1056/NEJMc2107799 (July 7, 2021) https://www.nejm.org/doi/full/10.1056/NEJMc2107799; Kathy Katella, Yale Med., *5 Things to Know About the Delta Variant* (July 15, 2021), https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid.

[81] *See See* Ian Mount *et al.*, *The Kids are (not) Alright: Europe Sounds the Alarm as Delta Variant Soars Among Teens and 20-Somethings*, Fortune (July 8, 2021, 11:58 AM), https://fortune.com/2021/07/08/kids-vulnerable-covid-delta-variant-vaccinated-europe/ (seeing surge of Delta cases among the 12-29 age group); *see also* Public Health England, *SARS-CoV-2 Variants of Concern and Variants under Investigation in England: Technical Briefing 17*, 15 (June 25, 2021), https://www.nature.com/articles/s41586-021-03777-9_reference.pdf. A recent United Kingdom study, albeit still abstracted, concluded that most Delta infections in a younger group (age 5-49) occurred in the unvaccinated population. *See* Steven Riley *et al.*, *REACT-1 Round 12 Report: Resurgence of SARS-CoV-2 Infections in England Associated with Increased Frequency of the Delta Variant*, medRxiv (June 21, 2021) (not peer-reviewed pre-print), https://www.medrxiv.org/content/10.1101/2021.06.17.21259103v1.

against the pandemic, or experience and training in relevant fields of study. The restart committee was led by Indiana University's Executive Vice President for University Clinical Affairs and the School of Medicine's Dean. The committee consisted of seven MDs, some with additional degrees in public health or other PhDs, and others with graduate degrees in public health, risk mitigation, law, and ethics [Ex. 300 at 5]. Of its 15 members, two were deans of public health and others were experts in public health, epidemiology, virology, and other relevant areas of the health sciences, including health equity [Ex. 116 ¶ 23]. The committee met regularly and considered a wide variety of sources and information [*id.* ¶ 24].

A mere sampling of presentations from committee meetings from December 8, 2020 to April 6, 2021 [Exs. 302-317] shows the committee focused on COVID-19 evolution; EUA data; reactogenicity data; communications with the Indiana State Department of Health; CDC guidelines and updates; university-wide surveillance testing and data; data trends based on vaccinated and unvaccinated individuals; on-campus and off-campus transmission events; morbidity and mortality figures; efficacy of mitigation efforts on and off campus; international, national, state, county, and school vaccine uptake data; vaccine efficacy against variants; vaccine risk data; vaccine hesitancy surveys and campus opinion polling; and policies and requirements of other universities across the country [*see also* Ex. 301 ¶ 2]. In addition, four MDs from this committee presented near-weekly from December 2020 to June 2021 to Indiana University's Executive Academic Leadership Council, including the President and Executive Vice Presidents as part of the medical response team's ongoing COVID-19 evaluation efforts [*Id.* ¶ 5]. The process ultimately

filtered through the judgment of the Board of Trustees. This was a deliberative decision based on a wealth of scientific, medical, empirical, and industry-wide data.

For the impact of this vaccine mandate, the students focus only on the student body; and that is certainly an important part of the analysis here. The students argue that the fatality rate for healthy individuals age 20-49 is far less than older individuals [*see*, *e.g.*, Ex. 117 at 21-24; Ex. 243]. Dr. McCullough calls the mortality rate 0.15 percent [Ex. 241 ¶ 3]. He testifies that 16 deaths of young adults (aged 18-29) occurred in 2020, but none thus far in 2021 [Ex. 117 ¶ 34]. The students point out that the university's student body had one death last year [*id.* ¶ 25]. Indiana University reasonably views a 0.15 percent death rate as unacceptable for its communities, particularly given the safe preventative measure of a vaccine [Ex. 319 ¶ 4]. At approximately 90,000 students, that rate would risk 135 student lives, not accounting for other mitigation efforts to the better or those with immunocompromising conditions to the worse. The university's student population is not a homogenous group of just young healthy adults [*id.*].

In addition, the student's position overlooks the larger Indiana University community. Dr. McCullough, in fairness, takes a wider snapshot yet, pointing to a longitudinal serosurvey (blood sampling) of community residents near Pennsylvania State University suggesting that students' return in August 2020 had limited transmissible effect on the local community [Ex. 117 ¶ 29-30].[82] But Indiana University's perspective was more intimate. The university analyzed the number of individuals

[82] *See* Callum R. K. Arnold *et al.*, *SARS-CoV-2 Seroprevalence in a University Community: A Longitudinal Study of the Impact of Student Return to Campus on Infection Risk Among Community Members*, medRxiv (Feb. 14, 2021) (non-peer reviewed pre-print), https://pubmed.ncbi.nlm.nih.gov/33619497/.

within its campus population known to have increased risk factors for COVID-19 and determined that over 8,500 faculty and staff remained at increased risk of complications if they contracted the disease [Ex. 116 ¶ 26], with the ongoing risk of asymptomatic spread that vaccines help address [Ex. 129 at 53-54]. Faculty and staff at Indiana University who have daily contact with students represent an even broader demographic than just the student body, and this policy was intended to protect them too. The court credits Dr. Carroll and Dr. Beeler over Dr. McCullough on this point given their firsthand knowledge of Indiana University's specific circumstances.

The university's policy has broad support within its community. As of June 25, 2021, over 42,000 students had received the vaccine; and that number has no doubt grown [Ex. 116 ¶ 46]. Two university faculty councils—elected representative bodies interested in the quality of learning and student life—issued statements in support [*id.* ¶ 47]. The staff council at Indiana University's main campus in Bloomington likewise endorsed the policy [*id.* ¶ 49]. The graduate and professional student government also issued a resolution supporting the policy [*id.* ¶ 50]. Eight students have filed this lawsuit, and perhaps others await this ruling to decide. Under the circumstances, on this preliminary record, the law respects the right of this university community to self-govern reasonably.

To that point, no one has argued that Indiana University's policy is *ultra vires*. Indiana's General Assembly endowed the university's Board of Trustees to act in the "best interests of the state and the state educational institution," Ind. Code § 21-40-3-1(b), including the power "to prevent unlawful or objectionable acts that . . . violate the reasonable rules and standards of the [university] designed to protect the academic

community from . . . conduct presenting a serious threat to person or property of the academic community," Ind. Code § 21-39-2-3(b). The university remains answerable to the legislature, particularly its coffers.

The Indiana General Assembly has prohibited a vaccine passport in this state, but not a vaccine requirement. *See* Ind. Code § 16-39-11-5. Still, in assessing the reasonableness of vaccination mandates, the law considers underlying legislative authority. *See Zucht*, 260 U.S. at 175; *Jacobson*, 197 U.S. at 12-13; *see also Washington*, 494 U.S. at 221-22 (recognizing liberty interest under both state's policy and due process clause, but "no greater right than that recognized under state law"). On this preliminary record, Indiana University faces still an "objectionable" and "serious threat" to the "academic community" that its vaccination policy seeks reasonably to address for campus health. *See Zimmerman v. Bd. of Trustees of Ball State Univ.*, 940 F. Supp.2d 875, 890-91 (S.D. Ind. 2013) (defining "objectionable"). This is consistent with the Fourteenth Amendment.

Focusing on just mortality risk from COVID-19 leaves out much of the debate. Dr. McCullough and Dr. Beeler (with Dr. Carroll), for instance, offer competing views on the risks of the novel coronavirus and the risks of the vaccines [Exs. 115-117, 222, 319].[83] This is precisely the debate of medical professionals that state policymakers, including

[83] The experts at times debate relatively modest side effects from vaccines after natural infection (*e.g.*, fever or fatigue), but these are self-limited and not dangerous [Ex. 319 ¶ 6], so the court addresses them no more here. Even Dr. McCullough admits that other longstanding vaccines, including those mandated by state law, have common side effects, such as a risk of a fever [Ex. 117 ¶ 56].

authorized arms of the state, are best suited to resolve in setting policy for constituents, including here for the students at Indiana University.

Without vaccination, college-aged students remain at risk for serious long-term complication from COVID-19, including prolonged debilitating symptoms that interfere with normal life such as myocarditis, reduced aerobic capacity, and brain damage [Ex. 319 ¶ 5].[84] Long COVID remains a studied phenomenon. With Indiana reporting that individuals aged 20-29 have had more positive cases than any other age demographic [Ex. 115 ¶ 14], and with more than 260,000 cases linked to American college and universities since January 1, 2021 [*id.* ¶ 17], this proves still a legitimate risk.[85] Focusing only on mortality disregards the serious compromise to the quality of life that face some students who contract the virus [*see also id.* ¶ 10-11].

The students say the risks of the vaccine, especially at this stage and to their age group, outweigh any benefits a vaccine might confer. These argued risks include

---

[84] *See* Mark W. Tenforde *et al.*, *Symptom Duration and Risk Factors for Delayed Return to Usual Health Among Outpatients with COVID-19 in a Multistate Health Care Systems Network — United States, March–June 2020*, 69:30 Morbidity and Mortality Weekly Report 993, 997-98 (July 24, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6930e1.htm?s_cid=mm6930e1_w ("Nonhospitalized COVID-19 illness can result in prolonged illness and persistent symptoms, even in young adults and persons with no or few chronic underlying medical conditions."); Giovanni Andrea Gerardo Crameri *et al.*, *Reduced Maximal Aerobic Capacity after COVID-19 in Young Adult Recruits, Switzerland, May 2020*, 25(36) Euro. Surveillance 1, 2 (Sept. 10, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7502899/pdf/eurosurv-25-36-2.pdf ("We observed a statistically significant decrease in VO_2 max among COVID-19 convalescents compared with naive and asymptomatically infected recruits"); Gwenaelle Douaud *et al.*, *Brain Imaging Before and After COVID-19 in UK Biobank*, medRxiv (Jun. 20, 2021) (not peer-reviewed pre-print), https://www.medrxiv.org/content/10.1101/2021.06.11.21258690v2 ("In both cases we identified significant (corrected-P<0.05) effects of COVID-19, primarily relating to loss of grey matter in cortical areas directly connected to primary olfactory and gustatory cortex.")

[85] The New York Times has tracked coronavirus cases at American college and universities, though its numbers have not been seemingly updated since May 26, 2021. *See* The New York Times, *Tracking Coronavirus Cases at U.S. Colleges and Universities*, https://www.nytimes.com/interactive/2021/us/college-covid-tracker.html (last visited July 18, 2021).

myocarditis, clotting, death, and others [Ex. 117 ¶ 48-49]. Some of these concerns are easier to assuage based on current science than others—and the court isn't the final arbiter of an evolving science, only of the law. The court must base today's decision on the snapshot of this preliminary record alone. It answers the question only whether the students have made a strong showing that Indiana University failed to act reasonably in achieving campus health to warrant the extraordinary remedy of a preliminary injunction.

That said, Dr. Beeler concludes that with millions of people getting the vaccine, experts "have [a] much tighter lens than we normally would for any other vaccine in history to identify some of those extremely rare concerns" [Ex. 128 at 80], and that younger people have a "higher probability" of facing issues with COVID-19 infection than after vaccination [*id.* 78]. All vaccine manufacturers conducted Phase 3 trials for EUA that never revealed the risks the students have presented [*id.* 79].

Since then, reports have shown the risk of myocarditis (heart inflammation), while present and something worthy of continued investigation, to be seemingly rare—one study suggesting the risk is about eight in one million and the other study suggesting the risk is about twenty in one million.[86] This issue has garnered increasing attention. The FDA reported CDC data (through May 31, 2021) of 475 cases of myocarditis (heart inflammation) and pericarditis (inflammation of membrane around heart) in vaccinated

[86] *See* Han W. Kim *et al.*, *Patients with Acute Myocarditis Following mRNA COVID-19 Vaccination*, JAMA Cardiol (June 29, 2021), https://jamanetwork.com/journals/jamacardiology/fullarticle/2781602; Israeli Ministry of Health, *Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021* (Feb. 6, 2021), https://www.gov.il/en/departments/news/01062021-03.

individuals age 30 and younger [Ex. 117 ¶ 49].[87] This data came from the Vaccine Adverse Event Reporting System (VAERS)—anecdotal data that, while important to analyze, requires further investigation before drawing conclusions. *See*, *e.g.*, *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) ("case reports alone ordinarily cannot prove causation"); *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989-90 (8th Cir. 2001) ("causal attribution based on case studies must be regarded with caution").[88] Still, on June 24, 2021, a CDC safety panel reported a "likely association" in young adults from mRNA COVID-19 vaccines and myocarditis and pericarditis, though it emphasized that it remained rare and typically mild, with the benefits of the vaccine still outweighing the risks [Ex. 117 ¶ 51].[89] This assessment of heart inflammation's rarity and the overarching benefits of the vaccines has a bench of current medical support on this record,[90] again

---

[87] *See* FDA, *Vaccines and Related Biological Products Advisory Committee June 10, 2021 Meeting Presentation*, https://www.fda.gov/media/150054/download#page=17 (last visited July 16, 2021).

[88] *See also* CDC, *The Vaccine Adverse Event Reporting System (VAERS) Results* (July 17, 2021), https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=DBF4A737A762F523202A55E30B57 ("While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness.").

[89] *See* Advisory Board, *CDC Panel Reports 'Likely Association' of Heart Inflammation and mRNA COVID-19 Vaccines in Young People* (June 24, 2021), https://www.advisory.com/daily-briefing/2021/06/24/heart-inflammation.

[90] *See also* Saif A. Mouch *et al.*, *Myocarditis Following COVID-19 mRNA Vaccination*, 39 Vaccine 3790, 3793 (May 28, 2021), https://pubmed.ncbi.nlm.nih.gov/34092429/ (noting "mild" myocarditis and only "possible"—not probable—connection to vaccination, and concluding that the "individual and public benefit from COVID-19 vaccination outweighs these rare findings"); *accord* Carolyn M. Rosner *et al.*, *Myocarditis Temporally Associated with COVID-19 Vaccination*, Circulation (June 16, 2021) (manuscript only), https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.055891 ("[N]o data are available specific to vaccine-associated myocarditis. The clinical course of vaccine-associated myocarditis-like illness appears favorable, with resolution of symptoms in all patients. Given the potential morbidity of COVID-19 infection even in younger adults, the risk-benefit decision for vaccination remains highly favorable."); Mayme Marshall *et al.*, *Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination*, 148(1) Pediatrics (July 2021) (peer-reviewed case report) https://pediatrics.aappublications.org/content/early/2021/06/04/peds.2021-052478 ("This report summarizes a series of US cases of myocarditis and myopericarditis following the Pfizer-BioNTech COVID-19 mRNA vaccine in adolescent males . . . . At present, there is no definite causal relationship between these

giving Indiana University a rational connection between its mandate and its aim of campus health. This proves no less true when contracting COVID-19 (without the vaccine) already presents a risk of myocarditis [Ex. 319 ¶ 5]. No one should blithely dismiss the call for further investigation, but the students' case isn't strong today.

The students argue the temporal association of these risks, but just because the rooster crows doesn't mean he caused the sun to rise. A close review of Dr. McCullough's testimony reveals a true failing. Even he, the students' own tendered expert, a credentialed and board-certified physician in internal medicine and cardiovascular disease, stops short of declaring a causative link between any vaccine and myocarditis. He uses soft and inconsequential language, calling his suspicion "possible" and "unpredictable" [Ex. 117 ¶ 48, 73], not probable or causative to a reasonable degree of medical certainty. *See Harris v. Owens-Corning Fiberglas Corp.*, 102 F.3d 1429, 1433 (7th Cir. 1996) ("mere possibility of . . . causation is not enough"). He says he has examined college-age patients with myocarditis after a vaccine injection [Ex. 117 ¶ 59], but once again never testifies that one was caused by the other. *See Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904–05 (7th Cir. 2007) ("mere existence of a temporal relationship between taking a medication and the onset of symptoms does not show a sufficient causal relationship").

---

cases and vaccine administration. . . . The benefits of vaccination significantly exceed possible risks."); Elisabeth Albert *et al.*, *Myocarditis Following COVID-19 Vaccination*, 16(8) Radiology Case Reports 2142, 2144 (May 2021) (case report) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8130498/ (University of Massachusetts researchers found "small risk" of myocarditis, and concluded that "there is a significantly higher risk of cardiac involvement from COVID-19 infection compared to COVID-19 vaccination" such that "vaccination should remain the cornerstone for population immunity").

With ever evolving COVID-19 science, more will be known tomorrow, next month, and next year; but a courtroom is no place for guesswork today, even if well-inspired. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *Constructora Mi Casita v. NIBCO, Inc.*, 448 F. Supp.3d 965, 970-71 (N.D. Ind. 2020). Dr. Beeler testifies that "there is no proof of causation between the vaccination and myocarditis" [Ex. 115 ¶ 69]. The court gives Dr. McCullough's testimony little weight on this record.[91] These statements are made with considered humility. The court isn't deciding causation today to be sure. At the same time, the students haven't marshaled strong evidence that would call into legitimate question the reasonableness of the university's actions, or to meet their burden of an extraordinary remedy of a preliminary injunction.

The students return to VAERS to discuss the risk of death from the vaccines. Dr. McCullough says VAERS reported 6,136 deaths after vaccines as of June 18, 2021 [Ex. 117 ¶ 45]. He says VAERS received more adult death reports from COVID-19 vaccines than all other vaccines combined [*id.*]. The students offer an interim abstract from clinically

[91] For additional examples, Dr. McCullough cites one article that "*speculate[s]* that adverse reaction against the COVID-19 vaccine was responsible for the development of myocarditis *due to its temporal relationship*." Tommaso D'Angelo *et al.*, *Myocarditis after SARS-CoV-2 Vaccination: A Vaccine-induced Reaction?*, Can. J. Cardio. (June 9, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8187737/ (last visited July 17, 2021) (emphases added). Even then, the authors say "substantial evidences other than temporal aspects still need to be provided to demonstrate the causality[.]" *Id.* Dr. McCullough also cites a Reuters article concerning an Israeli study, rather than the study itself, when the Reuters article appears to overstate the study. For instance, the article refers to 275 cases, but those cases included both COVID-19 exposures and vaccinations. Only 148 cases occurred after vaccination. Even so, the study's authors conclude merely that there is "*some probability for a possible link* between the second vaccine dose and the onset of myocarditis among young men aged 16 to 30," not a probable link. Israeli Ministry of Health, *Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021* (Feb. 6, 2021), https://www.gov.il/en/departments/news/01062021-03 (emphasis added).

trained reviewers that considered the VAERS data as of April 2021, who grouped the reports as those where the vaccine was most likely not a factor, where it may have been, and where it was the most likely factor [Ex. 254].[92] Of the 250 deaths reported at the time, the reviewers concluded that 13 deaths were most likely caused by vaccines, noting that these individuals had strong reactions soon after vaccination and died the same day or during the next couple days [*id.*], though again temporal anecdotes like these aren't as telling. *See Ervin*, 492 F.3d at 904–05. They warrant further investigation to be sure; but in close review this interim abstract offers no scientific or medical basis for drawing its conclusion. Indeed, when the court asked counsel at oral argument what the basis was for it, he too could offer no explanation [Tr. 34-37]. And more to the point, Dr. McCullough again stops short of testifying that any one reported death in VAERS was caused by a vaccine, despite this interim abstract [Ex. 117 at 21-26]. The students thus haven't presented evidence today demonstrating Indiana University's decision was irrational in pursuing its goal of campus health.

The CDC has explored this issue as well and seems to have marshaled data, at this time, that any risk of death is rarer than the risk of death from a young adult COVID-19 infection. According to the CDC, 25,038,458 individuals aged 18-29 have been given their first dose of the vaccine as of July 18, 2021, with VAERS reporting a total of 68 deaths, or

[92] *See* Scott McLachlan *et al.*, *Analysis of COVID-19 Vaccine Death Reports from the Vaccine Adverse Events Reporting System (VAERS) Database* (June 2021) (not peer-reviewed pre-print), https://www.researchgate.net/publication/352837543_Analysis_of_COVID-19_vaccine_death_reports_from_the_Vaccine_Adverse_Events_Reporting_System_VAERS_Database_Interim_Results_and_Analysis. Dr. Beeler calls this a "reliable study looking at an unreliable system" based on passive reports unvalidated by studies and unconfirmed data [Ex. 128 at 124-25].

approximately 0.00027 percent, if in fact any are related.[93] Alternatively, of the 6,174,415 cases of COVID-19 in this age group, 2,732 died, or approximately a 0.04 percent.[94] In balancing the risks,[95] Indiana University wasn't irrational in favoring the route that promoted greater safety for its students.

The experts disagree over the relative risk of asymptomatic transmission (and indeed over many scientific conclusions), with the students contending that transmission from asymptomatic infections is "trivial and inconsequential" [Ex. 117 ¶ 26-27],[96] and the university pointing to its own experience and national trends indicating that asymptomatic transmission is "certainly still very possible" [Ex. 115 ¶ 52].[97] As with any

---

[93] *See* CDC, *The Vaccine Adverse Event Reporting System*, https://wonder.cdc.gov/vaers.html (data contains reports processed as of July 9, 2021); CDC, *COVID-19 Vaccination Demographics in the United States, National*, https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Demographics-in-the-United-St/km4m-vcsb (last visited July 14, 2021).

[94] CDC, *Demographic Trends of COVID-19 Cases and Deaths in the U.S. Reported to CDC*, https://covid.cdc.gov/covid-data-tracker/#demographics (last visited July 18, 2021).

[95] The rate of community spread of COVID-19 in the counties in which the university's campuses are based is classified as "moderate" to "high" by the CDC. CDC, *COVID Data Tracker: COVID-19 Integrated County View*, https://covid.cdc.gov/covid-data-tracker/#county-view (last visited July 18, 2021).

[96] Zachary Madewell *et al.*, *Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis*, 3(12) JAMA Network Open e2031756 (Dec. 14, 2020) (Universities of Florida and Washington researchers conclude the rate of transmission from asymptomatic and presymptomatic carriers in a household is 0.7 percent, but acknowledge finding was based on a small sample size, did not differentiate between asymptomatic and presymptomatic carries, and that significant questions remain about infectiousness) https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102.

[97] *See* Michael A. Johansson *et al.*, *SARS-CoV-2 Transmission from People Without COVID-19 Symptoms*, 4(1) JAMA Network Open e2035057 (Jan. 7, 2021) (CDC Office of Deputy Directory for Infectious Disease researchers' disease model suggests that transmission from asymptomatic individuals account for 24% of all transmissions) https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707; Jennifer K. Bender *et al.*, *Analysis of Asymptomatic and Presymptomatic Transmission in SARS-CoV-2 Outbreak, Germany, 2020*, 27(4) Emerg. Infect. Dis. 1159 (April 2021) (European Centre for Disease Prevention & Control and Robert Koch Institute reviewed seven asymptomatic and 46 symptomatic cases and concluded little to no transmission from asymptomatic cases and 75 percent from presymptomatic cases) https://wwwnc.cdc.gov/eid/article/27/4/20-4576_article; *see also See* Sten H. Vermund & Virginia E. Pitzer, *Asymptomatic Transmission and the Infection Fatality Risk for COVID-19: Implications for School Reopening*, 72(9) Clin. Infect. Dis. 1493-96 (May 1, 2021) (Yale researchers conclude that asymptomatic transmission "likely represents a substantial proportion of total new infections")

new pathogen, scientific understandings of the character and risks of transmission are ever evolving, but a review of the balance of the current peer-reviewed research and other literature presented by the parties suggest that asymptomatic transmission, while less prevalent than symptomatic transmission, routinely occurs. Naturally, this conclusion may change as scientists continue to study the virus and population transmission events.

Other risks exist or may become known. For instance, the FDA warns of the potential for blood clots, reported the most in females ages 18-49, but calls this risk "remote."[32] Just four days ago, the FDA added a warning to its fact sheet for the Janssen COVID-19 vaccine that Guillain-Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells and causes muscle weakness and sometimes paralysis) has occurred in some people who have received the vaccine. The FDA calls this risk "very low."[98] In contrast, Dr. Beeler testifies that brain damage proves a risk from COVID-19 without a vaccine [Ex. 319 ¶ 5], as do several neurological diagnoses, particularly for those hospitalized by a COVID-19 infection.[99] The risks aren't all one-

---

https://pubmed.ncbi.nlm.nih.gov/32584967/; Diana Buitrago-Garcia *et al.*, *Occurrence and Transmission Potential of Asymptomatic and Presymptomatic SARS-CoV-2 Infections: A Living Systematic Review and Meta-analysis*, 17(9) PLoS Med e1003346 (Sept. 22, 2020) (University of Bern and World Health Organization researchers conclude risk of infection from an asymptomatic individuals exists but is decreased 65 percent compared to symptomatic) https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003346.

[98] See FDA, *Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older* (July 18, 2021), https://www.fda.gov/media/146305/download.

[99] *See, e.g.*, Maxime Taquet *et al.*, *6-Month Neurological and Psychiatric Outcomes in 236,379 Survivors of COVID-19: A Retrospective Cohort Study Using Electronic Health Records*, 8 Lancet Psychiatry 416-27 (published online April 6, 2021), https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(21)00084-5/fulltext (though calling for more data, concluding that the "severity of COVID-19 had a clear effect on subsequent neurological diagnoses"). In fairness, this same study said whether COVID-19 was associated with Guillain-Barré syndrome "remains unclear."

sided, but the wealth of data and studies on which Indiana University has relied makes the likelihood that the students will prevail on their claim here quite low.

Don't forget that vaccines generally aren't without medical risks. In 1993, the Indiana General Assembly required that all public university students receive vaccinations for five conditions, *see* Ind. Code § 20-12-71-11, which it later amended in 2007 to add one more, *see* Ind. Code § 21-40-5-2. Today that required list covers diphtheria, tetanus, measles, mumps, rubella, and meningococcal disease. Early diphtheria vaccines began in the 1920s, with more recent vaccines being developed in the 2000s. Tetanus vaccines were introduced in the late 1940s. The first measles vaccine was developed in 1963, with the MMR vaccine licensed for use in 1971. The MMRV vaccine (which protects against measles, mumps, rubella, and varicella) was licensed in 2005 per the CDC. The first meningitis vaccine was licensed in 1974 in the United States, but more modern vaccines were licensed in 2005, 2012, and then 2015. Risks of these vaccines are varied, including more minor issues of fever or headache to more serious concerns of seizure or death, though frequently low risks.

To be sure, EUA of the COVID-19 vaccines occurred on a tighter timetable and has existed only since December 2020 and February 2021. The students thus voice concerns about the experimental nature of the vaccines, though their counsel assures that their suit will persist even if the FDA grants the vaccine manufacturers full approval. Not all EUAs are equal, and the one required for COVID-19 vaccines was more robust than usual.

For an EUA to issue, the U.S. Department of Health and Human Services (HHS) must first conclude that the biological threat identified in the emergency declaration "can

cause a serious or life-threatening disease or condition[.]" 21 U.S.C. § 360bbb-3(c)(1). Additionally HHS must conclude, "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe" the new product is effective in diagnosing, treating, or preventing the disease and "the known and potential benefits of the product . . . outweigh the known and potential risks of the product, taking into consideration the material threat posed" by the public health emergency. 21 U.S.C. § 360bbb-3(c)(2). Further, there must be "no adequate, approved, and available alternative to the product" and the product must comport with "other criteria as the Secretary may by regulation prescribe." 21 U.S.C. § 360bbb-3(c)(3)-(4).

In addition to these criteria, HHS must ensure medical providers are informed of the product's EUA status, the "significant known and potential benefits and risks of the . . . product, and of the extent to which such benefits and risks are unknown," and the availability, risks, and benefits of alternative products. 21 U.S.C. § 360bbb-3(e)(1)(A)(i)(I)-(III). HHS must ensure that individuals who receive the product are informed of the product's EUA status, the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown," and "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." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)-(III). For these reasons, those who go to get these vaccines receive fact sheets from the FDA.

The impetus behind issuing an EUA, as opposed to going through the process for full FDA approval, comes from the urgency required. The standard process for vaccine approval requires a manufacturer to demonstrate compliance with statutory, regulatory, and agency standards. *See* 42 U.S.C. § 262(j); 21 U.S.C. § 355(b)(1)(A); 21 C.F.R. §§ 601.2(a), 600.3(n), (p). Among other things, a manufacturer must conduct various studies, including clinical trials, to prove that the vaccine is safe for use and is effective. 21 U.S.C. § 355(b)(1)(A)(i); 21 C.F.R. § 600.3(s). These trials must be complete before an application can be submitted; indeed for COVID-19, the FDA requires manufacturers to collect and include any data from severe adverse events for six months after the trials conclude.[100] Though this process is designed to ensure safe vaccines for public use, it can take an average of ten years to go from a mere idea to an approved vaccine.[101] This can occur more quickly too; indeed, just two days ago, the FDA granted priority review of one vaccine, reportedly meaning that full approval from the FDA could come as soon as early next year.[102]

On the other hand, as opposed to waiting until clinical trials conclude, an EUA allows a manufacturer to apply using interim clinical trial data, and the data need only

---

[100] 21 U.S.C. § 355(b)(1)(A)(i); 21 C.F.R. § 601.2(a), (e); § 601.20(a); *see also* FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* (June 2020); FDA, *Vaccine Development 101*, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (last visited July 13, 2021).

[101] *See* Mark M. Struck, *Vaccine R&D Success Rates and Development Times*, 14 Nature Biotech. 591, 592 (1996), https://www.nature.com/articles/nbt0596-591.pdf?origin=ppub.

[102] *See* BioNTech, *U.S. FDA Grants Priority Review for the Biologics License Application for Pfizer-BioNTech COVID-19 Vaccine* (July 16, 2021), https://investors.biontech.de/news-releases/news-release-details/us-fda-grants-priority-review-biologics-license-application.

demonstrate the product "may be effective" and the known and potential benefits outweigh the known and potential risks.[103] Additionally, distribution and testing can occur simultaneously.[104] Although at first blush, the efficiency of an EUA may seem to risk the greater surety of safety and efficacy, the statute anticipates the FDA will impose additional obligations beyond those enumerated. *See* 21 U.S.C. § 360bbb-3(e)(1)(B).

In October 2020, the FDA released industry guidance detailing the benchmark criteria for a COVID-19 vaccine to receive an EUA.[105] Though not legally binding,[106] the industry guidance acknowledged that a COVID-19 vaccine was a "complex biological product[] . . . intended to be administered to millions of individuals, including healthy people, to prevent disease . . . [and has] the potential for broad use under an EUA."[107] Because the virus would only be overcome through the sweeping immunity of the American public, the FDA informed manufacturers that approval would be given to

---

[103] 21 U.S.C. § 360bbb-3(c)(2)(A); FDA, *Emergency Use Authorization for Vaccines Explained*, https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (last visited July 12, 2021).

[104] *Compare* 21 C.F.R. § 601.21 (products under development cannot be shipped for the purpose of introduction into commerce), *with* 21 U.S.C. § 360bbb-3(e)(1)(B)(i) (allowing discretion for the agency to work with manufactures on distribution issues); *see also* FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#preparedness (last visited July 12, 2021).

[105] FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (October 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19.

[106] An industry guidance does not have the force of law, as it does not go through the rulemaking process. However, an industry guidance informs a manufacturer of the criteria the FDA would consider sufficient to receive approval pursuant to their statutory authority. *See, e.g.*, FDA, *Rules, Regulations and Guidance*, https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance (last visited July 18, 2021) (describing industry guidance as informing the tobacco industry of "pathways to legally market new tobacco products").

[107] FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* at 2.

those EUA applications that went beyond the safety and efficacy requirements prescribed by statute, and also expected manufacturers to consult with the FDA on the various non-clinical components of vaccine development and distribution as the clinical trial progressed.[108] The FDA wanted the same level of efficacy data as for full approval, enough safety data to justify providing the vaccine to healthy individuals, and confirmation of the technical procedures and verification steps necessary to support full approval.[109]

Thus, manufacturers were expected to submit "adequate manufacturing information to ensure its quality and consistency" as well as "data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner"—a heightened bar from the "may be effective" standard prescribed by statute—while still allowing the manufacturers to complete their trials for full authorization.[43] The FDA "strongly encourage[d]" manufacturers to provide interim data and analyses before applications were submitted, and noted that requirements described were "essential to ensure that clinical development of a COVID-19 vaccine has progressed far enough that issuance of an EUA for the vaccine would not interfere with the ability of an ongoing Phase 3 trial to demonstrate effectiveness of the vaccine to support licensure and to continue safety assessments[.]"[43]

---

[108] *See* FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 6-7, 9 (October 2020); 21 U.S.C. § 360bbb-3(c).

[109] FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 4, 9 (October 2020).

Although the FDA directs manufacturers to present evidence of efficacy that meet the standards necessary to receive full approval,[43] a key distinction between EUA and full approval remains. To receive full approval for a COVID-19 vaccine, a manufacturer must monitor and submit evidence of "serious and other medically attended adverse events in all study participants for at least 6 months after completion of all study vaccinations."[110] However, for an EUA, the manufacturer may submit its safety data based on a median two-months follow-up for every individual who completed the vaccine regimen.[111] The FDA concluded that a "2-month median follow-up (meaning that at least half of vaccine recipients in clinical trials have at least 2 months of follow-up) after completion of the full vaccination regimen will allow identification of potential adverse events that were not apparent in the immediate postvaccination period and will also provide greater confidence in their absence, if none are observed."[112] Based on its experience with vaccine studies and approvals, the FDA concluded that "adverse events considered plausibly linked to vaccination generally start within 6 weeks after vaccine receipt," regardless of the type of vaccine received, and thus the median two-month follow-up was justified "by extensive historical experience with adverse events after vaccination, the need for a vaccine to address the current pandemic, and the magnitude of vaccine effectiveness that will be required to support a favorable benefit–risk profile

[110] FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 15 (June 2020).

[111] *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 10 (October 2020).

[112] Philip R. Krause & Marion Gruber, *Emergency Use Authorization of Covid Vaccines – Safety and Efficacy Follow-up Considerations*, 383 N. Engl. J. Med. e107(2) (Nov. 5, 2020). Dr. Marion Gruber is the director and Dr. Phillip Krause is the deputy director of the Office of Vaccines Research and Review at the FDA.

for use of a Covid-19 vaccine under an EUA."[111] Thus, in setting these stringent expectations, the FDA invited EUA applications only for vaccines positioned well to receive full approval.[113]

The statute grants the agency flexibility to impose additional requirements necessary to meet the safety and efficacy concerns despite the urgency of a public health emergency. The agency understood that a vaccine designed to be given to hundreds of millions of Americans, healthy and otherwise, required significant safety and efficacy data for approval. The consequences of skimping on these steps, or even adhering to the statutory-minimum requirement of potential effectiveness, was too great; so the FDA directed manufacturers to present evidence of efficacy that led to standards necessary to receive full approval. And true, though the safety follow-up necessary to receive an EUA is much shorter than would otherwise be required, the FDA made this conclusion based on its expert assessment and experience that significant latent negative outcomes associated with vaccinations traditionally occur within six weeks of receipt.[114]

Indiana University closely considered the FDA's EUA requirements when adopting its policy. The specialists on the university restart committee appreciated that

---

[113] The industry guidance has since been superseded twice, once in February 2021 and once in May 2021. FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (May 2021). Pfizer, Moderna, and Johnson & Johnson's applications were submitted in accordance with the October 2020 guidance, *see* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer-BioNTech)* (2020) (application submitted November 20, 2020); FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Moderna)* (2020) (application submitted November 30, 2020); FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Janssen)* (2021) (application submitted February 4, 2021).

[114] Philip R. Krause & Marion Gruber, *Emergency Use Authorization of Covid Vaccines – Safety and Efficacy Follow-up Considerations*, 383 N. Engl. J. Med. e107 (Nov. 5, 2020).

all three COVID-19 vaccines had been "studied in robust multi-centered, international, randomized-controlled trials and proven both effective and safe in millions of people" [Ex. 115 ¶ 60; *see also* Ex. 115 ¶ 24, 61-69]. These specialists explained that the EUA vaccines had been based on technology that has been studied for decades [*id.* ¶ 87]. Though even "small differences in chemical structure can sometimes make very large differences in the type of toxic response that is produced," *McClain v. Metabolife Intern, Inc.*, 401 F.3d 1233, 1246 (11th Cir. 2005); *accord Glastetter*, 252 F.3d at 990, much like the FDA, the university concluded that campus safety reasonably outweighed any lingering risks with the vaccines. This wasn't just any ordinary EUA process, but EUA on proverbial steroids. The university reasonably concluded that the "benefit dwarfs the potential rare risks" [Ex. 115 ¶ 87].

Progress has been made because of the vaccine, not despite it. To the extent that lingering medical and scientific debate remain on this record, the court remains resolved that Indiana University has acted reasonably here in pursuing public health and safety for its campus communities [*cf.* Exs. 115, 116].[115] *See Gonzales*, 550 U.S. at 163 (state

[115] For instance, Dr. McCullough says the vaccine manufacturers "skipped testing" for genotoxity, mutagenicity, teratogen[i]city, and oncogenicity" [Ex. 117 ¶ 36]. Dr. Beeler explains that this claim, including the suspicion about mutagenesis, takes a "backwards view of how RNA works in the cell and [is] not currently supported by consensus opinion" [Ex. 115 ¶ 64]. Concerns about the impact of a vaccine on fertility are largely addressed by the policy because Indiana University allows exemptions for pregnant women [Ex. 115 ¶ 86]. Naturally, truly measuring the impact of any intervention, or disease for that matter, on overall fertility to any degree of certainty requires longitudinal and perhaps even generational studies. Even under the FDA's full approval requirements for a COVID-19 vaccine, a manufacturer is not required to submit data on the long-term impact on overall fertility in the population to receive approval. FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 7 (June 2020). Instead, the agency recommends conditioning the enrollment of pregnant women and "women of childbearing potential who are not avoiding pregnancy" in a clinical trial on the completion of Developmental and Reproductive Toxicology (DART) studies. FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 7, 11 (June 2020). A similar recommendation appears in the EUA guidance. *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 9 (October 2020). Though DART

legislatures have "wide discretion to pass legislation in areas where there is medical and scientific uncertainty"); *Zucht*, 260 U.S. at 176 ("municipality may vest in its officials broad discretion in matters affecting the application and enforcement of a health law").

Today, Indiana University has a rational basis to conclude that the COVID-19 vaccine is safe and efficacious for its students. The vaccine has been used on about 157 million Americans; and data now about eight months later, though it will grow more robust in years to come, is considerable and shows major side effects are rare. Much like over 500 universities and colleges in the United States that have done the same,[116] Indiana

studies review many components of fertility and pregnancy in animal models, FDA, *S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals Guidance for Industry* (May 2021), the application of these studies to the approval or a COVID-19 vaccine relate to the testing, marketing, and use of vaccines in pregnant women and in women who could imminently become pregnant, *see* FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 7, 11 (June 2020); *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 9 (October 2020). And though DART studies in animals certainly shed light on greater concerns about fertility and are important, full vaccine approval is not conditioned on fertility studies in women or men. *See id.* Instead, the impact of a vaccine on pregnancy and pregnancy outcomes in women is a vital post-approval safety assessment. *see* FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 17 (June 2020). Moderna and Johnson & Johnson submitted DART studies as part of their EUA applications. Both manufacturers identified no fertility or development concerns based on these studies. FDA, *Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation – Emergency Use Authorization (EUA) Application for mRNA-1273* (Dec. 17, 2020); Janssen Biotech, Inc, *Vaccines and Related Biological Products Advisory Committee Meeting February 26, 2021* (Feb. 26, 2021). Pfizer submitted DART results after its EUA was granted. The studies showed the vaccine did not impact female fertility or development, albeit in rats. Christopher J. Bowman *et al.*, *Lack of Effects on Female Fertility and Prenatal and Postnatal Offspring Development in Rats with BNT162b2, a mRNA-based COVID-19 Vaccine*, 103 Reproductive Toxicology 28 (Aug. 2021).

[116] Andy Thomason and Brian O'Leary, *Here's a List of Colleges That Will Require Students or Employees to Be Vaccinated Against Covid-19*, The Chronicle of Higher Education (July 15, 2021), https://www.chronicle.com/blogs/live-coronavirus-updates/heres-a-list-of-colleges-that-will-require-students-to-be-vaccinated-against-covid-19?cid2=gen_login_refresh ("*The Chronicle* has so far identified 583 such campuses."). Generally, courts "should not invade the domain of local authority except when it is necessary to do so" to enforce fundamental rights. *Jacobson*, 197 U.S. at 38. In addition to the Fourteenth Amendment's protections, a wide variety of states have enacted legislation relating to vaccine mandates or vaccine documentation, including Ohio just this last week. *See* 2021 Bill Text OH H.B. 244, Sec. 3792.04(B)(1) (signed into law on July 14, 2021); *cf., e.g.,* Ark. Code Ann. § 20-7-142 (prohibiting vaccine mandate); Fla. Stat. § 381.00316 (prohibiting governmental entities from requiring COVID-19 vaccination documentation and prohibiting educational institutions from requiring that students provide COVID-19 vaccination documentation); 2021 Bill Text CA A.B. 327 (proposed) (bill that would prohibit entities from requiring

University reasonably relies on the vaccine as a measure to return to normal school functioning. The students say the mandate is unreasonable because no other Indiana government agency mandates the vaccine. But just because it has gone above what others have done doesn't make it unreasonable. Indeed, universities are unique places, with lots of people gathered and living together in close quarters for months at a time. That Indiana University's mandate goes beyond what other public universities in Indiana have done doesn't compel a finding that this policy is unreasonable; indeed, other universities in the state have mandated the vaccine, and many others around the country have too.

Indiana University is following the recommendations of other well-established agencies, including the Centers for Disease Control, U.S. Department of Education, and the Indiana State Department of Health. These are reliable sources to assess the reasonableness of measures implemented, though the court must be cautious not to expand the guidance beyond what it says. *See United States v. Newton*, 996 F.3d 485, 489 (7th Cir. 2021); *Mays v. Dart*, 974 F.3d 810, 823 (7th Cir. 2020), *cert. filed*. To be sure, the CDC doesn't recommend that schools "mandate" the vaccine—a point the students make—but such a recommendation isn't consistent with the CDC's purview, which is to act as an informative agency. At the same time, the university's policy isn't inconsistent with the CDC's recommendations. The CDC says institutions of higher learning "can return to full capacity in-person learning, without requiring or recommending masking or physical distancing for people who are fully vaccinated" [Ex. 116 ¶ 12]. The CDC's

COVID-19 vaccination documentation). The court will not overstep into the legislative sphere when the state's or state arm's conduct has complied with the Constitution.

guidance to universities is that "[v]accination is the leading prevention strategy to protect individual from COVID-19 disease and end the COVID-19 pandemic."[117] This will enhance the student body's opportunities, allowing them to have a more fulfilling college experience.

Vaccination helps the university get to herd immunity. As its expert, Dr. Beeler, has said, COVID-19 vaccination is an important tool to help stop the pandemic because widespread vaccination will help achieve "herd immunity," which is when enough people in a community are sufficiently protected from COVID-19 to stem its spread [Ex. 115 ¶ 19-20].[118] To be sure, experts debate whether herd immunity is achievable for COVID-19 [Ex. 115 ¶ 21], but Indiana University rationally believes vaccination is the leading prevention strategy to protect individuals from COVID-19 disease. According to Dr. Beeler, "Indiana has not reached herd immunity" [Ex. 115 ¶ 43; *see also* Exs. 128 at 60, 129 at 23]. As Dr. Beeler explains, "immunity is not static with this virus, and things do change specifically as it relates to variants of concern. . . . The longer that the coronavirus remains in the population, each vulnerable individual that gets infected is the opportunity for further mutations in the virus. And eventually, just by evolutionary theory, the virus will develop ways to bypass the current immune stress" [Ex. 128 at 61]. The mutability of COVID-19 remains higher than other conditions addressed by a single

[117] CDC, *Guidance for Institutions of Higher Education (IHEs)* (last updated June 4, 2021), https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/considerations.html.
[118] *See* CDC, *COVID-19 Vaccines Are Free to the Public* (last visited June 27, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/no-cost.html; CDC, *Key Things to Know about COVID-19 Vaccines* (last visited June 27, 2021) ("CDC Key Things"), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html.

vaccine, like measles, mumps, and rubella [*id.* at 151-52]. With the variants of concern affecting recent numbers, and based on Dr. Beeler's well-reasoned explanation, the court tends not to credit Dr. McCullough's viewpoint that herd immunity has already been achieved.

Overall, the students' arguments amount to disputes over the most reliable science. But when reasonable minds can differ as to the best course of action—for instance, addressing symptomatic versus asymptomatic virus spread or any number of issues here—the court doesn't intervene so long as the university's process is rational in trying to achieve public health. *See, e.g.*, *Phillips*, 775 F.3d at 542 ("plaintiffs argue that a growing body of scientific evidence demonstrates that vaccines cause more harm to society than good, but as *Jacobson* made clear, that is a determination for the [policymaker], not the individual objectors"). There is a rational basis for making distinctions here. No student, including those not yet exempt, have shown that Indiana University's vaccine mandate as applied to them violates rational basis review. The court thus denies their request to enjoin it preliminarily.

5. *On This Preliminary Record, Exempt Students Haven't Shown a Likelihood of Success on their Claim that Indiana University Lacks a Rational Basis for Its Vaccine Policy, Including Additional Requirements.*

Six students are exempt from the vaccination mandate but challenge the additional measures of mask wearing, testing, and social distancing: Ryan Klaassen (Ex. 100 ¶ 180-81), Jaime Carini (¶ 182-95), Macey Policka (¶ 207-08), Daniel Baumgartner (¶ 196-200), Ashlee Morris (¶ 201-04), and Seth Crowder (¶ 205-06). Collectively, they argue that these requirements, oft-used over the last year, infringe on their bodily autonomy, medical

privacy, religious beliefs, and essentially become a "scarlet letter" targeting them for bullying and scorn from their peers for their medical conditions or religious beliefs.[119]

Indiana University first challenges this argument on a procedural ground. It says these students failed to challenge its masking or testing policies in their complaint. They cite to the well-known legal principle that "a plaintiff is the master of her own complaint," and that courts shouldn't read unalleged assertions into a complaint. *Thornley v. Clearview AI, Inc.*, 984 F.3d 1241, 1246 (7th Cir. 2021); *see also Caterpillar, Inc. v. Williams*, 482 U.S. 386, 398-99 (1987). The complaint isn't so narrowly pleaded. It gives fair notice that the students are challenging the vaccine mandate and the policy's additional requirements. *See* Fed. R. Civ. P. 8(a)(2); *Bell Atl. Corp. v Twombly*, 550 U.S. 544, 555 (2007).

Indiana University's vaccine mandate is multifaceted. It requires all students, faculty, and staff to receive a COVID-19 vaccine and report their vaccination status, or to obtain an exemption and comply with the additional requirements. The university lumps the various parts of this mandate under a general "COVID-19 vaccine requirement" umbrella. For instance, on Indiana University's "frequently asked questions" page about its COVID-19 vaccination requirement, the section provides that vaccinations are required, the deadlines for such vaccinations, the need for students to report vaccination status, the exempted categories, and the additional requirements imposed on exempted students, along with the consequences for failing to get a vaccine [Ex. 118 at 3-6].

[119] The scarlet letter is a literary reference to a mark that identifies one as belonging to a certain group in a scornful or ostracizing way. *See* Nathaniel Hawthorne, *The Scarlet Letter* (1850).

Because the students challenge the additional requirements under substantive due process, the court again begins by first examining the specific right they assert. *See Doe*, 377 F.3d at 768. These students argue that they have rights to refrain from wearing a mask and to refuse nasal testing. But there is no fundamental constitutional right to not wear a mask. *Kelly v. ImagineIF Library Entity*, 2021 U.S. Dist. LEXIS 111958, 8 (D. Mont. June 15, 2021); *Whitfield v. Cuyahoga Cnty. Pub. Library Found.*, 2021 U.S. Dist. LEXIS 92944, 4 (N.D. Ohio May 17, 2021); *Denis v. Ige*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 91037, 14 (D. Haw. May 12, 2021); *W.S. by Sonderman v. Ragsdale*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 98185, 5 (N.D. Ga. May 12, 2021); *Forbes v. City of San Diego*, 2021 U.S. Dist. LEXIS 41687, 11 (S.D. Cal. Mar. 4, 2021); *Stewart v. Justice*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 24664, 20 (S.D. W. Va. Feb. 9, 2021); *Oakes v. Collier Cnty.*, 2021 U.S. Dist. LEXIS 15174, 4 (M.D. Fla. Jan. 27, 2021); *Shelton v. City of Springfield*, 497 F. Supp.3d 408, 414 (W.D. Miss. 2020); *see also Ryan v. Cnty. of DuPage*, 45 F.3d 1090, 1092 (7th Cir. 1995) (no constitutional right to *wear* a mask); *United States v. Berglund*, 2021 U.S. Dist. LEXIS 78476, 2 (D. Minn. Apr. 23, 2021) ("Courts have repeatedly found that requiring participants at trial to wear face masks due to the COVID-19 pandemic does not violate a criminal defendant's constitutional rights.").[120] Nor is there a fundamental constitutional right to not be tested for a virus before entering a place of public accommodation. *Aviles v. De Blasio*, 2021 U.S. Dist. LEXIS 38930, 50 (S.D.N.Y. Mar. 2, 2021); *see also Webb v. Johnson*, 2021 U.S. Dist. LEXIS

[120] Plaintiffs cite to a recent Florida state court decision which held, based on its state constitution, that the right to privacy applies to a mask-wearing mandate, triggering strict scrutiny. *See Green v. Alachua Cnty.*, 2021 Fla. App. LEXIS 8634 (Fla. Dist. Ct. App. June 11, 2021). But as this case makes clear, it is based on Florida's state constitution, not the federal constitution. It is thus inapposite here.

95392, 13 (D. Neb. Mar. 2, 2021) (D. Neb. May 19, 2021) (prisoner had no fundamental right to refuse having his temperature taken); *Wilcox v. Lancour*, 2021 U.S. Dist. LEXIS 11968, 23-24 (W.D. Mich. Jan. 22, 2021) (prisoner had no fundamental right to refuse a nasal passage test for COVID-19); *Little Rock Family Planning Servs. v. Rutledge*, 458 F. Supp.3d 1065, 1074 (E.D. Ark. 2020) (applying *Jacobson* to uphold requirement that women obtain negative COVID-19 test before medical procedure).

The court declines the students' invitation to expand substantive due process rights to include the rights not to wear a mask or to be tested for a virus. These aren't rights so "deeply rooted in this Nation's history and tradition" and so "implicit in the concept of ordered liberty" such that "neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997) (quotation omitted); *Khan v. Bland*, 630 F.3d 519, 535 (7th Cir. 2010). These aren't issues of fundamental constitution import, but often transient and trivial inconveniences.

But wait, certain students say: mask wearing and testing violates their religion. The First Amendment says "Congress shall make no law . . . prohibiting the free exercise" of religion. U.S. Const. amend. I. The right to exercise religion is fundamental. *See Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940). As a fundamental right, it would trigger strict scrutiny, but the Supreme Court has held that general regulations that have the effect of incidentally burdening religious practices in general and neutral ways need only be rationally supported by the state. "[T]he right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his

religion prescribes (or proscribes)." *Smith*, 494 U.S. at 879 (quotation omitted); *accord Ill. Bible Colleges Ass'n v. Anderson*, 870 F.3d 631, 639 (7th Cir. 2017).

Indiana University's extra requirements fit within the neutral and generally applicable laws protected by *Smith*. The vaccine mandate contains an early reference to religion by way of exemption; but this isn't used to *burden* religion, but instead gives those of religious conviction the *benefit* of freely practicing their religious conviction to refuse the vaccine. *See Listecki v. Official Comm. of Unsecured Creditors*, 780 F.3d 731, 744 (7th Cir. 2015) ("A benefit to religion does not disfavor religion in violation of the Free Exercise Clause."); *see also Smith*, 494 U.S. at 888 (Scalia, J.) (no exemption required). The students who received the religious exemption are subject to the same extra requirements as those who receive the medical exemption.

One may well applaud the university for going beyond what the constitution requires: courts have consistently held that schools that provided a religious exemption from mandatory vaccination requirements did so *above and beyond* that mandated by the Constitution. *See Nikolao*, 875 F.3d at 316; *Phillips*, 775 F.3d at 543; *Workman*, 419 F. Appx. at 356; *Whitlow*, 203 F. Supp.3d at 1084; *Boone*, 217 F. Supp.2d at 954. What the students request now is a religious exemption from the religious exemption, but Indiana University has no obligation to provide this. *See Smith*, 494 U.S. at 879.

On this record, the court finds no merit in the students' contention that wearing masks essentially labels them with a "scarlet letter" that targets them for religious bullying. Indiana University has both medical and religious exemptions, and the same requirements are imposed on both groups. There is no evidence that any exempted

person must reveal publicly which exemption they obtained. Wearing masks thus doesn't signify to others that the individual religiously objects to the vaccination; they could fall within either exempted category, or they could be a vaccinated individual who chooses to take the extra (and unrequired) precaution to wear a mask. A student wearing a mask may well just be precautious in light of COVID-19 variants or because of immunosuppressing conditions. This record is devoid of any evidence of bullying or discrimination.

To be sure, there are some unique circumstances when wearing a mask could negatively impact the student's educational experience. For example, Jaime Carini is pursuing doctorates in organ performance and literature and musicology and, to complete her graduate program, she must perform at organ recitals [Ex. 121 at 22, 27]. She believes performing these recitals while masked will have an impact on her performance as an organist, who use their whole bodies to perform [*id.* 90]. Similarly, Macey Policka is pursuing a degree in theater with an emphasis on acting, and she says the mask requirement is "devastating" to her education [Ex. 125 at 41]. She says wearing a mask has a huge impact on how she can interact with other actors and will put her at a distinct disadvantage to other student actors who don't have to wear masks [*id.*]. Though the court sympathizes with these concerns, these are matters for the university reasonably to address, not matters of constitutional import.

The students once more assert another alleged right—this time the right to the confidentiality of their medical information—to obtain strict scrutiny. But this circuit has never recognized one's constitutional right to privacy to medical information. *Franklin v.*

McCaughtry, 110 F. Appx. 715, 719 (7th Cir. 2004); *Rowe v. Wexford of Ind.*, 2021 U.S. Dist. LEXIS 31766, 3-4 (N.D. Ind. Feb. 22, 2021). This right may exist by statute, but isn't found in the Constitution. And this circuit recognized that such a right, if any, is minimized when in the public context. *See Franklin*, 110 F. Appx. at 719 (describing hospital emergency rooms, doctor's offices, and school infirmaries). The court declines finding such a fundamental right in the context here.

That said, the court applies rational basis review for the extra requirements of masks and testing for the exempted students. Indiana University has a legitimate interest in promoting the health and safety of its students. And the masks and testing are rationally related to achieving those measures. This is true for several reasons.

First, both vaccinated and unvaccinated people can still get the virus. Though health experts differ on the efficacy of masks in preventing the spread of COVID-19, such a dispute is left to the resolution of the policymakers, particularly when studies have shown universal mask wearing resulted in decreases in COVID rates than populations that forewent masks [Ex. 128 at 108]. And social distancing continues to be recommended by the CDC and health experts as effective at eliminating the spread of the disease.[121] The students offer no sound evidence that social distancing isn't effective.

Second, the CDC says schools should account for students, faculty, and staff who aren't vaccinated.[122] And it has continued to recommend masks and social distancing for

[121] CDC, *How to Protect Yourself & Others*, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html (updated June 11, 2021).

[122] CDC, *Guidance for Institutions of Higher Education (IHEs)*, https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/considerations.html#section1 (updated June 4, 2021).

these individuals.[122] This is consistent with what Indiana University has already done for a semester as well.

Third, even students who feel fine and don't have a fever may still have the virus as an asymptomatic individual, so the heightened precautions as to them continue to be rational.[123] Despite the low mortality rates, young adults can still transmit the virus to others [Ex. 115 ¶ 10-11]. For those with milder or even asymptomatic cases, as is more prevalent in this age group, the risk of inadvertent transmission grows [Ex. 115 ¶ 53-55].

Fourth, these measures are reasonable in scope. The testing methods are reasonable for the circumstances: they plan to use a rather non-intrusive saliva test. *See Banks v. United States*, 490 F.3d 1178, 1189 (10th Cir. 2007) ("saliva tests impose minimal intrusions"); *Padgett v. Ferrero*, 294 F. Supp.2d 1338, 1342 (N.D. Ga. 2003) ("bodily intrusion of taking . . . saliva sample is minimal"); *see also Wilson v. Collins*, 517 F.3d 421, 428 (6th Cir. 2008) (saliva sample is less intrusive than blood drawing). Though this form of testing may be less reliable than nasal testing, it is significantly less intrusive—and given that the students' assert their right to bodily autonomy, this is a good thing. Though it may present some inconvenience for the students by taking time away from their studies, this impact is minimal and within the sound discretion of the school.

Fifth, students have lived with mask mandates for over a year now, so it is nothing that is unreasonable, at least not when the risk still exists. These students have worn

[123] *See, e.g.*, Sten H. Vermund & Virginia E. Pitzer, *Asymptomatic Transmission and the Infection Fatality Risk for COVID-19: Implications for School Reopening*, 72(9) Clin. Infect. Dis. 1493-96 (May 1, 2021) (Yale researchers conclude that asymptomatic transmission "likely represents a substantial proportion of total new infections").

masks at school, stores, work, church, and even at a casino. In other contexts, the government has lawfully mandated wearing protective gear, like a mask, when it also provides benefits to the public—like mandated bicycle helmets, hair nets, ear plugs, and any number of personal protective equipment. *See, e.g.*, *Burr v. Atty. Gen. Delaware*, 641 F. Appx. 194, 196 (3d Cir. 2016) (*per curiam*) (seatbelt mandate held constitutional); *Picou v. Gillum*, 874 F.2d 1519, 1519 (11th Cir. 1989) (Powell, J.) (state statute requiring motorcycle riders to wear protective headgear was constitutional). It is no less reasonable here.

B. *Irreparable Harm & Adequate Remedy at Law.*

Irreparable harm is "harm that cannot be repaired and for which money compensation is inadequate." *Orr*, 953 F.3d at 502 (quoting *Graham v. Med. Mut. of Ohio*, 130 F.3d 293, 296 (7th Cir. 1997)) (quotations omitted). To the extent that the students establish a constitutional harm, the law presumes irreparable harm. *See, e.g.*, *Cuomo*, 141 S. Ct. at 67-68 (First Amendment free exercise of religion); *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (First Amendment political association); *Christian Legal Society v. Walker*, 453 F.3d 853, 859 (7th Cir. 2006) ("loss of First Amendment freedoms is presumed to constitute an irreparable injury"); *Ezell v. City of Chicago*, 651 F.3d 684, 699 (7th Cir. 2011) (Second Amendment); *Preston v. Thompson*, 589 F.2d 300, 303 n.3 (7th Cir. 1978) ("The existence of a continuing constitutional violation constitutes proof of an irreparable harm."); *Doe v. Mundy*, 514 F.2d 1179, 1183 (7th Cir. 1975) (right to privacy); *Democratic Nat. Committee v. Bostelmann*, 447 F. Supp.3d 757, 769 (W.D. Wis. 2020); *Planned Parenthood of Ind. v. Commissioner*, 194 F. Supp.3d 818, 835 (S.D. Ind. 2016) (presuming equal protection and substantive due process harms irreparable); 11A Wright & Miller, Federal Practice &

Procedure § 2948.1 (2d ed. 1995) ("When an alleged deprivation of a constitutional right is involved . . . most courts hold that no further showing of irreparable injury is necessary."). That remains true only with the vaccine mandate.

That doesn't mean every alleged harm in this case is irreparable. A delay in collegiate or graduate education isn't typically irreparable harm. *See, e.g.*, *Phillips v. Marsh*, 687 F.2d 620, 622 (2d Cir. 1982); *Hodges v. Bd. of Supervisors*, 2020 U.S. Dist. LEXIS 153949, 7 (E.D. La. Aug. 25, 2020); *Pierre v. University of Dayton*, 143 F. Supp.3d 703, 714 (S.D. Ohio 2015) ("[C]ourts have also held that a suspension is not irreparable."); *Baer v. Nat'l Bd. of Med. Examiners*, 392 F. Supp.2d 42, 49 (D. Mass. 2005) (inability to continue as medical student without interruption is not a harm that is irreparable to potential medical career).

Each exempted student testified that he or she wore masks on many occasions during the pandemic.[124] Any concerns about the hypothetical segregation or discrimination are only speculative and don't constitute irreparable harm. *See Duthie v. Matria Healthcare, Inc.*, 543 F. Supp.2d 958, 960 (N.D. Ill. 2008). Several students have been tested for COVID-19 multiple times with no irreparable harm. And though a few students cite concerns about the safety of nasal testing swabs, Indiana University's testing uses saliva. Though some students say the extra requirements are unnecessary or inconvenient, neither concern rises to the level of irreparable harm. *See, e.g.*, *Students v. United States Dep't of Education*, 2016 U.S. Dist. LEXIS 150011, 125 (N.D. Ill. Oct. 18, 2016); *Right Field Rooftops, LLC v. Chicago Baseball Holdings, LLC*, 87 F. Supp.3d 874, 895 (N.D. Ill.

[124] *See* Ex. 120 at 27 (Ryan Klaassen); Ex. 121 at 44 (Jaime Carini); Ex. 122 at 19-20 (Danial Baumgartner); Ex. 123 at 35-36 (Ashlee Morris); Ex. 124 at 22 (Seth Crowder); Ex. 125 at 17 (Macey Policka); Ex. 126 at 31 (Margaret Roth); Ex. 127 at 29-32 (Natalie Sperazza).

2015) ("inconvenience does not show that harm would be irreparable); *Lewis v. Silverman*, 2005 U.S. Dist. LEXIS 20347, 6-7 (N.D. Ind. Sept. 16, 2005).

Wearing masks, undergoing surveillance testing, and social distancing also aren't indicative of irreparable harm, but consistent with CDC guidelines [Ex. 129 at 28]. *See Orr*, 953 F.3d at 502 (defining irreparable harm). For these particular circumstances, the students also have an adequate remedy at law—money damages. The presumption that money is never an adequate remedy for constitutional violation is wrong. *See Campbell v. Miller*, 373 F.3d 834, 835 (7th Cir. 2004). Such damages would be normal and adequate to address what, even in the most severe light, to be no more than a personal injury. *See id.*

To be inadequate, a remedy needn't be "wholly ineffectual," but it must be "seriously deficient as compared to the harm suffered." *Foodcomm Intern. v. Barry*, 328 F.3d 300, 304 (7th Cir. 2003). If there were to be a constitutional injury here, the court could see that there is no adequate remedy at law if it didn't issue the preliminary injunction. That is less potent when the likelihood of success is so low. *See Adams v. City of Chicago*, 135 F.3d 1150, 1154 (7th Cir. 1998) (if court finds neither irreparable harm nor a likelihood of success, the "analysis ends and the preliminary injunction should not be issued"); *Dish Network LLC v. Cox Media Grp., LLC*, 2020 U.S. Dist. LEXIS 126850, 20 (N.D. Ill. July 20, 2020) (plaintiff's "failure to demonstrate a reasonable likelihood of success on the merits alone is enough to deny its motion"); *Geneva Intern. Corp. v. Petrof, SPOL, S.R.O.*, 529 F. Supp.2d 932, 940 (N.D. Ill. 2007) ("Because [plaintiff] fails to demonstrate irreparable harm, we need not continue to analyze the remaining factors.").

In short, the court presumes the students could establish irreparable harm and the absence of an adequate remedy at law, except as noted here.

C. *The Balance of the Harms and Public Interest Favor Indiana University.*

The balance of harms against the parties and the public interest favor denying the preliminary injunction. This is a sliding scale analysis. The court "weighs the balance of potential harms" against "the movant's likelihood of success." *Turnell*, 796 F.3d at 662. The more likely the plaintiff is to win, the less the balance of harms needs to favor them; the less likely, the more it must weigh in their favor. *Id.* The court has already said the students' likelihood of success is low, and the odds favor the university.

To be sure, the students have a significant liberty interest in refusing unwanted medical treatment. Telling them they must take unwanted medical treatment is a significant intrusion on their liberty. And under the harm principle, "the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others." John Stuart Mill, *On Liberty* 9 (1859); *see Cassell*, 990 F.3d at 550. If the students' decision to refuse the vaccine affected themselves alone, the balance of harms would almost certainly weigh in favor of granting a preliminary injunction.

But the evidence reasonably shows that they aren't the only ones harmed by refusing to get vaccinated: refusing while also not complying with heightened safety precautions could "sicken and even kill many others who did not consent to that trade-off." *Cassell*, 990 F.3d at 550. This certainly impacts the public interest: the students "are not asking to be allowed to make a self-contained choice to risk only their own health" in

making this decision—their decision necessarily bears on the health of other students, faculty, and staff. *Id.* The balance of harms doesn't weigh in the students' favor here.

And because the students aren't being forced to take the vaccine against their will, the harm is demonstrably less. Though the students may have to forego a semester of school or transfer somewhere else—certainly a difficult and inconvenient choice, and not one lightly tossed aside—they have options. Other colleges in Indiana and around the nation haven't mandated vaccines. Indiana University says it will reassess the mandate after this semester. This mandate will also enhance the academic environment for all students, faculty, and staff by fostering in-person education and a more traditional college experience, educationally and socially. Today, based on this record, the balance of harms tilts heavily in favor of the university.

The public interest also favors denying a preliminary injunction. The court isn't a policymaker: that role is left to the States. On multiple occasions, the Supreme Court has "recognized the role of the States as laboratories for devising solutions to difficult legal problems." *Arizona State Legislature v. Arizona Independent Redistricting Commission*, 576 U.S. 787, 817 (2015) (quoting *Oregon v. Ice*, 555 U.S. 160, 171 (2009)); *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring) ("States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear"); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."). Enabling the this state

university to work through these problems reasonably fosters public health and safety in areas of scientific uncertainty. *See Gonzales*, 550 U.S. at 163 (citing *Jacobson*, 197 U.S. at 30-31) (the law gives "wide discretion to pass legislation in areas where there is medical and scientific uncertainty"); *Cassell*, 990 F.3d at 549 ("scientific uncertainty surrounding the pandemic further cautions against enjoining state coronavirus responses unless absolutely necessary"); *see also Cuomo*, 141 S. Ct. at 68 ("Members of this Court are not public health experts").

To be sure, if the students had shown a likelihood that the university was unreasonably infringing on their constitutional rights, enjoining that violation would be in the public interest. *See Joelner v. Village of Washington Park*, 378 F.3d 613, 620 (7th Cir. 2004) ("upholding constitutional rights serves the public interest") (quoting *Newsom v. Albermarle Cnty. Sch. Bd.*, 354 F.3d 249, 261 (4th Cir. 2003)); *Ind. Fine Wine & Spirits, LLC v. Cook*, 459 F. Supp.3d 1157, 1171 (S.D. Ind. 2020) (same). But this concern doesn't apply here because the students have a low likelihood of success.

In short, the balance of harms and the public interest favor Indiana University and the determination that it has reasonably determined the best course of action for the health of its academic community this upcoming fall semester. And in doing so, Indiana University plans to return sooner to normal operations—thus serving much more than just its academic community.

D. *What This Opinion Isn't.*

Don't misread it. The court is not declaring the absolute safety and efficacy of the vaccines, or for all people. People need to understand the risks, remain informed as the

science evolves, monitor the review before the FDA, and determine whether to take a vaccine. The court must decide this case on the evidence before it. The evidence today shows that the students have little chance of success: Indiana University is reasonably pursuing a legitimate aim of public health for its students, faculty, and staff.

This university policy isn't forced vaccination. The students have options—taking the vaccine, applying for a religious exemption, applying for a medical exemption, applying for a medical deferral, taking a semester off, or attending another university. This policy applies for the fall 2021 semester only. Students may make their choice after being advised of the risks and benefits of the vaccines, thereby giving informed consent. The court recognizes that for certain students this may prove a difficult choice, but a choice nonetheless. The choice isn't so coercive as to constitute irreparable constitutional harm. Although it proves a condition to attend this fall, it is reasonable under the Constitution.

This isn't a decision after a final trial on the merits. The court has made this decision based on evidence, testimony, and briefing that the parties produced on an emergent timetable. They and their skilled counsel should be commended for the quality of their submissions, particularly under tight demands. But not every stone has been unturned by the parties. Not every study has been hashed out or submitted for the court to read. Not every witness has testified. Although constituting more than 100 exhibits and testimony from many individuals, including proposed experts, much of which then refers the court to innumerable studies and articles that it has endeavored to review

carefully, much in these five days, this still is a preliminary record, with an opinion issued urgently given the interests of these parties.

The court also isn't saying Indiana University (or any other State or state entity) may do whatever it wants to address COVID-19. Given the liberty at stake for these students here, the university must act reasonably in achieving a legitimate state goal of public health. The Fourteenth Amendment's due process clause checks that authority. Today's decision doesn't provide *carte blanche* authority for Indiana University to do as it pleases without regard to the Constitution. For instance, in the future, the goal of seeing zero or very low new positive cases as a rolling average in attainment of herd immunity may or may not prove reasonable [*see* Ex. 242 at 62-63], but those aren't the circumstances now facing the university, and those aren't the circumstances now presented to the court. Speculative concerns about hypothetical future events don't show irreparable harm. *Duthie v. Matria Healthcare, Inc.*, 543 F. Supp.2d 958, 960 (N.D. Ill. 2008).

The policy will no doubt evolve. The court questioned the parties about the scope of the university's medical exemption. The university's standard vaccination policy, originating from the General Assembly's mandate that public university students receive certain vaccinations, contains an exemption for medical contraindications,[125] with support from a physician's statement [Ex. 229]. Whereas, curiously, the university's COVID-19 policy preserves medical exemptions only for allergies to vaccine ingredients,

[125] A contraindication is any "condition[] in a recipient that increases the risk for a serious adverse reaction." CDC, *General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)*, https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

not contraindications—ostensibly a narrower basis for exemption for an EUA vaccine than for other decades-existing vaccines.

At oral argument, Indiana University explained that, at the time of adoption, allergies proved the only contraindication and that the university has applied its medical exemption more broadly. There is some evidence for this in the record [*see*, *e.g.*, Ex. 128 at 84-88]. Four physicians on the university medical team consider any requested medical exemption and work with the student's physician to address any immunocompromising condition (and, at times, try to educate the physician on certain pathophysiologies that aren't of concern) [*id.*]. In doing so, the university follows CDC guidance. The university thus has considered for exemption such conditions as vaccine-suppressing medications, pregnancy, steroids, chemotherapy, and organ transplants, to name a few [*id.* at 85-88]. In truth, the medical exemption has been applied more broadly than it is written.

Wisdom might counsel its update to reflect reality and an evolving science. Jumping on this concern, the students call the medical exemption arbitrary in oral argument. The record doesn't bear this out. Indeed, no matter the seeming problematic nature of a narrow medical exemption as written, it has been reasonably broad as applied [*id.*]. The simple truth is that none of the eight students here have sought a medical exemption with the support of a physician's statement to trigger this issue.

Jaime Carini says she wanted a medical exemption, but she never sought one; and she has a religious exemption that she secured in any event [Ex. 121 at 58-60, 69; Tr. 53]. She doesn't present facts that show the university chose to ignore a doctor's recommendation. Margaret Roth has legitimate concerns about taking the vaccine, but

she too hasn't applied for a medical exemption or been denied [Ex. 126 at 26]. Natalie Sperazza believes it unsafe, but she too provides no physician's statement to support this view or shows she applied for a medical exemption [Ex. 127 at 64]. A future case might raise an issue under the medical exemption, but that's not today's case. *See Jacobson*, 197 U.S. at 36-37 (leaving option to challenge vaccine mandate for contraindications). The court won't issue an advisory opinion. *See Brixen*, 908 F.3d at 280.

CONCLUSION

Even assuming in certain respects irreparable harm and an inadequate remedy at law, the students here haven't established a likelihood of success on the merits of their Fourteenth Amendment due process claim, or that the balance of harms or the public's interest favors the extraordinary remedy of a preliminary injunction, before a trial on the merits. The court thus DENIES their preliminary injunction motion [ECF 7].

Recognizing the significant liberty interest the students retain to refuse unwanted medical treatment, the Fourteenth Amendment permits Indiana University to pursue a reasonable and due process of vaccination in the legitimate interest of public health for its students, faculty, and staff. Today, on this preliminary record, the university has done so for its campus communities. That leaves the students with multiple choices, not just forced vaccination.

One might well hale a certain Emersonian self-reliance and self-determination as preference—an unfettered right of the individual to choose the vaccine or not—but, given a preliminary record such as today's, the court must exercise judicial restraint in superimposing any personal view in the guise of constitutional interpretation.

Reasonable social policy is for the state legislatures and its authorized arms, and for the People to demand through their representatives.

SO ORDERED.

July 18, 2021

s/ Damon R. Leichty
Judge, United States District Court