No. 21-2326

In the United States Court of Appeals for the Seventh Circuit

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Ryan Klaassen, **Jaime Carini**, **Daniel J. Baumgartner**, **Ashlee Morris**, **Seth Crowder**, **Macey Policka**, **Margaret Roth**, and **Natalie Sperazza**,
Plaintiffs-Appellants

v.

The Trustees of Indiana University,
Defendant-Appellee

On Appeal from the U.S. District Court for the Northern District of Indiana, Case No. 1:21-cv-00238-DRL-SLC, Honorable Damon R. Leichty, District Judge

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Emergency Motion of Appellants Klaassen *et al.* for an Injunction Pending Appeal Relief Requested by July 30, 2021

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Introduction

Students challenged IU's Mandate requiring students to take COVID vaccinations, despite their objection. Students' refusal is based on legitimate concerns including underlying medical conditions, having natural antibodies, and the risks associated with the vaccine. All students are adults, are entitled to make their own medical treatment decisions, and have a constitutional right to bodily integrity and autonomy in the context of a vaccination mandate. IU, however, is treating its students as children who cannot be trusted to make mature choices and has substituted itself for both the student and her attending physician, mandating a choice which is the student's to make, based on her physician's advice.

The only way such rights can be infringed is for IU to justify its override of the student's choice within the boundaries of the U.S. Constitution. The court below, however, did not require this, because it erroneously applied rational basis scrutiny instead of the heightened scrutiny appropriate to infringements of the rights at stake here. Under proper heightened scrutiny, IU's Mandate cannot be justified and should be enjoined pending appeal.

Facts

A. IU's Mandate

On May 21, 2021, Indiana University ("**IU**") announced that faculty, staff, and students would be required to receive a COVID vaccine ("**IU's Mandate**"). Compl., ¶¶17-20, Ex. 1; Opinion, 11-12, Ex. 2. If a student refuses to receive the vaccine, IU has promised the student will suffer "strong consequences," including canceled class registration, terminated IU identification cards, and restrictions from participation in any on campus activity. Compl., ¶21; *see also* Op., 12.

IU students can apply for an exemption to IU's Mandate under an "extremely limited" criteria, which only include a religious exemption, a documented allergy to the vaccine, medical deferrals, and an online-only student exemption.[1] Compl., ¶¶22-24; *see also* Op., 12. It does not include an exemption for those with natural immunity, including those who have previously been infected and fully recovered or for many medical contra-indications. Compl., ¶24.

Those who qualify for and are granted an exemption are still subject to additional requirements, including *inter alia* participating in twice a week testing and mandatory face masks in public spaces. Compl., ¶¶28-30; Op., 13. IU does not allow for any exemptions from these extra requirements. Compl., ¶¶31-32, 197,

[1] On or about July 20, 2021, IU added an "ethical exemption" to their website but has given no other information about this new exemption or stated who would qualify.

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B. The Context surrounding IU's Mandate

Currently, all three publicly-available COVID vaccines have only "Emergency Use Authorization" ("**EUA**") status and have not received full FDA approval. Compl., ¶¶44-47; Op., 15-21. A vaccine authorized under EUA requires complete, informed, and voluntary consent. Compl. ¶¶48-51; Op., 52-54. This requirement is based on a fundamental tenet of medical ethics which requires voluntary and informed consent for any procedure or drug that imposes a medical risk to an individual.

Here, the risk of serious morbidity and mortality from COVID for those under 30 are close to virtually zero. *See infra* Part II.B.1. To Students, the known and unknown risks associated with COVID vaccines, particularly in their age group, outweigh the risks to that population from the disease itself, so they do not consent to the vaccine.[2] Despite this, IU's Mandates the vaccine for them.[3]

While IU is not a provider and not directly subject to this informed consent requirement, Students believe the required consent is undermined by IU's Mandate and rendered a nullity for them. This is contrary to the FDA's EUA and modern

[2] The district court elaborates on the vaccines risks, including those to Students' age group. Op., 22-24.

[3] None of the relevant authorities, including the CDC, State of Indiana, relevant counties, or other public university in Indiana mandate vaccinations.

medical ethics.

C. Plaintiffs

Plaintiffs include eight IU students, ranging from undergraduate studies to masters and doctorate studies. *See* Op., 3-5. Six students (Klaassen, Carini, Baumgartner, Morris, Crowder, and Policka) have received a religious exemption from IU's Mandate, but all have objections to the Extra Requirements (some for religious reasons and some for general reasons). Two students (Roth and Sperazza) have not received any exemptions. Roth has a religious objection to IU's Mandate, but has not sought a religious exemption because it does not provide her with the relief she seeks. Sperazza does not qualify for any of the exemptions, based upon IU's written criteria for the same. Three of the students (Baumgartner, Carini, and Roth) have specific medical conditions or histories that make it unreasonable and unsafe for them to get the vaccine and, in one case, against their attending physician's advice. Nevertheless, they do not qualify for IU's medical exemption as written.

Legal Standard

The Seventh Circuit reviews a district court's decision to grant or deny a preliminary injunction for an abuse of discretion. *Cassell v. Snyders*, 990 F.3d 539, 545 (7th Cir. 2021). The district court "abuses its discretion when it commits

a clear error of fact or an error of law. Absent such errors, we accord a district court's decisions during the balancing phase of the analysis great deference." *Id.*

Granting an injunction pending appeal turns on the same analysis as a preliminary injunction motion. *Cavel Int'l, Inc. v. Madigan*, 500 F.3d 544, 547-48 (7th Cir. 2007). A party seeking a preliminary injunction must demonstrate (1) some likelihood of succeeding on the merits, (2) that it has no adequate remedy at law and will suffer irreparable harm if preliminary relief is denied, (3) the irreparable harm the non-moving party will suffer if preliminary relief is granted, balancing that harm against the irreparable harm to the moving party if relief is denied; and (4) the public interest, meaning the consequences of granting or denying the injunction to non-parties. *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 11 - 12 (7th Cir. 1992) (internal citations omitted). The more likely the plaintiff is to win, the less heavily the balance of harms to the other parties and the public policy arguments for non-parties need to weigh in the plaintiff's favor; the less likely a plaintiff is to win, these factors must weigh more heavily in the plaintiff's favor. *See Valencia v. City of Springfield*, 883 F.3d 959, 966 (7th Cir. 2018).

Standing

The district court properly found that Plaintiffs have standing to bring this

suit. Op., 29-30.

Argument

I. The Court Below Erred in Holding That Heightened Scrutiny Was Not Required in the Context of a Mandated Vaccine.

Students' rights to bodily integrity and autonomy and to choose medical treatment, as applied to a vaccination mandate, requires heightened scrutiny and government justification. The district court defined the constitutional right at stake in reviewing IU's Mandate as a liberty interest that "has remained confined by . . . the state's legitimate interests that it had rationally pursued in regulation," Op., 49 (citing *Washington v. Harper*, 494 U.S. 210, 221-22 (1990)), to which the district court applied rational basis review. *Id.* at 51 (citing *inter alia* *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 30-31 (1905)).

Over the past 100 years, the Supreme Court has developed a constitutional jurisprudence that gives robust protection to an individual's right to control his or her own body in certain important circumstances, including to refuse medications. In those important circumstances, heightened scrutiny is required where the government must demonstrate that it has sufficient justification to violate that right. The court below made a clear error in law by applying rational basis review to Students' claims and therefore abused its discretion.

A. The Right to Bodily Integrity and Autonomy and to Choose Medical Treatment in the Context of a Vaccine Mandate Requires Heightened Scrutiny.

The Court's recent constitutional jurisprudence gives greater weight to the protection of bodily integrity and autonomy and to choose medical treatment than it did a century ago.[4] During modern times, the Court has applied heightened scrutiny in two lines of cases regarding the right to bodily integrity and autonomy:

(1) When an important personal choice has been **prohibited** by the government. *See, e.g.*, *Griswold v. Connecticut*, 381 U.S. 479 (1965) (contraception); *Roe v. Wade*, 410 U.S. 113 (1973), modified by *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992) (abortion), and *Obergefell v. Hodges*, 576 U.S. 644 (2015) (same-sex marriage).

(2)When an important personal choice has been **mandated** by the government, contrary to the decision of the person. *See, e.g.*, *Cruzan by Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 278 (1990) (right to consent to or refuse medical treatment for incompetent person); *Riggins v. Nevada*, 504 U.S. 127, 135 (1992); *Sell v. United States*, 539 U.S. 166, 186 (2003) (pre-trial forced administration of antipsychotic drugs).

The district court failed to recognize this since it limited its analysis in two

[4] *See* Weiler, *Bodily Integrity: A Substantive Due Process Right to Be Free from Rape by Public Officials*, 34 Calif. West. L. Rev. 591, 596-604 (1998) (compilation and analysis of modern bodily integrity and autonomy cases).

ways: (1) by ignoring all of the prohibition cases, except *Glucksberg*, Op., 49-52, which established fundamental rights to bodily integrity and autonomy in certain important circumstances of personal choice; and (2) by limiting its review of the mandate cases to searching in vain for the magic words "fundamental right." *See id.* at 32. The Court, however, signals that heightened scrutiny is applied by:

(1) either the description of the right involved (i.e., "fundamental," "significant liberty interest");

(2) the weight of the government interest that is needed to overcome the right (i.e. "essential" or "overriding"); or

(3) the procedural burdens placed on the government when acting to advance its interest (i.e., "clear and convincing evidence" or robust procedural requirements).

See e.g.,*Washington v. Glucksberg*, 521 U.S. 702 (1997); *Cruzan*, 497 U.S. 261; *Sell*, 539 U.S. 166. In these instances of heightened scrutiny, the key difference is the shift in the burden of proof to the government, from the Plaintiff, to justify its mandate.

The district court relied on two mandate cases, *Cruzan* and *Harper*, for its erroneous conclusion that mandating vaccines implicates only a liberty interest, triggering only rational basis review. Op., 49-52. *Cruzan* is particularly important since it addresses the right to make medical treatment decisions, under which IU's

Mandate falls, and clearly views that right to require heightened scrutiny. First, *Cruzan* held that "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions." *Cruzan*, 497 U.S. at 278. It then upheld the requirement of "clear and convincing evidence" in proceedings to terminate life-sustaining medical care for an incompetent patient, under a due process analysis, because the "individual interests at stake . . . are both 'particularly important'" and "substantial, both on an individual and societal level, than those involved in a run-of-the-mine civil dispute." *Id*. at 282-283. Obviously, the Court was describing a right that demanded heightened scrutiny. *See also Glucksberg*, 521 U.S. at 721 n. 17 (In *Cruzan*, the Court "concluded that the right to refuse unwanted medical treatment was so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment."); *Union Pac. R. Co. v. Botsford*, 141 U.S. 250 (1891) (holding "the inviolability of the person is as much invaded by a compulsory stripping and exposure as by a blow."); *Rochin v. California*, 342 U.S. 165 (1952) (holding forced "stomach pumping" in hospital to obtain evidence of narcotics violated Due Process Clause).

The district court's reliance on *Harper* is also misplaced because, properly interpreted, *Harper* supports heightened scrutiny here, which *Harper*'s progeny makes clear, which the district court ignored. As the district court acknowledged,

Op., 49, *Harper* recognized a "significant liberty interest" in refusing unwanted administration of antipsychotic drugs under the Due Process Clause. 494 U.S. at 221-22. The district court, however, interpreted *Harper*'s failure to call that right "fundamental" meant that it was just a run-of-the-mill liberty interest. PI Order 49-52. However, *Harper* was actually referring favorably to the Washington Supreme Court's characterization of the right, which required strict scrutiny to protect, 494 U.S. at 220-221, and held that "the forcible injection of medication into a nonconsenting person's body . . . represents a substantial interference with that person's liberty," *id*. at 229, which is "impermissible absent a finding of overriding justification and a determination of medical appropriateness." *Riggins*, 504 U.S. at 135. The *Harper* Court applied rational basis review exclusively based on Harper's penal confinement, which furthers the state's important interest in prison safety and security. *Id*. at 134-135 (*citing Harper*, 494 U.S. at 227).

Finally, the Court in *Sell* looked to *Harper* and *Riggins* to establish the standard of review of a government mandate of medical treatment contrary to an individual's choice for those outside of penal confinement, such as those awaiting trial. *Sell*, 539 U.S. at 177-178. First, the Court found that an individual has a constitutionally protected liberty "interest in avoiding involuntary administration of antipsychotic drugs"—an interest that only an "essential" or "overriding" state interest might overcome, *id.* at 178-79 (citing *Riggins*, 504 U.S. at 134, 135), and

only if the "involuntary medication will significantly further the concomitant state interests." *Id.* at 181. Furthermore, the government must show "the efficacy, the side effects, the possible alternatives, and the medical appropriateness" of the course of treatment, "sufficient to overcome the individual's protected interest in refusing it." *Id*. at 183. And finally, the government had the burden to prove that the "current circumstances" justifies overriding a person's right to refuse medication. *Id*. at 186, *see generally* *United States v. Breedlove*, 756 F.3d 1036, 1040 (7th Cir. 2014) (citing *Sell*, 539 U.S. at 180-82). This surely describes strict scrutiny which should be applied here.

However, if rational basis review applies, as the district court applied here, "the challenging party (the Students here) bears the burden of negating every conceivable basis which might support a regulation." *Platt v. Brown*, 872 F.3d 848, 852 (7th Cir. 2017). But *Griswold*, *Roe*, *Casey*, *Cruzan*, *Glucksberg*, *Harper*, *Riggins*, *Sell*, and *Obergefell*[5] all required the *government*, not the challenger, to prove it meets the heightened standard of review for interference with the individual's right to bodily integrity and autonomy at issue, which the district court fail to require.

Students are all competent adults who are capable of making their own

[5] The substantive due process requirements for involuntary commitment to a mental hospital for treatment follows the same path. *See* *Humphrey v. Cody*, 405 U.S. 504 (1972); *Addington v. Texas*, 441 U.S. 418 (1979); *Vitek v. Jones*, 445 U.S. 480 (1980).

decisions about their bodily integrity and autonomy and medical choices, but IU is treating them like children, who need IU administrators to make medical treatment decisions for them, even when contrary to the Student's own attending physician's advice. Of course, there will be times that the government can make the requisite showings, such as when the person is a prisoner or when in the midst of a raging pandemic. But the Students are not children, prisoners, or mentally ill patients, and the COVID pandemic has largely waned, *see infra* Part II.A. The government needs to justify its mandate, which it failed to do and which the district court failed to require.

B. The Court below Erred in Applying *Jacobson*'s Rational Basis Test Rather than Heightened Scrutiny.

As noted, the district court relied heavily on his view that *Jacobson* established that "(a) vaccine is implemented as a matter of public health, and historically hasn't been constitutionally deterred from state mandate." Op., 51 (*citing* *Zucht v. King*, 260 U.S. 174, 176-77 (1922);[6] *Jacobson*, 197 U.S. at 30-31). However, *Jacobson* gave no such plenary authority and in fact recognized that the exercise of the police power to protect public health was subject to judicial review.

[6] Other than confirming the limited holding of *Jacobson*, *Zucht* adds nothing to the analysis. *Zucht* correctly explained *Jacobson*'s narrow holding that "it is within the police power of a state to provide compulsory vaccination," and that power may be delegated to public health authorities. *Zucht*, 260 U.S. at 176 (*citing Jacobson*, 179 U.S. 11). *Zucht*, therefore, relied on *Jacobson* that this ordinance "confer(s) not arbitrary power, but only that broad discretion required for the protection of the public health," *Zucht*, 260 U.S. at 177, and adds nothing new.

Thus, the district court erred in conferring such plenary authority on IU.

1. *Jacobson*'s Holding Did Not Negate the Government's Obligation to Exercise its Powers Within the Boundaries of the U.S. Constitution.

In the past 100 years, much has been made of *Jacobson,* 197 U.S. 11.[7] The *Jacobson* Court upheld giving certain state police powers in public health authorities regarding the smallpox vaccine. *Id*. at 24-27. Even the Progressive era *Jacobson* Court recognized that such police powers could be exercised in a way to violate the federal constitutional or statutory law, "exercised . . . in . . . an arbitrary, unreasonable manner," or exercised in a way to go "beyond what [i]s reasonably required for the safety of the public," *Id.* at 28. This left judicial review of the exercise of those police powers to subsequent courts.

Thus, if violations of constitutional rights occur in exercise of those powers as here, then, under *Jacobson*, the government needs to show that the exercise passes constitutional muster. It cannot do so here when the proper heightened constitutional scrutiny level is applied.

2. *Jacobson* Preceded the Development of Modern Recognition of Heightened Scrutiny for Infringements on Bodily Integrity and Autonomy in Certain Important Contexts.

In the 117 years since the *Jacobson* Court approved delegation of the police

[7] *See generally,* Mariner, Annas, Glantz, *Jacobson v. Massachusetts: It's Not Your Great-Great-Grandfather's Public Health Law*, 95 Am. J. Public Health 581 (2005).

power to protect public health and safety to public health officials, the doctrine of substantive due process developed and individual liberties have been recognized, in many cases requiring heightened scrutiny to protect against government prohibitions and mandates that limit personal choice. *See supra,* Part I.A. The Court itself recognized this development when it said that "our cases since *Roe* accord with *Roe's* view that a state's interest in the protection of life falls short of justifying any plenary override of individual liberty claims." *Casey*, 505 U.S. at 857.

In 2020, as a result, the Court in *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63 (2020), applied modern strict scrutiny to a violation of fundamental rights which the government sought to justify as a result of the COVID pandemic. As Justice Gorsuch reasoned, "*Jacobson* hardly supports cutting the Constitution loose during a pandemic." *Roman Catholic Diocese*, 141 S. Ct. at 70 (J. Gorsuch, concurring). Justice Gorsuch explained that *Jacobson* never gave states a *carte blanche* for intrusions into settled constitutional rights nor any contradictions with the Constitution, and "(t)ellingly no Justice now disputes any of these points." *Id.* Consequently, even when there is a public health crisis, governments do not have the power to infringe on fundamental rights without proving a compelling justification.

This Circuit agrees. "The pandemic is not a permissible excuse for invidious

discrimination." *Cassell*, 990 F.3d at 549 (recognizing *Roman Catholic's* modern application of *Jacobson* in seeking to choose the best course of action with the least mistakes in an evolving modern pandemic).While *Cassell* dealt with a First Amendment claim against an Illinois executive order, this Court recognized that, when evidence of infringement upon fundamental rights is present, the judiciary may act to halt it. *Id*.

The Seventh Circuit is not alone in its reasoning—the Second Circuit noted that *Jacobson*'s holding predated the modern tests of constitutionality, and "we grant no special deference to the executive when the exercise of emergency powers infringes on constitutional rights. That is precisely what the three-tiered framework for analyzing constitutional violations is for, and courts may not defer to the Governor simply because he is addressing a matter involving science or public health." *Agudath Israel of Am. v. Cuomo*, 983 F.3d 620, 635 (2d Cir. 2020).

Thus, over the past 100 years, the Supreme Court has developed a constitutional jurisprudence that gives robust protection to an individual's right to bodily integrity and autonomy and the right to consent to medical treatment. And as even *Jacobson* has made clear, the government does not have plenary power to violate that right, even in contexts where the government's interests are considered important. The court below erred in applying *Jacobson*'s rational basis test rather than the heightened scrutiny required in this context by modern developments of

constitutional law.

C. IU's Mandate Violates Students' Rights to Bodily Integrity and Autonomy and to Medical Choice by Placing an Unconstitutional Condition on Attending IU.

Students assert that IU's Mandate violates Students' fundamental rights of bodily integrity and autonomy and to medical treatment choice by threatening a "loss of an education," if the student does not comply with the Mandate. *See* Op., 48. While IU argued that Students were arguing for a right to attend college rather than a right to consent to COVID vaccines, Judge Leichty correctly found that the "'unconstitutional conditions doctrine' forbids the university from pulling the rug out from under the students in a roundabout way." *Id.*

It is well established that "the government may not deny a benefit to a person because he exercises a constitutional right. *Regan v. Taxation With Representation*, 461 U.S. 540, 545 (1983). Here, IU is coercing students to give up their right to bodily integrity and autonomy and to medical treatment choice in exchange for the discretionary benefit of matriculating at IU. Even if "someone refuses to cede a constitutional right in the face of coercive pressure, the impermissible denial of a governmental benefit is a constitutionally cognizable injury," *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 607 (2013), where the U.S. Supreme Court has "often concluded that denials of government

benefits were impermissible under the unconstitutional conditions doctrine." *id*. at 606, even where there is "no entitlement to that benefit." *Id*. at 608.

This is the situation here, so the Students' rights are violated.

II. Under Heightened Scrutiny, the Students Are Likely to Prevail on Their Due Process Claim That, Under the Current Circumstances and as Applied to this Age Group, IU Has Failed to Prove That Their Mandate Is Justified.

The court below held that on the preliminary record Students haven't shown a likelihood of success that IU lacked a *rational basis* for its Mandate. *See* Op., 55. If the court would have applied heightened scrutiny, which requires the government to justify restrictions, Students would have been likely to succeed. Additionally, emerging facts continue to undermine IU's rationale for the Mandate.

Since heightened scrutiny applies, the court should consider both the strength of the government's interest and the tailoring of its regulations to the current stage of the pandemic.

A. IU's Interest in Public Health and Safety is no longer Compelling Enough to Justify the IU Mandate at this Stage of the COVID Pandemic.

The COVID pandemic is in the final stage of "recovery" or "preparation". According to the CDC, the preparation phase "is characterized by low pandemic [ ] activity, although outbreaks might continue to occur[.]" CDC, *Updated*

Preparedness and Response Framework for Influenza Pandemics, 2, Ex. 3. During this phase, the primary focus should be to discontinue community mitigation measures. *Id*.

Even if it could be argued that we are only in the deceleration phase, IU should still be planning to discontinue mitigation measures. *Id.* The district court agrees that "the overall trend line may well support a seeming deceleration," but applied rational basis to the implications of that conclusion. Op., 57. Evidence supports that we are in the CDC's preparation phase. Cases and deaths have significantly decreased since March 2020.[8] U.S. and Indiana Case and Death Bell Curves, Exs. 4-7. The decelerating pandemic data supports The Supreme Court's view on policy analysis within this context.

"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 Dayton Valley v. Sisolak*, 140 S. Ct. 2603, 2605 (2020) (J. Alito, dissenting). Just as the Court recognized that Sell's condition must be evaluated given his current circumstances, *Sell*, 539 U.S. at 186, as the science around the pandemic evolves

[8] Note that while day to day rises and falls will occur, and variants will emerge (which CDC model acknowledges), the overall trend line and current average rates relative to that overall trend line is what is relevant. Temporary spikes do not show a trend and are not relevant to determining whether the pandemic is declining as a whole.

and the pandemic runs its course, so does the legal landscape surrounding it evolve too.

The district court asserted that "[s]temming the spread of COVID-19 is unquestionably a compelling interest." Op., 56 (citing *Cuomo*, 141 S. Ct. at 67). However, evidence suggests that stemming the spread may no longer be an achievable goal, no matter the vaccination status of Students. Emerging data from around the world suggests that vaccination may not prevent the spread of COVID, particularly against COVID variants, but may simply lessen the severity of symptoms among those who do contract it.[9] IU's President Whitten, who is fully vaccinated, recently contracted COVID. She acknowledged, "the vaccine is not 100% effective," but was "protected from more serious symptoms." Email from President Whitten, Ex. 8. For college-aged students, the risk of severe COVID consequences, such as hospitalizations and death, were already near zero without vaccination *(see* Op., 61), so lessening the risk of death is not a compelling interest.

Under the proper standard of review, IU cannot prove that it has a compelling interest at this stage in the pandemic or for this age group. IU cannot prove that IU's Mandate would prohibit the spread of COVID, and lessening the

[9] https://www.deseret.com/coronavirus/2021/7/20/22584134/whats-going-on-in-israels-outbreak-among-vaccinated-people

risks of COVID for this age group is not a compelling interest when severity was already minimal and deaths almost nonexistent.

B. The IU Mandate Is Not Narrowly Tailored.

1. College-aged persons are at a very low risk of adverse effects of a COVID infection.

There is little risk of adverse effects of a COVID infection for college and graduate students. As of July 11, 2021, IU had one COVID death case for students over the 18 months of the COVID pandemic. Op., 61.

A study of 100 major universities and colleges indicated that even in the height of the pandemic, there were a mere 17—typically short-term—reported COVID hospitalizations and only one possible COVID death. Compl., ¶¶131-135.

Furthermore, the overall risk for this age group of developing serious side effects from COVID is extremely low. The district court agreed that "young adults are less likely to experience serious illness or death from infection." Op., 5. In fact, studies show that there is only a .02% chance of dying from COVID for people ages 20-49. Nickie Louise, *CDC data shows that COVID-19 survival rate for adults is 99.98%; chances of surviving coronavirus is over 99.9% for most age groups*, Nov. 21, 2021, Ex. 9.

Accordingly, the risks of COVID to college-age students is extremely low and the risk of death is almost non-existent. Mandating college-aged persons to

get vaccinated is not narrowly tailored to protecting public health and safety.

2. Older people, who are not subject to a mandate, are at a much greater risk of adverse effects of a COVID infection than young people, who are subject to a mandate.

IU's Mandate requires the younger population to receive the vaccine, but the older population is at the greatest risk for a COVID infection. Older people can be up to 870 times more likely to die from COVID than the student population. Compl., 27 (Tables D and E); *see also* Beeler Deposition, 49:6-12, Ex. 10 (indicating that it is reasonable to state that the older population is 600 times at greater risk than the younger population).[10]

Mandating the vaccine for the younger, student age population, rather than those much older, is not narrowly tailored to protect public health and safety.

C. IU's Mandate Is Not the Least Restrictive Means to Protect Health and Safety.

Existing measures (including voluntary vaccination, masking, social distancing, sanitizing, and testing) have already gotten IU and Indiana to the CDC's preparation phase, so continuing such measures, rather than a mandate, would be the least restrictive means of accomplishing IU's goal.[11]

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[10] The district court did not determine how much greater risk the older population had versus the younger population.

[11] The district court agrees that new COVID infections are waning and that the bell curves show the trend moving "sharply down[.]" Op, 6-7.

Additionally, IU has failed to prove that the vaccines are sufficiently safe and effective to justify mandating their use for this age group. There are emerging risks of the COVID vaccines, including some that primarily effect students. *See e.g.,* Op., 22-24. And there are emerging questions about the COVID vaccines effectiveness, particularly against COVID variants. Because IU has mandated the vaccines, substituting themselves for students and their attending physicians, it is IU's burden to prove that the vaccines are safe and effective for this age group, which they have failed to do.[12]

The IU Mandate is thus not the least restrictive means to accomplish its interest in public health and safety.

III. Students have suffered irreparable harm.

Students have shown irreparable harm and that there is no adequate remedy at law.

The district court correctly held that "[t]o the extent that the students establish a constitutional harm, the law presumes irreparable harm," Op., 91, and likewise, there would be "no adequate remedy at law." *Id*. at 93. Students have shown a constitutional injury, so it must follow that there is irreparable harm and

[12] The district court only evaluated whether IU had a rational basis to conclude that the COVID vaccine is safe and efficacious for its students, not whether the same conclusion could be reached under heightened scrutiny. Op., 80.

no adequate remedy at law. *See* Part II.

IV. The Balance of Equities Weighs in Students' Favor.

Given the significant constitutional injury here, the balance of harms and public interest favor Students.

Since Students are likely to succeed on the merits of their claim, the balance of harms does not need to favor them as strongly. Op., 94. Nevertheless, Students have shown that the balance of harm tips in their favor, where their constitutional rights are being violated. In contrast, IU cannot show that it will be harmed, as the risk of COVID has significantly declined and a significant portion of IU's population is already vaccinated. Moreover, anyone that wants to be vaccinated can do so, free of charge, so Students decision to not vaccinate does not harm others.

This district court correctly held that "[i]f 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." Op., 96. Students have shown that IU is unreasonably infringing on their constitutional rights when the correct constitutional standard is employed, so enjoining that violation is in the public interest.

Conclusion

The Court should grant this Motion.

July 23, 2021

Respectfully submitted,

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July 23, 2021

/s/ James Bopp, Jr.
James Bopp, Jr.
Lead Counsel for Plaintiffs-Appellants and
Director of Litigation
America's Frontline Doctors

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I certify that counsel of record have been served by this Court's ECF service and by email.

/s/ James Bopp, Jr.
James Bopp, Jr.
Lead Counsel for Plaintiffs-Appellants
and
Director of Litigation
America's Frontline Doctors

Verified Complaint for Declaratory and Injunctive Relief

Exhibit 1

United States District Court
Northern District of Indiana

Ryan Klaassen, Jaime Carini, D.J.B., by and though his next friend and father, Daniel G. Baumgartner**, Ashlee Morris, Seth Crowder, Macey Policka, Margaret Roth,** and **Natalie Sperazza**, *Plaintiffs,* *v.* **The Trustees of Indiana University**, *Defendant*.	**Civ. No.** 1:21-cv-238 **Verified Complaint for Declaratory and Injunctive Relief**

Verified Complaint for Declaratory and Injunctive Relief

Plaintiffs Ryan Klaassen, Jaime Carini, D.J.B., by and though his next friend and father, Daniel G. Baumgartner, Ashlee Morris, Seth Crowder, Macey Policka, Margaret Roth, and Natalie Sperazza complain against Defendant as follows:

Introduction

1. This is a civil action for declaratory and injunctive relief arising under the Fourteenth Amendment and Indiana Code § 16-39-11-5 (Indiana's "**Vaccine Passport Law**").

2. It concerns the constitutionality of Indiana University's Vaccine Mandate (**"IU's Mandate**"), which requires that all students to receive one of the available COVID vaccines.

3. IU's Mandate violates the liberty protected by the Fourteenth Amendment to the U.S. Constitution, which includes rights of personal autonomy and bodily integrity, and the right to reject medical treatment.

4. IU's Mandate also violates Indiana's new Vaccine Passport Law which prohibits state

and local units (including Indiana University ("**IU**")) from requiring or issuing vaccine "passports" that indicate an individual's COVID immunization status.

Jurisdiction and Venue

5. This action arises under the Fourteenth Amendment and Indiana Code § 16-39-11-5.

6. This Court has jurisdiction over all claims pursuant to 28 U.S.C. Sections 1331 and 1343(a). It also has jurisdiction pursuant to the Declaratory Judgment Act as codified at 28 U.S.C. Sections 2201 and 2202.

7. Venue is proper under 28 U.S.C. Section 1391(b) because Defendant resides in this District and because a substantial part of the events giving rise to the claim occurred in this District.

Parties

8. Plaintiff Ryan Klaassen is a resident of Noble County, Indiana and an incoming sophomore at IU.

9. Plaintiff Jaime Carini is a resident of Rogers County, Oklahoma and is currently pursuing two doctorates at IU—a Doctor of Music (D.M.) in organ performance and literature, and a Ph.D. in musicology.

10. Plaintiff D.J.B., by and though his next friend and father, Daniel G. Baumgartner, is a resident of Cook County, Illinois and an incoming freshman at IU.

11. Plaintiff Ashlee Morris is a resident of Jennings County, Indiana and an incoming 1L at the McKinney School of Law.

12. Plaintiff Seth Crowder is a resident of Marion County, Indiana and is currently pursuing

his Masters of Business Administration at the Kelley School of Business.

13. Plaintiff Macey Policka is a resident of Hamilton County, Indiana and a senior at IU.

14. Plaintiff Margaret Roth is a resident of Marion County, Indiana and an incoming freshman at IU.

15. Plaintiff Natalie Sperazza is a resident of Hendricks County, Indiana and an incoming sophomore at IU.

16. Defendant The Trustees of Indiana University ("**Board of Trustees**") is the governing body, legal owner, and final authority of IU. IU "is recognized as the university of the state." IC § 21-20-2-1. The Board of Trustees has broad "powers, duties, and responsibilities" to govern IU. *See* IC § 21-27 *et seq.*; *see also* IC § 21-39-2-2 ("The board of trustees . . . may govern, by regulation and other means, the conduct of students, faculty, employees, and others while upon the property owned, used, or occupied by the state educational institution.") and Indiana University Board of Trustees, *About the Board of Trustees*, https://trustees.iu.edu/about-the-board/index.html (last visited on June 17, 2021) ("The Board of Trustees is Indiana University's governing board, its legal owner, and its final authority."). The Board of Trustees is a body politic. IC § 21-20-2-2. The Board of Trustees may "in the name of 'The Trustees of Indiana University' . . . be sued." *Id.* at § 21-27-4-2.9.

I. Facts

A. IU's Mandate Overview and Implementation

1. IU's Mandate and Exemptions

17. On May 21, 2021, IU announced to all faculty, staff, and students that there would be a requirement to receive a COVID-19 ("**COVID**") vaccine for the fall 2021 semester. Indiana University, *New COVID-19 vaccine requirement*, attached as Exhibit 1.

18. This announcement was delivered via email to all current faculty, staff, and students of every IU campus. *See id.*

19. IU's Mandate requires that all students, faculty, and staff receive one of the available COVID vaccines by either August 15 or when they return to campus after August 1, whichever is earlier. Indiana University, *COVID-19 Vaccine*, https://www.iu.edu/covid/prevention/covid-19-vaccine.html (last visited June 17, 2021).

20. In order to comply with IU's Mandate, IU has suggested that students have their first dose of the COVID vaccine by July 1, 2021. *Id.*

21. There are "strong consequences" for those who refuse the vaccine and do not receive an exemption. *Id.* Students will have their class registration canceled, their university-issued IDs, known as "Crimson Cards," terminated, and will be restricted from any on-campus activity. *Id.*

22. Under IU's Mandate, individuals may request an exemption if they fit an extremely limited and narrow set of criteria. *Id*; *see also* Indiana University, *COVID-19 Frequently Asked Questions*, https://www.iu.edu/covid/faq/index.html#vaccine-req (last visited June 17, 2021) ("exemptions will be extremely limited").

23. Exemption from IU's Mandate applies to anyone with a religious objection, a documented allergy to the vaccine, medical deferrals, and for online students in a completely online course with no on-campus presence. *Id*.

24. IU's Mandate does not include an exemption for those with natural immunity to COVID, including those who have previously been infected and fully recovered, or those students will a medical condition where the COVID vaccination is contra-indicated, even under their attending physician's advice.

25. Initially, IU stated that the exemption process would become available on June 15, 2021; however on June 1, 2021, all faculty, staff, and students received an email with a live exemption form. *Fall 2021 Restart Guidance*, Indiana University, attached as Exhibit 2.

26. The exemption request form provides three exemption options coinciding with the aforementioned criteria. *Exemption Criteria*, attached as Exhibit 3.

27. Once an exemption form is completed online, IU's Medical Response Team reviews the exemption request and responds within five business days, presumably to approve or deny the exemption. Indiana University, *COVID-19 Vaccine*, https://www.iu.edu/covid/prevention/covid-19-vaccine.html (last visited June 17, 2021).

28. Those who qualify for and are granted an exemption are still subject to additional requirements ("**Extra Requirements**").

29. These Extra Requirements include requiring exempt individuals to participate mitigation testing twice a week, a mandatory quarantine if exposed to someone who tests positive for COVID, mandatory face masks in public spaces, and a mandatory return to their home address if

the campus has a serious outbreak of the virus. Indiana University, *COVID-19 Frequently Asked Questions*, https://www.iu.edu/covid/faq/index.html#vaccine-req (last visited June 17, 2021)

30. These Extra Requirements apply to all types of exemptions, regardless of which exemption an individual qualifies for. *Id*.

31. There are no exemptions from these Extra Requirements for those who qualify for a religious or medical exemption. *See infra* ¶¶ 197, 199. There is no exemption from wearing a face mask in public spaces. *Id*. There is no exemption from participating in the mandatory twice a week mitigation testing. *Id*.

32. If a person with an exemption is discovered not wearing a face mask or does not participate in the mitigation testing, they face "disciplinary action up to and including dismissal or termination from the university." *Id*.

33. If a person chooses to receive the vaccination, IU requires that such person use "IU's COVID-19 vaccine report form to attest that they are vaccinated and report all doses of [the] vaccine." Indiana University, *COVID-19 Vaccine*, https://www.iu.edu/covid/prevention/covid-19-vaccine.html (last visited June 17, 2021). The form should be completed after each dose. *Id*; *see also* Indiana University, COVID-19 Frequently Asked Questions, https://www.iu.edu/covid/faq/index.html#vaccine-req (last visited June 17, 2021) ("All students, faculty and staff will need to report their vaccine using IU's COVID-19 vaccine self report form. As part of this process, you will need to know the dates of your vaccine dose(s) and can upload a photo or scan of your verified vaccine card received at your vaccine appointment (for example, CDC card) to be entered in the incentive program.").

34. Alternatively, the reporting individual can upload a copy of their vaccine documentation to be eligible to be entered into IU's incentive program. Indiana University, *COVID-19 Vaccine*, https://www.iu.edu/covid/prevention/covid-19-vaccine.html (last visited June 17, 2021). "In most cases, this [documentation] will be a photo or scan of the CDC card [received at the] vaccination appointment that notes the date and type of vaccine [ ] received." *Id*.

35. IU's incentive program includes: a student parking permit, bookstore giftcard, on-campus dining credit, Apple watch, AirPods Pro, JBL speaker, Yeti cooler, credit for full-time in-state tuition, and season tickets for the Colts or Indiana Repertory Theatre. Indiana University, *Get vaccinated, win prizes*, https://www.iu.edu/covid/prevention/incentive-program.html (last visited June 17, 2021).

2. Decision to Implement IU's Mandate

36. IU's Mandate came from the recommendation of IU's Restart Committee. *Indiana University Restart Committee Recommendations For Fall 2021* (May 26, 2021), attached as Exhibit 4.

37. The IU Restart Committee was charged by IU President Michael McRobbie with delivering recommendations and advice on how to restart the entire university's "normal" pre-pandemic operations. *Id*. at 4. Executive Vice President and Dean of the School of Medicine Jay Hess was the chair of the Restart Committee. *Id*.

38. The Restart Committee's report does not provide a clear process as to how the Committee came to the decision to recommend IU's Mandate. *See generally Indiana University Restart Committee Recommendations For Fall 2021* (May 26, 2021), attached as Exhibit 4. However, it

does establish that "[i]n developing recommendations for the 2021 Fall semester, we are operating under the *assumption* that the vast majority of our constituents will be vaccinated, allowing us to achieve herd immunity in our community." *Id*. at 7 (emphasis added).

39. No explanation for this assumption is given. Nor is there any explanation as to why IU's Mandate is needed if the vast majority of students will already be vaccinated, allowing IU's community to achieve herd immunity.

40. Without evidence to the contrary, it appears the Restart Committee arbitrarily decided that IU's Mandate would be necessary due to an unsupported premise.

41. The Restart Committee did not explain why it was necessary to implement IU's Mandate, the provisions of which far exceed those imposed by the CDC, state and county authorities on the general public, and other universities. *See infra* Parts I.B.2.–I.B.6. (detailing the requirements for each).

42. No other details have been released by the Restart Committee. None of their meeting minutes, records, or decision-making processes have been released to the IU community or public at large.

43. Plaintiffs' counsel filed a public records request, requesting copies of all public records related to IU's decision to implement IU's Mandate. To date, no documents have been provided.

B. Context Surrounding IU's Mandate

1. IU's Mandate is Contrary to the FDA Emergency Use Authorization

44. Currently, all three publicly-available COVID vaccines have only "Emergency Use Authorization" status. These COVID vaccines are not vaccines licensed by the Food and Drug

Administration ("FDA"), as they have not received full FDA approval.

45. A drug classified under "Emergency Use Authorization" is a drug authorized by the Secretary of Health and Human Services for the duration of an emergency under 21 U.S.C.A. § 360bbb-3.

46. As a matter of law, a drug given Emergency Use Authorization (EUA) status is one not already approved or licensed under the Public Health Service Act. 21 U.S.C.A. § 360bbb-3.

47. A drug receives EUA status once the Secretary, in consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention, concludes that (1) "that an agent . . . can cause a serious or life-threatening disease or condition;" (2) it is reasonable to believe the drug may be effective in diagnosing, preventing, or treating, the agent, and the known benefits of taking the drug outweigh the known risks; and (3) "that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition[.]" 21 U.S.C.A. § 360bbb-3©

48. A vaccine authorized under Emergency Use Authorization requires complete, informed, and voluntary consent. Indeed, as a condition of authorization under the Emergency Use Authorization provisions, the Secretary is required:

> "to ensure that individuals to whom the product is administered are informed—
> (I) that the Secretary has authorized the emergency use of the product;
> (II) *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
> (III) *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.A. § 360bbb-3(e)(1)(A)(ii)(I)-(III) (emphases added).

49. Consequently, all COVID vaccines currently available under EUA can only be administered to individuals in accordance with 21 U.S.C.A. § 360bbb-3(e)(1)(A)(ii)(III), which requires the informed consent of the consumer before they receive the vaccination and the option to refuse or accept the drug.

50. The statute requires and, if followed, produces *medical* informed consent—consent based on medical information from medical providers. The "consequences" of refusing the product that are considered *and for which consent is secured* are medical consequences, not other types of consequences, like loss of employment or virtual expulsion from school.

51. The threat of virtual expulsion from school for students who refuse to take the vaccine and who do not qualify for an exemption is not an attempt to garner consent—it is coercion. In other contexts, even subtle, implied threats cannot constitutionally support "consent." *Schneckloth v. Bustamonte*, 412 U.S. 218, 228 (1973) (coerced police searches unconstitutional); *see also*, *Stolt-Nielsen S.A. v. AnimalFeeds Int'l Corp.*, 559 U.S. 662, 681 (2010) (arbitration "is a matter of consent, not coercion").

52. While IU is not a provider and is not directly subject to the informed consent statute, the principles supporting EUA itself, as well as the informed consent law, supports voluntary informed consent from IU students—not coercion from IU's administration.

53. Accordingly, the same processes should be used, and consents obtained, when suggesting that students get a vaccine that has only been approved for emergency use.

54. IU's Mandate is contrary to these principles, processes, and consents. It does not inform

students that (1) the vaccines are only authorized for emergency use, (2) that there are "significant known and potential benefits and risks of such use" (or "the extent to which such benefits and risks are unknown") or (3) that students have the "option to accept or refuse administration of the product[.]"

55. Contrary to the requirements imposed the general public, no IU student is given the option to accept or refuse the vaccine, it is mandated.

2. IU's Mandate is Contrary to Modern Medical Ethics

56. IU's Mandate is contrary to the fundamental tenet of medical ethics which require voluntary and informed consent for any procedure, or drug that imposes a medical risk to an individual. "A person may freely choose to accept medical risks for the benefit of others . . . we don't harvest organs without consent, even if doing so would save many lives. Those who make such sacrifices for others must truly be volunteers, not conscripts drafted by college administrators." Aaron Kheriaty and Gerard V. Bradley, *University Vaccine Mandates Violate Medical Ethics*, WALL STREET JOURNAL (June 14, 2021, 12:47 PM), https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited June 18, 2021).

57. In some circumstances, our society has resolved this medical ethics quandary in favor of mandatory vaccines. But it is critical to look at the specific contexts in which this has occurred.

58. In elementary schools, pediatric vaccines are mandatory for illnesses that *pose significant medical risks to those children*, like polio or measles. *See id.* Likewise, colleges usually require its students to have been vaccinated against these illnesses.

59. The risks of side effects and serious complications from these types of mandatory

vaccines are generally known due to long-time use and years of research on the specific population in question. The risks of serious illness or death due to the diseases far outweighs the known risks of the vaccines to those same diseases.

60. Here, the risk of serious morbidity and mortality from COVID for those under 30 are close to zero. *Id.*; *see also*, Part I.C.2. The known and unknown risks associated with COVID vaccines, particularly in those under 30, outweigh the risks to that population from the disease itself, by any rational measure.

61. For instance, "a June 10 review by the FDA's Vaccines and Related Biological Products Advisory Committee indicated an excess risk for heart inflammation, especially in men 30 and younger." Kheriaty, *supra.*

62. Forced COVID vaccinations are also imposed on "populations that were deliberately excluded from clinical trials," such as patients who have recovered from COVID, as well as pregnant and breast-feeding women. *Id.* Thus, any risks to them were completely unknown.

63. People with higher risks of serious COVID complications, such as individuals over 60 and people with underlying health conditions, are not required to be vaccinated and can choose to take the vaccine to protect themselves, if they wish.

64. The much smaller subset of people who are at higher COVID risk and who cannot safely receive the vaccine can mitigate their risks by practicing social distancing and wearing a mask.

65. "Protection of others," especially in the COVID context, does not relieve our society from the central canon of medical ethics requiring voluntary and informed consent.

66. The FDA requirement of voluntary and informed consent is based on the medical ethics. However, history is replete with societies which violated this central tenet of medical ethics. In 1932, the United States did not receive voluntary and informed consent from African Americans for a study in conjunction with the Tuskegee Institute on syphilis. The Tuskegee Study intentionally refused to reveal to the participants that they had syphilis, intentionally withheld widely available treatments, like penicillin, from them and intentionally failed to get their informed consent to participate in the study. *The* Centers for Disease Control and Prevention, *U.S. Public Health Service Syphilis Study at Tuskegee Timeline*, https://www.cdc.gov/tuskegee/timeline.htm (last visited June 18, 2021).

67. It took *forty years* for the U.S. government to put an end to the Tuskegee Study. *Id.* The Tuskegee Study prompted then-President Bill Clinton to state, "with [scientific and technical changes] we must work harder to see that as we advance we don't leave behind our conscience. No ground is gained and, indeed, much is lost if we lose our moral bearings in the name of progress." Pres. Bill Clinton, *Apology For Study Done in Tuskegee* (May 16, 1997), https://clintonwhitehouse4.archives.gov/textonly/New/Remarks/Fri/19970516-898.html (last visited June 18, 2021).

68. Of course, the historical example of the Tuskegee Study differs from IU's Mandate because IU has no intent to risk harm to its students and they are not conducting a "study." And Plaintiffs do not claim otherwise. However, However, IU's Mandate does not provide for voluntary and informed consent to the taking of the vaccine, a fundamental tenet of medical ethics, which the Tuskegee Institute also failed. Thus, IU's Mandate is contrary to modern

medical ethics.

3. IU's Mandate is Contrary to CDC's Recommendations

69. The CDC guidelines for unvaccinated people remain largely unchanged from when the pandemic officially began on March 11, 2020. Currently, the CDC's guidance for unvaccinated people is to wear a mask, social-distance at least six feet apart from other individuals, avoid any sort of crowd whether it be outside or inside, and sanitize often. *See* Center for Disease Control, *Guidance for Unvaccinated People: How to Protect Yourself and Others*, Updated June 11, 2021, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html (last visited June 18, 2021).

70. Furthermore, the CDC suggests that people get vaccinated, but does *not* require it. *Id*.

71. IU's Mandate is contrary to CDC recommendations, as the CDC simply suggests that individuals get vaccinated and use other protective measures. The CDC does not recommend *requiring* any individual to be vaccinated.

4. IU's Mandate is Contrary to Indiana State Requirements.

72. The current guidelines for Indiana were established in Governor Holcomb's latest executive orders. 2021 *Ind. Exec. Order 21-14* (May 28, 2021), https://www.in.gov/gov/files /Executive-Order-21-14-Fiftenth-Renewal-of-Emergency-Declaration.pdf (last visited June 18, 2021) and 2021 *Ind. Exec. Order 21-15* (May 28, 2021) https://www.in.gov/gov/files/Executive-Order-21-15-Continuation-of-Health-and-Welfare-Provsions.pdf (last visited June 18, 2021).

73. In *Order 21-14*, the Governor rescinded most statewide guidelines for COVID. However, several statewide guidelines remain in place temporarily. *See* Amelia Pak-Harvey,

Gov. Eric Holcomb extends health emergency, lifts some requirements starting in June, Indianapolis Star, (May 28, 2021), https://www.indystar.com/story/news/politics/2021/05/28/indiana-gov-holcomb- renews-health-emergency-lifts-some-requirements/5248601001/ (last visited June 18, 2021).

74. General requirements for all Hoosiers are to follow CDC guidelines depending on whether an individual is vaccinated or unvaccinated. *Order 21-15* at 3.

75. The State encourages anyone who has not obtained a vaccine to do so. *Id.* at 3.

76. Furthermore, the State still encourages an individual to be tested for COVID if they show its symptoms, regardless of vaccination status. *Id*. at 3.

77. Those who have not obtained a vaccination are still "encouraged" to socially distance themselves, but there is no longer a requirement to do so. *Id.* at 4.

78. Lastly, face-masks are no longer required in state facilities, except for anyone in State facilities ran by the Department of Corrections, State Hospitals, the Indiana Veterans Home, and the Indiana Law Enforcement Academy. *Id*. Masks are also required at COVID testing or vaccination sites and all K-12 educational facilities. *Id.*

79. However, Governor Holcomb has announced that "[a]ll directives in executive orders which have continued throughout the public health emergency will be rescinded and cease on June 30." State of Indiana, *Gov. Holcomb Signs COVID-19 Executive Orders* (May 28, 2021), https://events.in.gov/event/gov_holcomb_signs_covid-19_executive_orders_4054?utm_campaign=widget&utm_medium=widget&utm_source=State+of+Indiana (last visited June 20, 2021).

80. The State of Indiana has not issued a vaccination mandate.

81. The State of Indiana has not even issued a vaccination mandate for its State employees.

82. Indiana does not require that anyone show proof of vaccination. Such proof would violate State law. *See infra* Part I.B.7.

83. IU's Mandate is contrary to Indiana recommendations, going significantly further than any recommendations from the State and violating State law in the process, by requiring that students prove their vaccination status.

5. IU's Mandate is contrary to Allen County, Marion County, and Monroe County's Recommendations

84. While IU has multiple campuses and contacts across the State, three of the bigger locations are in Allen County, Marion County, and Monroe County. The recommendations for these counties are discussed in turn.

85. Allen County has no COVID requirements for its residents. Allen County Department of Health, Health Commissioner Recommends County Residents Continue COVID-19 Precautions (Apr. 1, 2021), https://www.allencountyhealth.com/health-commissioner-recommends-county-residents-continue-covid-19-precautions/ (last visited June 18, 2021) ("the Department will not implement any local restrictions at this time.").

86. Allen County is recommending that residents continue to wear masks, social distance, sanitize regularly, stay home when sick, get vaccinated, etc. *Id*.

87. Allen County is not requiring its residents or county employees to get vaccinated. And it is not requiring any proof of vaccination status. *Id*.

88. Marion County has lifted the mask mandate for vaccinated persons. Marion County Public Health Department, *Public Health Order 12-2021* (June 8, 2021), https://www.wishtv.co

m/wp-content/uploads/2021/06/Community-Updated-Final-PHO-12-2021-for-June-8-2021.pdf (last visited June 18, 2021). It still requires masks for non-vaccinated persons. *Id*. Marion County encourages social distancing, frequent sanitizing, vaccination, etc. *Id*. It limits large gatherings and capacity for certain places, like bars, restaurants, and nightclubs. *Id*.

89. Marion County is not requiring its residents or county employees to get vaccinated. And it is not requiring any proof of vaccination status. *Id*.

90. Monroe County has rescinded any mask requirements and the limitations on gatherings of people. Dr. Thomas Sharp, Monroe County Health Department, *COVID-19 Health Order/ Regulation will be Rescinded Starting Monday, May 17* (May 14, 2021), https://www.co.monroe.in.us/egov/documents/1621029168_52145.pdf (last visited June 18, 2021). No other restrictions have been issued by the county government since.

91. Monroe County is not requiring its residents or county employees to get vaccinated. And it is not requiring any proof of vaccination status.

92. No local governments in Indiana have issued a vaccination mandate for their residents.

93. No local governments in Indiana has even issued a vaccination mandate for local county employees.

94. IU's Mandate is contrary to applicable county requirements—going significantly further than any of the relevant counties' recommendations and requirements.

6. IU's Mandate is Contrary to other Public Universities

95. No other public university in the State of Indiana has issued a vaccination mandate. Indiana University is the sole public education institution to require the Vaccine. As a result,

students attending Indiana University are treated differently and unequally as a result of IU's Mandate.

96. Ball State University does not have a COVID vaccination mandate. Instead, Ball State University simply "encourage[s] all to adhere to essential protective behaviors such as wearing face coverings, physical distancing, maintaining proper hygiene, and receiving the COVID-19 vaccine as they become eligible[.]" Ball State University, *Cardinals Care*, https://bsu.edu/about/administrativeoffices/emergency-preparedness/pandemicfluprep/coronavirus/cardinals-care (last visited June 18, 2021).

97. Indiana State University does not have a COVID vaccination mandate. Indiana State University is simply encouraging "students living in residence halls and apartments on campus . . . to get vaccinated." Indiana State University, *Student FAQs*, https://www.indstate.edu/sites/default/files/media/student-covid-faq-21-22.pdf (last visited June 18, 2021). Indiana State also stated that "every individual is expected to take responsibility for their own health and safety and act in a manner that demonstrates respect and consideration for others around them." Indiana State University, *Students and Families*, https://www.indstate.edu/covid/students-families (last visited June 18, 2021).

98. Purdue University does not have a vaccine mandate. Purdue's current vaccine policy is to strongly encourage students to get vaccinated and to document their status. Purdue University, *Vaccine Information*, https://protect.purdue.edu/vaccine-information/ (last visited June 18, 2021).

99. Ivy Tech Community College does not have a vaccine mandate. Indiana's largest community college system is only encouraging students to get vaccinated. Ivy Tech Community

College, *Current COVID-19 Policies*, https://www.ivytech.edu/coronavirus.html (last visited June 18, 2021).

100. The University of Southern Indiana does not have a vaccine mandate. It is only encouraging, but not mandating, that students be vaccinated. University of Southern Indiana, *COVID-19 (coronavirus) Information*, https://www.usi.edu/covid-19/ (last visited June 18, 2021).

101. Vincennes University does not have a vaccine mandate. The university is simply encouraging students to get vaccinated. Vincennes University, *Frequently Asked Questions*, https://www.vinu.edu/covid-19-faq (last visited June 18, 2021).

102. Indiana University stands alone as the sole public university in Indiana with a vaccine mandate. *See* Shari Rudavsky and Isaiah Seibert, *Here's which Indiana colleges and universities will require COVID-19 vaccines this fall*, Indianapolis Star (May 21, 2021), https://www.indystar.com/story/news/education/2021/05/21/iu-requiring-covid-vaccine-ball-state-iupui-purdue-notre-dame/5207192001/ (last visited June 18, 2021).

7. IU's Mandate Violates Indiana's Ban on Vaccine Passports

103. Under Indiana law, state and local units are prohibited from requiring or issuing vaccine "passports" that indicate an individual's COVID immunization status. IC § 16-39-11-5.

104. Legislative intent to prevent the state from requiring vaccine passports can be inferred from Representative Jacob's comments on the House floor, "The thought of a state mandating that people take a vaccine that is still experimental according to the manufacturers of the vaccine would be considered a gross violation of the individual freedom of Hoosiers." Taylor

Dixon, *Indiana government will be prohibited from requiring 'vaccine passports' under new amendment*, TheStateHouseFile.com (Apr. 22, 2021), http://thestatehousefile.com/indiana-government-will-be-prohibited-from-requiring-vaccine-passports-under-new-amendment/ (last visited June 18, 2021).

105. In a recent opinion, Indiana Attorney General Todd Rokita advised the Vaccine Passport Law applies to public colleges and universities like IU because they are "arm[s] of the state." State of Indiana Office of the Attorney General, *Official Opinion 2021-1 on University Policies on COVID-19 Vaccination* (May 26, 2021) ("Opinion Letter or "Op. Letter") attached as Exhibit 5.

106. Attorney General Rokita made clear that the Vaccine Passport Law does not prohibit an entity from requesting proof of COVID immunization status, *provided no negative consequence arises from not producing the record*. Op. Letter, Exhibit 5, at 4 (emphasis added).

107. As shown above, every IU student is required to be vaccinated for COVID, unless they qualify for an exemption. But it is not enough for an IU student to merely *receive* the COVID vaccine—he or she "will need to report their vaccine using IU's COVID vaccine self report form." *See* Indiana University, *Frequently Asked Questions*, https://www.iu.edu/covid/faq/index.html#vaccine-req (last visited June 18, 2021). Therefore, IU mandates not only the vaccine, but also mandates the student *prove* his or her COVID immunization status.

108. IU students who fail to provide proof of their COVID immunization status (or who have not been granted an exemption) will suffer severe negative consequences in direct violation of the Vaccine Passport Law. *See supra* Part I.A.1.

109. In short, if a student doesn't provide IU with his or her COVID immunization status, IU virtually expels that student. Virtual expulsion from school for refusing to provide COVID immunization status is a "negative consequence" that directly violates Indiana law.

110. IU's Mandate "unquestionably violates the new law." Op. Letter, 7.

C. Current Risk to IU Students of COVID Infection and Adverse Outcomes

1. Current State of the Pandemic

111. The pandemic is virtually over. The CDC recently reported the lowest number of cases since March of 2020 (the beginning of the COVID pandemic). Sam Baker & Andrew Witherspoon, *COVID-19 cases hit lowest point in U.S. since pandemic began*, AXIOS (June 3, 2021), https://www.axios.com/coronavirus-cases-infections-vaccines-success-fa7673a1-0582-4e69-aefb-3b5170268048.html (last visited June 20, 2021).

112. In Indiana, Governor Holcomb has already declared the end of the COVID emergency on June 30, when nearly all State COVID restrictions will end. *See* ¶ 79.

113. According to a report from Harvard doctors, a pandemic is over when herd immunity is reached, which they define as at least 70% of the population either being vaccinated or exposed to the virus. Alvin Powell, *Vaccines can get us to herd immunity, despite the variants*, HARVARD GAZETTE (Feb. 25, 2021), https://news.harvard.edu/gazette/story/2021/02/vaccines-should-end-the-pandemic-despite-the-variants-say-experts/#:~:text=A%20Harvard%20immunologist%20said%20current,fight%20against%20the%20disease.

114. Further, according to Dr. Peter McCullough who has extensively researched COVID and its treatments, herd immunity is calculated by a specific formula.

115. Dr. McCullough's formula is as follows: ((CC*6) + V + (.15*P)) ÷ P = HIN

CC= COVID cases in the state
6= the current CDC multiplier[1]
V= number of vaccinated in the state
15%= of the total people in the state, this represents the number of people in a given state that will not get COVID
P=Population of a state (i.e. Indiana)
HIN=Herd Immunity Totals

116. According to Dr. McCullough, you take the total cases of COVID in Indiana (753,000[2]) times 6—this equals 4,518,000—then add the total number of vaccinated (2,880,635[3]), and finally add 15% of the population (1,009,800), which equals 8,408,435, as shown below:

(753,000*6) + 2,880,635 + (.15*6,732,000) = 8,408,435

4,518,000 + 2,880,635 + 1,009,800 = 8,408,435

117. If you add all these numbers together you get 8,408,435, which you then divide by the total population of Indiana (6,732,000[4]), which equals 125% of the population.

8,408,435 ÷ 6,732,000 = 125%

118. This number is over 100% due to the overlap of people who were infected with COVID and also received the vaccine, so they are counted twice. While the number of people in

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[1] Centers for Disease Control and Prevention, Estimated Disease Burden of COVID-19 (May 19, 2021), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

[2] Indiana State Department of Health, *Indiana COVID-19 Dashboard and Map* (June 18, 2021), https://www.coronavirus.in.gov/2393.htm (last visited June 20, 2021).

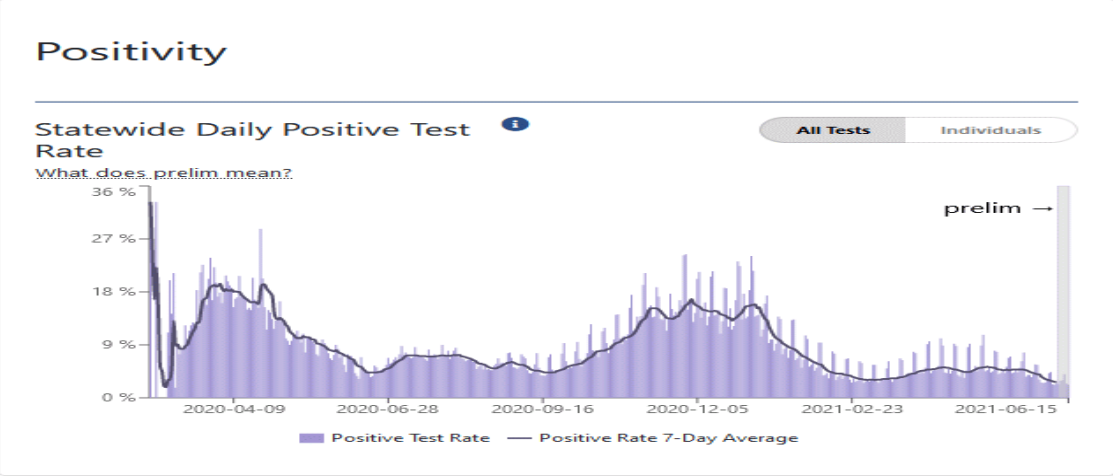
[3] Indiana State Department of Health, *Vaccine Dashboard*, (June 18, 2021), https://www.coronavirus.in.gov/vaccine/2680.htm (last visited June 20, 2021).

[4] United States Census, *QuickFacts Indiana* (July 1, 2019), https://www.census.gov/quickfacts/IN (last visited June 20, 2021).

this group is not known,[5] the percentage of overlap would have to be over 50% to get below the number for herd immunity to fall below 70%, which is very unlikely.

119. Additionally, infection rates continue to decline. According to the official Indiana COVID numbers, the infection rate was a mere 2.7% during the week of June 2, 2021, and it continues to decline daily.

Table A.



Indiana State Department of Health, *Indiana COVID-19 Dashboard and Map* (June 18, 2021), https://www.coronavirus.in.gov/2393.htm.

120. The June 14, 2021, infection rate was only 2.4%. *Id.*

121. As the numbers continue to decline, such draconian measures as requiring all students to be vaccinated is not reasonable.

2. Risk to the College-Age Group from a COVID Infection

122. Moreover, as of May 30, 2021, the positivity test rate for new COVID cases at IU-

[5] There is no specific data from the CDC or the Indiana Department of Health detailing how many people have had both.

Bloomington was 0%. Indiana University, *IU Bloomington COVID-19 Testing Dashboard*, https://www.iu.edu/covid/dashboard/bloomington (last visited June 20, 2021). The highest IU infection rate ever was 7.51% on August 30, 2020, and it has steadily declined since then with no indication of a new wave. *Id*.

123. The current risk of getting COVID is very low, and college and graduate students do not generally spread it.

124. The lack of so called "super spreader events" further shows that the pandemic is over. This generally occurs where large masses of people gather in close quarters and the virus spreads rapidly and easily.

125. However, the Indianapolis 500 recently occurred and there were over 135,000 fans in the stadium. Vocal opponents of the event said that there would be a huge uptick in COVID cases.

126. However, since the event on May 30, 2021, there has been a continued decline of COVID in Indiana. *See* **Table B** COVID-19 Cases Continue to Decline after Indy 500, attached as Exhibit 6.

127. This is because large gatherings are not the problem. Epidemic spread of COVID, like all other respiratory viruses, notably influenza,[6] is driven by symptomatic persons; asymptomatic spread is trivial and inconsequential.

128. A meta-analysis of contact tracing studies published in The Journal of the American Medical Association showed asymptomatic COVID spread was 0.7%. Zachary J.

[6] Eleni Patrozou & Leonard A. Mermel, *Does Influenza Transmission Occur from Asymptomatic Infection or Prior to Symptom Onset?*, 124 Pub. Health Rep. 193 (2009).

Madewell, PhD; Yang Yang, PhD; Ira M. Longini Jr, PhD; M. Elizabeth Halloran, MD, DSc; Natalie E. Dean, PhD, *Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis*, JAMA Network Open, available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102 (last visited June 20, 2021).

129. Accordingly, a rational and ethical prevention measure to reduce the spread of COVID is a simple requirement, as part of formal policies, that persons with active symptomatic, febrile (feverish) respiratory illnesses, like COVID, should isolate themselves. Indeed during the H1N1 influenza A pandemic, fully open, unmasked college campuses were advised by federal health officials, *"Flu-stricken college students should stay out of circulation"* and *"if they can't avoid contact they need to wear surgical masks."* Great Falls Tribune, *Advice: Flu-stricken college students should stay out of circulation*, August 21, 2009, page 5, section A, available at https://www.newspapers.com/image/243611045.

130. Specifically in Monroe County, where one of IU's campuses is located, only four cases per 100,000 people have been reported for the past seven days, and statistically there has been less than one death per 100,000 people. CNNhealth, *Tracking Covid-19 cases in the US*, https://www.cnn.com/interactive/2020/health/coronavirus-us-maps-and-cases/ (last visited June 20, 2021).

131. Despite a high frequency of COVID infections, as determined by standard testing, serious COVID cases among college and graduate students is a rare event. Brown University physician epidemiologist, Andrew Bostom, MD, MS, compiled data from 100 major university and college COVID data dashboards, in conjunction with national and local news reports of

campus-related hospitalizations, August 2020 through the November 2020, Thanksgiving holiday break (11/22/20).

132. The COVID positive tests and related hospitalizations from 100 universities/ colleges, from August 2020–November, 2020 are detailed in **Table C**, attached as Exhibit 7.

133. As depicted in Table C, among students on campus during this period, even though there were 139,000 positive COVID tests, there were a mere 17—typically short-term— reported COVID hospitalizations. This was driven by a cluster of seven hospitalizations from Dayton University, i.e., only 0.012% of total positive tests resulting in hospitalization.

134. Within this large sample, there were zero medically-confirmed, albeit one possible, COVID related death. This very reassuring data accrued in the absence of any COVID vaccination of the student population.

135. Importantly, as shown by this data, no one has died from COVID at Indiana University and only one person was hospitalized—even at the peak of the pandemic. The risks for this age group to developing serious side effects from COVID is extremely low. Studies show that there is only a .0002% chance of dying from COVID for people ages 20-49.

136. Further, the CDC has released charts depicting the risks by age, as shown below.

Table D.

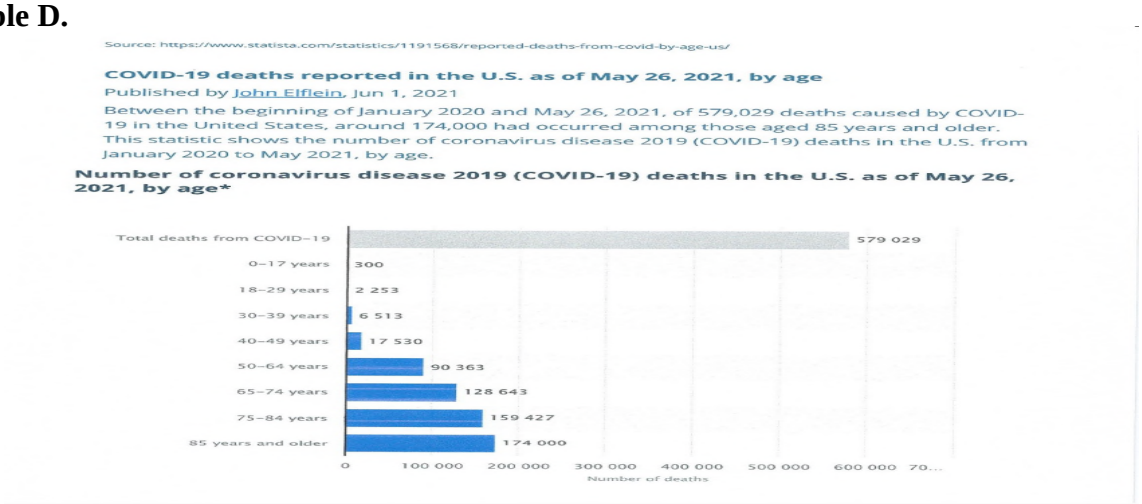
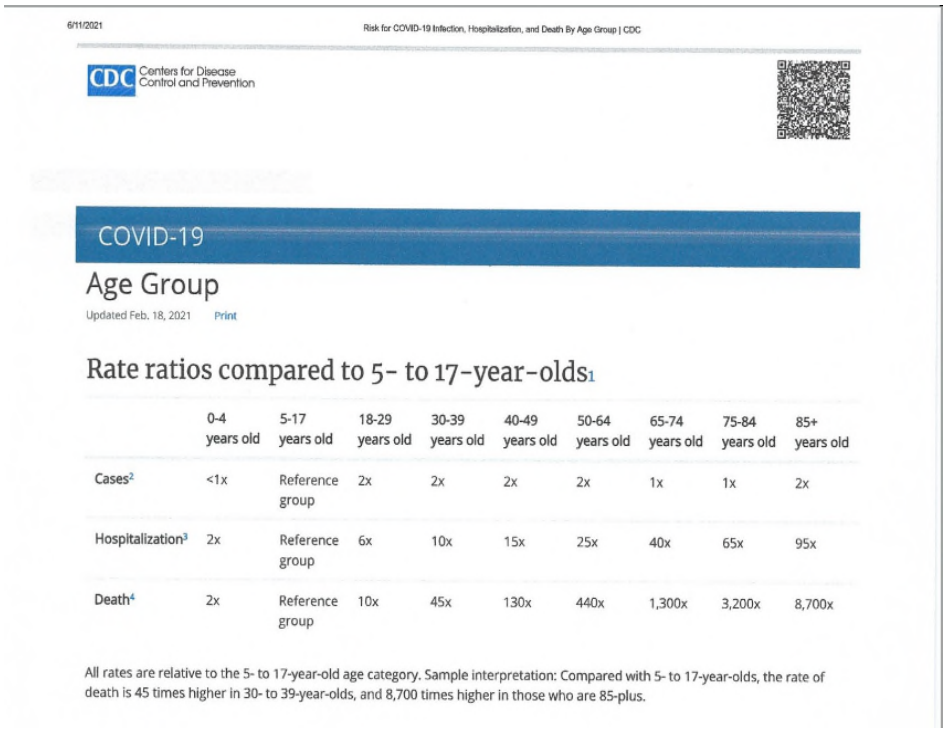


Table E.



137. These charts (Tables D and E) show the minimal risk 18-29 year olds face across the United States. For example, for every one 18-29 year old that dies from COVID, 4.5 30-39 year olds die, 13 40-49 year olds die, 44 50-64 year olds die, 130 65-74 year olds die 320 75-84 year olds die, and 870 over 85 die.

138. These studies do not take into account pre-existing conditions and co-morbidities, which greatly increase the likelihood of death in COVID patients. The people who are at the highest risk and have the greatest need for the vaccine are those over the age of fifty. The risk for young people is near minuscule with the achievement of herd immunity and highly effective treatments.

139. As shown, according to the CDC, no 18-29 year olds have died from COVID in 2021 in Indiana.

140. The lower risks associated with catching and treating COVID make IU's Mandate unreasonable.

141. Further, college students are not the spreaders of the virus to the community. There was a recent study from Dr. Arnold and colleagues that reported the results of a longitudinal serosurvey (blood sampling) of community residents in Centre County, Pennsylvania, home to Pennsylvania State University, University Park campus. *See* Callum R K Arnold, Sreenidhi Srinivasan, Catherine M Herzog, Abhinay Gontu, Nita Bharti, Meg Small, Connie J Rogers, Margeaux M Schade, Suresh V Kuchipudi, Vivek Kapur, Andrew Read, Matthew J Ferrari, *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. 19, 2021), available at https://pubmed.ncbi.nlm.nih.gov/33619497/ (last visited June 20, 2021).

142. The return of approximately 35,000 students to the campus in August 2020 increased the county population size by nearly 20%. *Id*. Over 4,500 cases of COVID infections were detected among the student population during the Fall 2020 term (before and just after

student return). *Id*. Between August 7, 2020, and October 2, 2020, these investigators enrolled community residents and tested their serum for the presence of anti-Spike Receptor Binding Domain (S/RBD) IgG (a class of immunoglobulin "antibodies"), to confirm prior COVID exposure. *Id*. This was repeated in the same community during December 2020 (after the departure of students), and seroprevalence for both sampling waves was recorded and analyzed. Moreover, returning students were enrolled in a longitudinal cohort, and IgG seroprevalence results were reported from the first wave of sampling (between October and November 2020, prior to the end of the term). Here is how Arnold and colleagues summarized their findings:

> Of 345 community participants, 19 (5.5%) were positive for SARS-CoV-2 IgG antibodies at their first visit between 7 August and 2 October. Of 625 returning student participants, 195 (31.2%) were positive for SARS-CoV-2 antibodies between 26 October and 23 November. 28 (8.1%) of the community participants had returned a positive result by 9 December. Only contact with known SARS-CoV-2-positive individuals and attendance at small gatherings (20-50 individuals) were significant predictors of IgG antibodies among returning students (adjusted odds ratio, 95% Confidence Interval: 3.24, 2.14-4.91, $p<0.001$; and 1.62, 1.08-2.44, $p<0.05$; respectively).

They concluded:

> Despite high seroprevalence observed within the student population, seroprevalence in a longitudinal cohort of community residents was low and stable from before student arrival for the Fall 2020 term to after student departure, implying limited transmission between these cohorts…The demographic shift associated with student return to campus was not associated with increased SARS-CoV-2 seroprevalence in this cohort of community residents.

Id.

143. College students face little chance of actually catching COVID and little chance of spreading it to the greater community.

144. Even if students catch the virus, the treatment of the virus has improved tremendously since the advent of COVID. Studies have shown several different treatment methods, which have proven effective. A combination of medications for a minimum of five days and acutely administered supplements used for the initial ambulatory patient with suspected and or confirmed COVID-19 (moderate or greater probability) has proven effective. Brian C Procter, Casey Ross, Vanessa Pickard, Erica Smith, Cortney Hanson, Peter A McCullough, *Clinical outcomes after early ambulatory multidrug therapy for high-risk SARS-CoV-2 (COVID-19) infection*, Reviews in Cardiovascular Medicine (December 30, 2021), available at https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.260 (last visited June 20, 2021).

Table F

Agent (drug)	**Rationale**
Zinc	Inhibits SARS-CoV-2 RNA synthesis
Hydroxychloroquine 200 mg po bid	Inhibits endosomal transfer of virions, anti-inflammatory
Ivermectin (200 mcg/kg) usual dose 12 mg po qd x 3 days	Attenuates importin α/β-mediated nuclear transport of SARS-CoV-2 into nucleus
Azithromycin 250 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Doxycycline 100 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Inhaled budesonide, Dexamethasone 8 mg IM	Treats cytokine storm
Folate, thiamine, vitamin 12	Reduce tissue oxidative stress
Intravenous fluid	Intravascular volume expansion

145. This study, conducted by Dr. McCullough, evaluated patients between the ages of 12 and 89 years. The average age was 50.5 and 61.6% were women. The study found that primary care physicians can treat COVID patients with low hospitalization and death. The study showed that administration of the medicines and supplements shown in table produces a less than 2% chance of facing hospitalization or death. As this study was done with mainly higher risk patients

at the peak of the pandemic, this is a highly successful treatment plan and just one of the many new treatments that have been used in the last year. *Id.*; *see also* National Institutes of Health, *Therapeutic Management of Adults With COVID-19* (Updated May 24, 2021), https://www.covid19treatmentguidelines.nih.gov/management/therapeutic-management/ (last visited June 21, 2021).

146. Treatment has improved so drastically for COVID that according to the CDC, there were 16 deaths in Indiana for young adults aged 18-29 in 2020, but zero in 2021. This is evidence of better treatment and less risk for college aged students.

147. Even the Restart Committee acknowledged that "The IU population to date has had a very low rates of hospitalization and death due to COVID-19 infection." *Indiana University Restart Committee Recommendations For Fall 2021*, Exhibit 4, p. 8. This was true even in the height of the pandemic.

148. As shown, the pandemic is virtually over, herd immunity has been achieved, and there is an extremely minimal risk of COVID to IU students, making IU's Mandate irrational and unreasonable.

3. Risks to the College-Age Groups for other Causes.

149. Table G shows the numbers of deaths for Indiana residents between the ages of 15 - 24 in 2019, for various non-COVID causes:

Table G

Cause of Death	Number of Indiana Residents, Ages 15 - 24
Homicide	146
Road Traffic Accidents	143
Suicide	117
Poisonings	107
Other Injuries	18
Inflammatory/Heart	13
Congenital Anomalies	11
Endocrine Disorders	10

World Life Expectancy, *Indiana Health Rankings*, https://www.worldlifeexpectancy.com/indiana-cause-of-death-by-age-and-gender (last visited June 19, 2021) (citing recent data from the CDC, NIH, and individual state and county databases for verification and supplementation for USA data).

150. Plaintiffs' counsel has submitted a public record's request to the Indiana Department of Health to supplement this data, but have not yet received a response. However, even using the general data in the table above shows the risk of death for college-age students from any number of causes unrelated to COVID far outnumber the risk of death from COVID.

D. Current Benefits and Risks to IU Students of COVID Vaccinations

1. Benefits of COVID Vaccination for IU Students

151. The vaccine has proven to be effective to prevent COVID—studies show that the Vaccines are anywhere from 70-95% effective in preventing COVID.

2. Known Risks of COVID Vaccination for IU Students

152. Even if the pandemic was still occurring, it is unreasonable for students to get a risky, relatively untested vaccine.

153. There are emerging trends showing that the vaccine is especially risky for those 18-

29.

154. Increasingly the medical community is acknowledging the possible risks and side effects including myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology, and severe allergic reaction causing anaphylactic shock. *See* Chien-Te Tseng, Elena Sbrana, Naoko Iwata-Yoshikawa, Patrick C Newman, Tania Garron, Robert L Atmar, Clarence J Peters, Robert B Couch, *Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus*, https://pubmed.ncbi.nlm.nih.gov/22536382/ (last visited June 21, 2021); Centers for Disease Control and Prevention, *Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020* (Jan 15, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm (last visited June 21, 2021).

155. For example, 19-year-old Simone Scott at Northwestern University died from complications of myocarditis after receiving her second dose of the Moderna COVID vaccine. Megan Redshaw, *19-Year-Old College Freshman Dies From Heart Problem One Month After Second Dose of Moderna Vaccine*, Children's Health Defense, (June 15, 2021) https://childrenshealthdefense.org/defender/19-year-old-dies-heart-problem-moderna-vaccine/ (last visited June 21, 2021).

156. Also, a 21-year-old in New Jersey who was required to get the vaccine to attend college in the fall developed myocarditis after receiving the vaccine and had to be hospitalized. Megan Redshaw, *Exclusive: Dad Says Life 'Not the Same' for 21-Year-Old Student Who Developed Myocarditis After Second Moderna Shot*, Children's Health Defense (June 15, 2021),

https://childrenshealthdefense.org/defender/21-year-old-new-jersey-student-severe-heart-inflammation-moderna-covid-vaccine/ (last visited June 21, 2021).

157. Multiple recent studies and news reports detail people 18-29 dying from myocarditis after receiving the COVID vaccine. According to the CDC, 475 cases of pericarditis and myocarditis[7] have been identified in vaccinated citizens aged 30 and younger. *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 June 21, 2021).

158. The FDA found that people 12-24 account for 8.8% of the vaccines administrated, but 52% of the cases of myocarditis and pericarditis reported. *Id.*

Table H

Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. (data thru May 31, 2021)

Age groups	Doses admin	Crude reporting rate*	Expected†,‡ Myocarditis/ pericarditis cases	Observed† Myocarditis/ pericarditis reports
12–15 yrs	134,041	22.4	0–1	2
16–17 yrs	**2,258,932**	**35.0**	**2–19**	**79**
18–24 yrs	**9,776,719**	**20.6**	**8–83**	**196**
25–39 yrs	26,844,601	5.0	23–228	124
40–49 yrs	19,576,875	3.0	17–166	51
50–64 yrs	36,951,538	1.3	31–314	39
65+ yrs	42,124,078	0.9	36–358	26
NR	—	—	—	11

8.8% of doses admin

n=277 reports

52.5% of total reports

* Per million doses administered; † Assumes a 31-day post-vaccination observation window; 528 reports with symptom onset within 30 days of vaccination shown; ‡ Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8.

159. The CDC even has a warning on their website now, stating that myocarditis is a potential risk for young adults, but they believe the risks outweigh the benefits even though this is a surging problem and a risk with both the Moderna and Pfizer vaccine. Centers for Disease

[7] Myocarditis is inflammation of the heart muscle, whereas pericarditis is inflammation of the sac-like tissue around the heart called the pericardium.

Control and Prevention, *COVID-19 Vaccines for Children and Teens* (Updated May 27, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/adolescents.html (last visited June 21, 2021).

160. Multiple medical studies are starting to come out detailing this problem.[8]

161. Further, milder side effects from the vaccine include changes in hormone and menstrual cycles in women, fever, swelling at the injection site, etc. Jill Seladi-Schulman, Ph.D,, *Can COVID-19 or the COVID-19 Vaccine Affect Your Period?* (May 25, 2021), https://www.healthline.com/health/menstruation/can-covid-affect-your-period#covid-19-and-menstrual-cycles (last visited June 21, 2021); Rachael K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, David R. Chadwick, *Previous COVID-19 infection but not Long-COVID is associated with increased adverse events following BNT162b2/Pfizer vaccination*, (pre-print) https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 21, 2021).

162. Additionally, there are a host of unknown side effects that may exist as the vaccine has only gone through human testing for seven months.

3. Known Risk of Administering COVID Vaccinations to IU Student who have already had a COVID Infection.

163. There is also recent research on the fact that the COVID vaccine is dangerous for

[8] *See, e.g.*, Tommaso D'Angelo MD, Antonino Cattafi MD, Maria Ludovica Carerj MD, Christian Booz MD, Giorgio Ascenti MD, Giuseppe Cicero MD, Alfredo Blandino MD, Silvio Mazziotti MD, *Myocarditis after SARS-CoV-2 Vaccination: A Vaccine-induced Reaction?*, Pre-proof, Canadian Journal of Cardiology, https://www.onlinecjc.ca/action/showPdf?pii=S0828-282X%2821%2900286-5 (last visited June 21, 2021); Jeffrey Heller, *Israel sees probable link between Pfizer vaccine and myocarditis cases* (June 2, 2021), https://www.reuters.com/world/middle-east/israel-sees-probable-link-between-pfizer-vaccine-small-number-myocarditis-cases-2021-06-01/ (last visited June 21, 2021).

those who have already had COVID.

164. A medical study of United Kingdom healthcare workers who had already had COVID and then received the vaccine found that they suffered higher rates of side effects than the average population. Rachel K. Raw, et al., *Previous COVID-19 infection but not Long-COVID is associated with increased adverse events following BNT162b2/Pfizer vaccination*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 21, 2021).

165. The test group experienced more moderate to severe symptoms than the study group that did not previously have COVID. *Id*.

166. The symptoms included fever, fatigue, myalgia-arthralgia and lymphadenopathy. *Id*.

4. Comparison of Immunity Conferred by a previous COVID Infection and by the COVID Vaccination.

167. Those who have previously had COVID do not even need the vaccine.

168. In a CDC document entitled "Questions & Answers: Vaccine Against 2009 H1N1 Influenza Virus," the CDC stated that: *"If you have had 2009 H1N1 flu, as confirmed by an RT-PCR test, you should have some immunity against 2009 H1N1 flu and CAN CHOOSE NOT (emphasis added) to get the 2009 H1N1 vaccine."* Centers for Disease Control and Prevention, *Questions & Answers: Vaccine Against 2009 H1N1 Influenza Virus*, https://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm (last visited June 21, 2021).

169. Fast forward just over a decade later, and after intensive investigation for the past 16-months, both laboratory and real world clinical data demonstrate convalescent, unvaccinated COVID immunity is just as robust as vaccine-acquired COVID immunity.

170. Indeed multiple laboratory studies conducted by highly respected U.S. and European academic research groups have reported that convalescent mildly or severely infected COVID patients who are unvaccinated can have greater virus neutralizing immunity—especially more versatile, long-enduring T- cell immunity—relative to vaccinated individuals who were never infected. *See* Athina Kilpeläinen, et al., *Highly functional Cellular Immunity in SARS-CoV-2 Non-Seroconvertors is associated with immune protection*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.05.04.438781v1 (last visited June 21, 2021); Tongcui Ma, et al., *Protracted yet coordinated differentiation of long-lived SARS-CoV-2-specific CD8+ T cells during COVID-19 convalescence*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.04.28.441880v1 (last visited June 21, 2021); Claudia Gonzalez, et al., *Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.05.11.21256578v1 (last visited June 21, 2021); Carmen Camara, et al. *Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.03.22.436441v1 (last visited June 21, 2021); Ellie N. Ivanova, et al., *Discrete immune response signature to SARS-CoV-2 mRNA vaccination versus infection*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255677v1(last visited June 21, 2021); Catherine J. Reynolds, et al, *Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose*, (pre-print), https://pubmed.ncbi.nlm.nih.gov/33931567/ (last visited June 21, 2021); Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from*

Israel, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1 (last visited June 21, 2021).

171. An enormous real world Israeli national follow-up study of ~6.4 million individuals, demonstrated clearly that naturally-acquired COVID convalescence immunity was equivalent to vaccine-acquired immunity in preventing COVID infection, morbidity, and mortality. Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1 (last visited June 21, 2021).

172. Faring at least as well as those vaccinated, 187,549 unvaccinated COVID positive persons who tested positive between June 1, 2020 to September 30, 2020, and were followed through March 20, 2021, revealed 894 [0.48%] were reinfected; 38 [0.02%] were hospitalized, a mere 16 [0.008%] hospitalized with severe disease, and only 1 [one]/187,549 died—an individual over 80 years old. *Id*.

173. The Israeli investigators concluded, *"Our results question the need to vaccinate previously infected individuals." Id.*

174. Cleveland Clinic investigators have confirmed the Israeli findings in a study of their own employees. Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Paul Terpeluk, Steven M. Gordon, *Necessity of COVID-19 vaccination in previously infected individuals*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2 (last visited June 21, 2021). They found zero SARS-CoV-2 reinfections during 5-month follow-up among n=1359 infected employees who remained unvaccinated and concluded such persons are *"unlikely to*

benefit from covid-19 vaccination." Id.

175. The risks of the vaccine and the fact that people who have already had COVID have at least equally strong protection from the virus makes IU's Mandate irrational and unnecessary.

5. Comparison of Risks of COVID Vaccinations with Vaccinations for other Infectious Diseases

176. The vaccine is also far less safe than previous vaccines like the meningicoccal meningitis vaccine that is typically required on college campuses.

177. For example, the VERS (Vaccine Adverse Event Reporting System) data from the CDC shows, for 18-29 year olds in Indiana, there have been no deaths from the meningitis vaccine.

178. The main side effects people reported are headache, injection site pain, nausea, chills, and a fever, and even these were limited as no more than fifteen of each were reported . Centers for Disease Control and Prevention, WONDER data, https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=18AD7080CCFA8D95903AEDB6B601 (last visited June 21, 2021).

Table I

Vaccine Adverse Event Reporting System (VAERS) Data for Indiana 18 to 29 Year Olds, Comparing Covid-19 and Influenza Vaccines

Vaccine-Associated Adverse Events Among 18 to 29 Year Olds in Indiana	Covid-19 Vaccines Given in <6 Months (Feb 1-June 4, 2021)[a]	Influenza Vaccines Given in >20 Years (2000-2021)[b]
Hospitalizations	23	13
Life Threatening Events	7	3
Myocarditis/Myopericarditis	7	0
Anaphylaxis/Severe Allergic Reaction	3	1*
Bell's Palsy (Facial Paralysis)	3	3
Pulmonary Embolus	1	0
Thrombocytopenia/Low Platelets	1	0
Deaths	1	0

[a,b] Using a very conservative comparison the denominator for the number of persons given influenza vaccines over 20 years would be at least 10-fold the denominator for the number of persons receiving covid-19 vaccines in the past < 6 months. Data accessed at the VAERS weblink, https://wonder.cdc.gov/vaers.html 6/12/21
* The individual received pneumococcal pneumonia vaccine in addition to influenza vaccine

179. However, in the brief time the COVID vaccines have been available, there have been many more serious symptoms and even a death reported for 18-29 year olds in Indiana. *See* Table

I.

E. Factual Allegations of Plaintiffs

180. Plaintiff Ryan Klaassen is an incoming Sophomore at IU. He has a sincerely held religious objection to receiving the COVID Vaccine. As a result, he sought and was granted a religious exemption to the Vaccine.

181. Mr. Klaassen also objects generally to the extra requirements of masks and testing applied to him. He objects to these extra requirements given their unreasonableness and the extremely minimal risk of COVID to those in his age group.

182. Plaintiff Jaime Carini is currently pursuing two doctorates at IU— a Doctor of Music (D.M.) in organ performance and literature, and a Ph.D. in musicology. She has a sincerely held religious objection to receiving the COVID Vaccine. As a result, she sought and was granted a religious exemption to the Vaccine.

183. Miss Carini also objects generally to IU's Mandate. She objects to taking the Vaccine, given the known and unknown risks associated with it, and the extremely minimal risk of COVID to her age group. Specifically, Miss Carini does not feel safe taking the Vaccine which hasn't been around long enough to know the long-term side effects.

184. Miss Carini suffers from multiple chronic illnesses. As a result of these illnesses, Miss Carini is treated by a world-renowned infectious disease doctor. Infectious disease doctors treat illnesses caused by various pathogens, including bacteria, viruses, and parasites—so diseases like HIV/AIDS, Lyme disease, malaria, West Nile virus, and COVID-19 fall under their purview.

185. When Miss Carini saw her physician at her last appointment, the doctor's parting

words were, “No vaccine for you. Let me know if you need a letter for the university.”

186. Miss Carini’s physician provided such a letter stating that “Due to the inflammatory nature of [her] illness it’s our strong medical opinion that she not receive any immunization at this time.” The physician further stated that the Vaccine could cause a relapse, impede progress, and prolong recovery.

187. Despite all this, Miss Carini was horrified to discover that IU’s Mandate prohibits Miss Carini from receiving a medical exemption, given the Mandate’s extremely narrow criteria for obtaining such exemption.

188. What is most troubling to Miss Carini about IU’s Mandate is that it allows hardly any exemptions at all. Most critically, the medical exemption form gives Miss Carini’s practitioner no room to express his expert medical opinion outside the confines of IU’s Mandate.

189. IU is saying that it has the right to insert itself into the relationship between Miss Carini and her physician. IU is saying that they know better than world-renowned infectious disease physicians what Miss Carini’s vaccination status should be. IU is saying that it has the right to change Miss Carini’s highly skilled physician’s medical treatment plan for her.

190. Miss Carini wants to be free to follow her provider’s directives. IU’s Mandate directly interferes with and contradicts the medical treatment prescribed for Miss Carini by her physician.

191. Miss Carini should not be required to put her health at risk in order to comply with IU’s Mandate and objects to doing so.

192. Miss Carini also objects to the extra requirements of masks and testing applied to

him. She objects to these extra requirements given their unreasonableness and the extremely minimal risk of severe complications or death from COVID for somebody in her age group.

193. Miss Carini has been notified by her physician that given the medications she is on (specifically, Ivermectin), she is protected against COVID. As a result, she sought an exemption from the mandatory testing, which IU denied, despite her not being at risk for COVID.

194. While Miss Carini did obtain a religious exemption, she would rather be exempt from IU's Mandate for medical reasons. Doing so ensures that she is not targeted, harassed, or bullied for her religious views. Yet, Miss Carini has not had the option to obtain a medical exemption.

195. Miss Carini does not have to option to simply transfer universities, to one which wouldn't require the vaccine or the extra requirements, due to her significant time investment in the IU doctoral programs and the fellowships she has been awarded at IU.

196. Plaintiff D.J.B. is an incoming freshman at IU. As a minor, he is represented in this case by his father and next friend, Daniel G. Baumgartner. Mr. D.J.B. has a religious objection to receiving the COVID Vaccine. As a result, he sought and was granted a religious exemption to the Vaccine.

197. Mr. D.J.B. also has a sincerely held religious objection to the extra requirements applied to him. He sought a religious exemption to these requirements but was refused. Mr. D.J.B. received a response from the IU COVID Response Team, stating that:

> Exemptions from IU's vaccine mandate for religious reasons are only available to those individuals who attest that their sincerely held religious beliefs prevent them from receiving a vaccination. Anyone who is granted an exemption on this basis is required to wear a mask at all times on IU property and is subject to routine mitigation testing. There are no

> exemptions from these masking and mitigation testing requirements. Failure to comply with masking and mitigation testing requirements will result in disciplinary action up to and including dismissal or termination from the university.

198. Mr. D.J.B. recently had a COVID antibody test which revealed that he still has antibodies. As a result, he sought a medical exemption to IU's Mandate (and attached the relevant lab results showing the antibodies). This request for medical exemption was refused.

199. The IU COVID Response Team stated that "[n]atural antibodies are not a criteria for medical exemption" and that:

> there are no exemptions from masking and mitigation testing requirements at Indiana University unless fully vaccinated. Failure to comply with masking and mitigation testing requirements will result in disciplinary action up to and including dismissal or termination from the university.

200. Mr. D.J.B. also objects generally to the extra requirements of masks and testing applied to him. He objects to these extra requirements as they are not necessary, since he already has natural antibodies. He also objects given their unreasonableness and the extremely minimal risk of COVID to those in his age group.

201. Plaintiff Ashlee Morris is an incoming 1L at the McKinney School of Law. She has a sincerely held religious objection to receiving the COVID Vaccine. As a result, Miss Morris sought and was granted a religious exemption to the Vaccine.

202. Miss Morris also has a sincerely held religious objection to the extra requirements applied to her. She tried to apply for an exemption to the masking and testing requirements but the IU COVID Response Team refused her request. Miss Morris received a substantially similar response as detailed in ¶ 197 from the IU COVID Response Team.

203. Miss Morris has worked for six years to be accepted into law school, taking the

LSAT multiple times and applying four times. After years of hard work, she accomplished her goal and was accepted into McKinney School of Law. However, if required to comply with these unreasonable requirements, she will not attend. This will result in years of hard work and money wasted.

204. Miss Morris would still like to attend McKinney School of Law if her religious objections are respected and she is not subjected to extra requirements, which make her a target for discrimination, bullying, and unwanted attention.

205. Plaintiff Seth Crowder is currently pursuing his Masters of Business Administration through the Kelley School of Business. He has a sincerely held religious objection to receiving the COVID Vaccine. As a result, Mr. Crowder sought and was granted a religious exemption to the Vaccine.

206. Mr. Crowder also has a sincerely held religious objection to the extra requirements applied to him. He tried to apply for an exemption to the masking and testing requirements but the IU COVID Response Team refused his request.

207. Plaintiff Macey Policka is a senior at IU. She has a sincerely held religious objection to receiving the COVID Vaccine. As a result, she sought and was granted a religious exemption to the Vaccine.

208. Miss Policka also objects generally to the extra requirements of masks and testing applied to her. She objects to these extra requirements given their unreasonableness and the extremely minimal risk of COVID to those in her age group.

209. Plaintiff Margaret Roth is an incoming freshman at IU. Miss Roth objects generally

to IU's Mandate. She objects to taking the Vaccine, given the known and unknown risks associated with it, and the extremely minimal risk of COVID to all age groups, especially her age group.

210. Miss Roth has a significant family history of cancer and other health conditions. Her mother passed away from cancer at 35, her sister is in treatment for Hodgkin's Lymphoma, two of her aunts suffered from early-onset breast cancer, and her great-aunt passed away from breast cancer. Her aunt suffered from Bell's Palsy. Miss Roth also suffers skin reactions from cosmetics, moisturizers, hygiene products, and often has hives/skin rashes that appear without known cause. All of this makes it much more likely that Miss Roth will suffer adverse reactions from the Vaccine. As a result, she is not willing to take the Vaccine for medical reasons. Despite this, Miss Roth does not qualify for a medical exemption under IU's extremely narrow set of exemptions.

211. Additionally, asthma runs in Miss Roth's family, so masks are also not an acceptable alternative. Nor is repeated exposure to the carcinogenic chemicals on the nasal testing swabs, especially with her family history of cancer.

212. Miss Roth should not be required to put her health at risk in order to comply with IU's Mandate and objects to doing so.

213. Miss Roth also has a sincerely held religious objection to IU's Mandate. Miss Roth has not filed for such exemption because she does not believe that it adequately protects her from IU's Mandate.

214. Plaintiff Natalie Sperazza is an incoming sophomore at IU. Miss Sperazza objects generally to IU's Mandate. She objects to taking the Vaccine, given the known and unknown risks

associated with it, and the extremely minimal risk of COVID to her age group.

215. Miss Sperazza has spent significant time researching the Vaccine and does not feel safe taking it when those in her age group are developing heart problems as a result of the Vaccine, and when the long-term side effects of the Vaccine are unknown. She believes that taking the Vaccine puts her health at risk.

216. Miss Sperazza also objects to the extra requirements of masks and testing applied to her. She objects to these extra requirements given their unreasonableness and the extremely minimal risk of COVID to those in her age group.

217. For all of the reasons shown above (*see generally* ¶¶ 17-216), all Plaintiffs object to IU's Mandate.

218. All Plaintiffs also object to the Vaccine on the basis that it has only received Emergency Authorization from the FDA. None are willing to take the Vaccine while it is only approved under that Emergency Authorization.

219. Plaintiffs should not be required to put their health at risk (given the known and unknown risks of the Vaccine) in order to comply with IU's Mandate and object to doing so.

220. Plaintiffs are irreparably harmed by IU's Mandate.

221. Plaintiffs have no adequate remedy at law.

Count I
IU's Mandate Violates Fourteenth Amendment Liberty.

222. Plaintiffs re-allege and incorporate by reference all of the allegations contained in all of the preceding paragraphs.

223. IU's Mandate violates the liberty protected by the Fourteenth Amendment to the

U.S. Constitution, which includes rights of personal autonomy and bodily integrity, *see, e.g.*, *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905), and the right to reject medical treatment, *Cruzan v. Director, Missouri Dep't Health*, 497 U.S. 261 (1990).

224. Historically, many have understood *Jacobson v. Commonwealth of Massachusetts*. 197 U.S. 11 (1905), to authorize near *carte blanche* for government to mandate vaccinations in response to pandemics on the basis that such individual liberty must yield to the common good—all with great deference to legislatures and little or no evidence contrary to their choice reviewed. So cases entitled to higher scrutiny have instead received the highly deferential *Jacobson* analysis. But even *Jacobson* was not absolute *carte blanche* because it recognized an exception where rights are violated or a mandate is unreasonable for not advancing health:

> If there is any . . . power in the judiciary to review legislative action in respect of a matter affecting the general welfare, it can only be when that which the legislature has done comes within the rule that, if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, [1] has no real or substantial relation to those objects, or [2] is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge, and thereby give effect to the Constitution.

Id. at 31 (citations omitted).

225. *Jacobson*'s analysis doesn't resemble today's jurisprudence, which has less or no deference where rights are involved and requires evidence. Since *Jacobson*, Fourteenth Amendment liberty has been recognized as strongly protecting contraception, *Griswold v. Connecticut*, 381 U.S. 479 (1965), abortion, *Roe v. Wade*, 410 U.S. 113 (1973), same-sex marriage, *Obergefell v. Hodges*, 576 U.S. 644 (2015), and refusing medical treatment, *Cruzan*, 497 U.S. 261. And *Jacobson* was part of a Progressive Era emphasis on enhancing governmental power at the expense of the individual that included a eugenics movement culminating in the infamous

decision approving involuntary sterilization in *Buck v. Bell*, 274 U.S. 200 (1927), which cited *Jacobson* as authority for its decision. *Id.* at 207. Those attitudes have since been widely repudiated along with their low valuation of individual liberty.

226. Under *today's* jurisprudence, even rational-basis review, applicable for example to economic regulations, is "not toothless." *See, e.g.*, *Mathews v. Lucas*, 427 U.S. 495, 510 (1976) (citing, e.g., *Jimenez v. Weinberger*, 417 U. S. 628 (1974); *Frontiero v. Richardson*, 411 U. S. 677, 691 (Stewart, J., concurring in judgment, Powell, J., concurring in judgment)); *Reed v. Reed*, 404 U.S. 71 (1971)). Even under rational-basis review there must be "a sufficient factual context for [a court] to ascertain some relation between [what the restriction does] and the purpose it served," *Romer v. Evans*, 517 U.S. 620, 632-33 (1996), so the judiciary definitely has power to weigh evidence considered by the legislature and hear expert testimony on competing views.[9] Thus, there must be, demonstrably, "a rational relationship to an independent and legitimate legislative end." *Id.* at 633.

227. In 2020, in light of these discrepancies between *Jacobson* and current jurisprudence, the Supreme Court implicitly narrowed the perceived breadth of *Jacobson* in *Roman Catholic Diocese of Brooklyn v. Cuomo*. 141 S. Ct. 63 (2020) (per curiam), not by mentioning *Jacobson* and expressly abrogating it, but by holding that (i) *normal* strict scrutiny applied to a Free Exercise Clause challenge to non-neutral pandemic restrictions on the number people in houses of worship, (ii) challengers had likely merits success and other injunction factors weighed in their

[9] And though *Jacobson* disallowed evidence as to the efficacy and safety of the vaccination itself, which would not be precluded under today's jurisprudence, *Jacobson*'s own stated exception to its deference would have required (and thus allowed) relevant evidence.

favor, and (iii) this justified an injunction during appeal, *id.* at 66-69. Under *Jacobson*, a highly deferential, limited-judicial-role, little-evidence-required analysis would have applied, not strict scrutiny, so without any need to mention *Jacobson* the Court simply abandoned it by applying its *current* jurisprudence. Strict scrutiny requires the government to prove its restriction to be the least restrictive means to further a compelling interest, and to do so by evidence. The normally applicable scrutiny level is applicable to challenges to restrictions under pandemic-fighting authority, i.e., not *Jacobson*'s analysis.

228. *Roman Catholic Diocese* was preceded by a similar case (church occupancy limits in the pandemic) in *Calvary Chapel Dayton Valley v. Sisolak*, 140 S. Ct. 2630 (2020) (Mem. Op.). There Justice Alito dissented, joined by Justices Thomas and Kavanaugh, noting that "at 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 as long as the medical problem exists." *Id.* at 2605. Rather, "[a]s 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." *Id.* That dissenting view was essentially adopted by *Roman Catholic Diocese*, meaning that "blunt rules" may be permitted initially, but fine-tuning to actual scientific evidence is then required—requiring an *evidence-focused* inquiry in judicial review. Applying the normally required, current jurisprudence in that case required the government to justify itself under strict scrutiny, which eschews blunt rules and mandates narrow tailoring to the least restrictive means to further a compelling interest.

229. The Seventh Circuit noted the sea-change wrought by *Roman Catholic Diocese* in

Cassell v. Snyders, 990 F.3d 539, 543, 545 (7th Cir. 2021).

230. So *Jacobson*'s analysis does not control here. States no longer have near *carte blanche* to impose restrictions in the name of preventing pandemics, Instead, the applicable scrutiny under *today's* jurisprudence applies, with evidence clearly admissible and needed to determine whether government action meets the relevant level of scrutiny. And even were *Jacobson* deemed yet viable and applicable here, it recognized an exception where restrictions violate rights or are unreasonable, e.g., by not actually promoting public health, and *Roman Catholic Diocese* eliminated *Jacobson*'s extreme deference.

231. In modern jurisprudence, fundamental-liberty burdens require strict scrutiny. *Washington v. Glucksberg*, 521 U.S. 702 (1997) ("narrowly tailored to serve a compelling state interest").

232. Refusing medical treatment is a fundamental right. The test is whether it was deemed fundamental in "our nation's history, legal traditions, and practices," *Glucksberg*, 521 U.S. at 710. The *Cruzan* majority assumed such refusal is fundamental and five Justices said it was. 497 U.S. at 287, 301, 330.

233. As mandated vaccinations are a substantial burden, IU must prove narrow tailoring to a compelling interest that *justifies mandatory vaccinations*, not any more general interest. But while government may have a general interest in mitigating COVID, the following problems reveal no narrow tailoring to any compelling interest exists. Indiana imposes no student vaccination requirement, Ind. Dept. Health, Back to School Guidance (Fall 2021),[10] and Indiana Univer-

[10] https://www.coronavirus.in.gov/files/Fall%202021%20COVID-19%20One%20Page%20Guidance%20(6.8.21).pdf (last visited June 21, 2021).

sity lacks any uniqueness to justify doing so. University students have very low risk for serious COVID illness, Part I.C.2, so IU lacks an interest in forcing vaccinations for such risks. University students pose little risk of COVID transmission to the surrounding community. *Id*. University students' higher adverse-reaction risk from COVID vaccinations versus those for influenza, Part I.D., undercuts an interest in compelling COVID vaccinations. Naturally acquired immunity from COVID is as robust as vaccine-acquired immunity, Part I.D.4., so there is no compelling interest in vaccinating those who've had COVID. Given natural and vaccine immunity, Indiana has de facto COVID herd immunity. *See generally* Parts I.C. and I.D. So IU has no compelling interest in mandating student COVID vaccination.

234. The same evidence establishes that, even if there were a compelling interest in mandating vaccinations, IU's Mandate is not narrowly tailored to such an interest. For example, a blanket mandate ignores individual factors increasing (older age, co-morbidities) or decreasing (having had COVID) students' risks to themselves or to others. Mandating vaccines for all is the sort of blunt rule perhaps appropriate at the beginning of a pandemic but not when the pandemic has faded and much more is known about the risks in light of available treatments and studies.

235. Furthermore, IU's Mandate fails modern rational basis scrutiny and under Jacobson's exemption, since IU's Mandate is "unreasonable" and "has no real or substantial relation" "to protect[ing] the public health." 197 U.S. at 31, *i.e.*, it goes "beyond what [i]s reasonably required for the safety of the public," *id.* at 28. The same evidence that shows there is no compelling interest or narrow tailoring with IU's Mandate shows that it fails even under *Jacobson*.

236. Furthermore, note the internal illogic of IU's position. In some situations it mandates

masks and distancing. For that to be rational, it must be presumed that those work for preventing virus spread. But if those work, there is no need for vaccination. IU blurs three groups: (1) those who had COVID, who need no vaccination for their sake or others'; (2) those who have COVID, who can and should be quarantined to protect others, after which these will have natural immunity; and (3) those who haven't had and don't have COVID and are unvaccinated. No protection is needed against the first two groups, other than quarantining those now affected, and no vaccine is warranted. Others can protect themselves against the third group obtaining a vaccination, if they wish, by masking and distancing. Mandating vaccination in the present state of knowledge has no real, substantial relation to protecting public health.

237. In sum, IU's Mandate is unconstitutional under both current strict-scrutiny jurisprudence and *Jacobson*'s exception.

Count II
IU's Mandate Violates Indiana's Vaccine Passport Law.

238. Plaintiffs re-allege and incorporate by reference all of the allegations contained in all of the preceding paragraphs.

239. Under Indiana law, state and local units are prohibited from requiring or issuing vaccine "passports" that indicate an individual's COVID immunization status. IC § 16-39-11.

240. IU's Mandate not only requires IU students to take the COVID vaccine, but it also requires them to prove they have taken it by filling out a form which requires them to: (1) certify they took the COVID vaccine, and (2) report the dates they received COVID vaccine doses—this violates the Vaccine Passport Law.

241. Indiana Attorney General Todd Rokita asserted the Vaccine Passport Law applies to

public colleges and universities like IU because they are "arm[s] of the state." Op. Letter Ex. 5, p. 1; *see also Severson v. Bd. of Trustees of Purdue Univ.*, 777 N.E.2d 1181, 1191-92 (Ind. Ct. App. 2002).

242. Attorney General Rokita made clear that the Vaccine Passport Law does not prohibit an entity from requesting proof of COVID immunization status, *provided no negative consequence arises from not producing the record*. Op. Letter, Exhibit 5, p. 4 (emphasis added).

243. Every IU student is required to be vaccinated for COVID, unless they qualify for an exemption. But it is not enough for an IU student to merely *receive* the COVID vaccine—he or she "will need to report their vaccine using IU's COVID vaccine self report form." *See* Indiana University, *COVID-19 Frequently Asked Questions*, https://www.iu.edu/covid/faq/index.html#vaccine-req (last visited June 17, 2021).

244. Therefore, IU's Mandate does not only require the vaccine, but also requires the student *prove* his or her COVID immunization status.

245. IU students who fail to provide proof of their COVID immunization status (or who have not been granted an exemption) will suffer severe negative consequences in direct violation of the Vaccine Passport Law.

246. "Students who fail to comply [with the vaccination mandate or an exemption and the required reporting of same] 'will have their class registration cancelled, CrimsonCard access terminated, access to IU systems (Canvas, email, etc.) terminated, and will not be allowed to participate in any on campus activity.'" *See* ¶ 21.

247. In short, if a student doesn't provide IU with his or her COVID immunization status,

IU virtually expels that student. Virtual expulsion from school for refusing to provide COVID immunization status is a "negative consequence" that directly violates Indiana law.

248. Plaintiffs Roth and Sperazza are students at IU who have not been vaccinated for COVID and who not qualify for an exemption. Therefore, they cannot provide IU's requested proof of COVID vaccination and will be subject to virtual expulsion by IU, in violation of Indiana law.

249. In sum, IU's Mandate violates Indiana's Vaccine Passport Law.

Prayer for Relief

Wherefore, Plaintiffs request the following relief:

250. Declare IU's Vaccine Mandate unconstitutional on its face;

251. Declare IU's Mandate unconstitutional as applied to each Plaintiff;

252. Enjoin IU from enforcing IU's Mandate on its face or as applied;

253. Grant Plaintiffs their costs and attorneys fees under 42 U.S.C. Section 1988 and any other applicable authority; and

254. Grant any and all other such relief as this Court deems just and equitable.

Dated: June 21, 2021

Respectfully Submitted,

/s/ James Bopp, Jr.

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District Court, Opinion and Order

Exhibit 2

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]

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[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

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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]

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[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

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[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]

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[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,

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[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]

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[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

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[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

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[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

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[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

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[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

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[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

Ex. 2

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

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[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

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[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").

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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

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[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-

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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

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[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

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[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]

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[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

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[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

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[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.

Ex. 2

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

CDC, Updated Preparedness and Response Framework for Influenza Pandemics

Exhibit 3

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™
Morbidity and Mortality Weekly Report (*MMWR*)

Updated Preparedness and Response Framework for Influenza Pandemics

Recommendations and Reports

September 26, 2014 / 63(RR06);1-9

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Summary

The complexities of planning for and responding to the emergence of novel influenza viruses emphasize the need for systematic frameworks to describe the progression of the event; weigh the risk of emergence and potential public health impact; evaluate transmissibility, antiviral resistance, and severity; and make decisions about interventions. On the basis of experience from recent influenza responses, CDC has updated its framework to describe influenza pandemic progression using six intervals (two prepandemic and four pandemic intervals) and eight domains. This updated framework can be used for influenza pandemic planning and serves as recommendations for risk assessment, decision-making, and action in the United States. The updated framework replaces the U.S. federal government stages from the 2006 implementation plan for the National Strategy for Pandemic Influenza (US Homeland Security Council. National strategy for pandemic influenza: implementation plan. Washington, DC: US Homeland Security Council; 2006. Available at http://www.flu.gov/planning-preparedness/federal/pandemic-influenza-implementation.pdf). The six intervals of the updated framework are as follows: 1) investigation of cases of novel influenza, 2) recognition of increased potential for ongoing transmission, 3) initiation of a pandemic wave, 4) acceleration of a pandemic wave, 5) deceleration of a pandemic wave, and 6) preparation for future pandemic waves. The following eight domains are used to organize response efforts within each

interval: incident management, surveillance and epidemiology, laboratory, community mitigation, medical care and countermeasures, vaccine, risk communications, and state/local coordination.

Compared with the previous U.S. government stages, this updated framework provides greater detail and clarity regarding the potential timing of key decisions and actions aimed at slowing the spread and mitigating the impact of an emerging pandemic. Use of this updated framework is anticipated to improve pandemic preparedness and response in the United States. Activities and decisions during a response are event-specific. These intervals serve as a reference for public health decision-making by federal, state, and local health authorities in the United States during an influenza pandemic and are not meant to be prescriptive or comprehensive. This framework incorporates information from newly developed tools for pandemic planning and response, including the Influenza Risk Assessment Tool and the Pandemic Severity Assessment Framework, and has been aligned with the pandemic phases restructured in 2013 by the World Health Organization.

Introduction

Planning for and responding to the range of possible consequences following the emergence of a novel influenza A virus is complex. These viruses can spread quickly and explosively worldwide, as did the influenza pandemics in 1918, 1957, 1968, and 2009 (*1*,*2*); cause limited outbreaks, such as the influenza A(H3N2) variant (H3N2v) virus in the United States associated with agricultural fairs in the summer months of 2011, 2012, and 2013 (*3*); or continue causing limited animal-to-human transmission of virus, such as the influenza A(H5N1) and influenza A(H7N9) viruses in Asia (*4*,*5*). Furthermore, novel influenza A viruses, even when transmissible in a closed setting, do not always result in a pandemic, such as the 1976 influenza A(H1N1) outbreak in Fort Dix, New Jersey, and the 2011–2013 H3N2v outbreak in the United States (*3*,*6*). Identifying and responding to this wide range of situations require systematic frameworks that describe the progression of events; weigh the risk of emergence and potential public health impact of the novel virus; evaluate the potential for ongoing transmissibility, antiviral resistance, and disease severity; and can be used to develop time-sensitive decisions about interventions (e.g., community mitigation measures, medical countermeasures, and vaccines). Preparedness and response frameworks provide a common basis for planning across different jurisdictions and ensure transparency in decisions made and actions taken.

Significant progress has been made toward developing pandemic plans, as well as preparedness and response frameworks, during the past decade. Efforts by the World Health Organization (WHO), CDC, other U.S. government agencies, and state and local jurisdictions have addressed pandemic preparedness planning. Lessons regarding gaps in U.S. influenza decision-making frameworks have become evident with each event and exercise (*7*). The recent emergence of human disease caused by H3N2v in the United States (*3*) and H7N9 in China (*5*) has demonstrated the need to align existing documents and frameworks into one useful tool that can be used to guide ongoing planning and response efforts.

Background

Frameworks describing the progression of influenza pandemics have evolved over time. The 2005 WHO global pandemic plan introduced the concept of pandemic phases (*8*). Six phases were used to describe the evolving risk of efficient human-to-human transmission as a basis for defining a pandemic.

In November 2005, the president of the United States released a national strategy for pandemic influenza (*9*), and the associated implementation plan was released in May 2006 (*10*). These documents introduced the concept of using stages to determine the response to pandemic influenza, including stage 0 (new domestic animal outbreak in an at-risk country), stages 1–3 (human outbreaks suspected, confirmed, and widespread overseas), and stages 4–6 (first case in a human in North America, spread throughout the United States, and recovery and preparation for subsequent waves). The U.S. government stages provided greater specificity for U.S. preparedness and response efforts than the WHO

phases and facilitated initial planning efforts by identifying objectives, actions, policy decisions, and message considerations for each stage. The stages provided a general overview of the approach to a pandemic response; however, detailed pandemic response planning requires a greater level of specificity to determine federal, state, and local response actions during the course of a pandemic. In addition, the stages framework presumed geographic spread from outside the United States into the United States. In 2007, CDC developed the CDC intervals, a common framework from which CDC and other federal, state, and local governments and agencies could plan and coordinate their pandemic response actions. The 2007 CDC intervals refined the stages framework in the following ways:

- Provided greater detail to reflect the progression of a pandemic, including when decisions and actions might occur
- Provided improved definitions to identify the transition points between intervals to reduce variability in interpretation
- Considered that pandemic influenza might emerge inside or outside of the United States
- Accommodated the likely asynchrony of pandemic stages and progression in different jurisdictions to allow for local, state, regional, and national actions appropriate to jurisdiction-specific conditions
- Provided a structure that allowed for planning for multiple waves

The resulting document (*Proposal for the Use of Intervals, Triggers, and Actions in CDC Pandemic Influenza Planning, 2008*) was revised, published as an appendix to the U.S. Department of Health and Human Services pandemic influenza operational plan (*11*), and used during the 2009 H1N1 pandemic to describe progression of the pandemic and to help guide the response. This report provides an update to the 2008 framework to reflect experiences with 2009 H1N1 and recent responses to localized outbreaks of novel influenza A viruses.

The revised framework also incorporates the recently developed Influenza Risk Assessment Tool (IRAT) (*12*) and Pandemic Severity Assessment Framework (PSAF) (*13*). IRAT makes an assessment of potential pandemic risk for a novel virus on the basis of the likelihood of emergence and the public health impact if it were to emerge. Emergence refers to the risk of a novel (i.e., new in humans) influenza virus acquiring the ability to spread easily and efficiently in humans. Public health impact refers to the potential severity of human disease caused by the virus (e.g., deaths and hospitalizations), as well as the impact on society (e.g., missed workdays, strain on hospital capacity and resources, and interruption of basic public services) if a novel influenza virus were to begin spreading efficiently and sustainably among humans (*12*). After a novel virus has achieved efficient and sustained transmission, PSAF can be used to characterize the potential impact of a pandemic relative to previous influenza epidemic and pandemic experiences. PSAF replaces the Pandemic Severity Index as a severity assessment tool (*13*).

In 2013, WHO released interim guidance for pandemic influenza risk management, which includes restructured WHO phases (*14*). The revised WHO phases are based on virologic, epidemiologic, and clinical data. WHO uses the phases to describe evolving situations pertaining to the circulation of novel influenza viruses. The WHO phases are distinct from declarations of either a public health emergency of international concern (*15*) or a pandemic and are not specifically aligned with national risk management decisions. In the interim guidance, WHO strongly advises countries to use local circumstances and information provided by the WHO global assessments to develop their own national risk assessments (*13*).

The framework described in this report is a revision of the 2008 CDC interim guidance (*11*) to 1) update the novel influenza virus pandemic intervals as the basis for U.S. planning efforts; 2) align the intervals with the new WHO phases; 3) add and align tools to aid in decision-making and actions throughout the progression of an event; 4) serve as recommendations for U.S. risk assessment, decision-making, and action as advised by WHO; and 5) replace the U.S. government stages with six intervals for pandemic influenza planning. This framework is designed for decision-making by federal, state, and local health authorities and is not meant to be prescriptive or comprehensive.

The framework was reviewed for accuracy, feasibility, and clarity by several stakeholders, including representatives of the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, the Association of Public Health Laboratories, the Council of State and Territorial Epidemiologists, and the National Public Health Information Coalition. In addition, feedback also was incorporated from departments and agencies across the U.S. government.

Novel Influenza A Virus Pandemic Intervals

The novel influenza A virus pandemic intervals are based on what is known about past influenza transmission and on experience from recent events (e.g., 2009 H1N1 pandemic, H3N2v in the United States, H7N9 in China, and continuing sporadic human cases of H5N1).Typically, epidemic curves are used to monitor an outbreak as it is occurring, describe the outbreak retrospectively, and document the timing of interventions relative to the acceleration and deceleration of the outbreak. Modeled epidemic or pandemic curves also can be used to describe potential events over time. Using these models for forecasting purposes might be particularly valuable for anticipating conditions and identifying actions that might flatten or otherwise attenuate the epidemic or pandemic curve.

For the purposes of responding to novel influenza viruses and potential pandemics, the six intervals (investigation, recognition, initiation, acceleration, deceleration, and preparation) represent events that occur along a hypothetical pandemic curve (Figure). Pandemic curves differ by duration and intensity depending on many factors, including the geographic area in which they occur, the season of their emergence, and related population dynamics. The WHO pandemic influenza phases, which can be used to describe and communicate worldwide disease progression, provide a general view of the emerging epidemiologic situation essentially by aggregating epidemic curves from around the world. The CDC intervals serve as additional points of reference to provide a common orientation and clearer epidemiologic picture of what is taking place and when to intervene. The intervals are flexible enough to accommodate the likely asynchrony of pandemic progression in different areas to allow for local, state, and federal actions appropriate to jurisdiction-specific conditions (e.g., a jurisdiction with cases versus a jurisdiction with no cases but that is close to an area with cases). State and local health authorities might even elect to implement interventions asynchronously within their jurisdictions by focusing early efforts on communities that are first affected. The state/local initiation, acceleration, deceleration, and preparation indicators can be asynchronous to the federal indicators (Appendix).

For state and local planning, the intervals describe the progression of the pandemic within communities and provide a detailed framework for defining when to respond with various actions and interventions at any point in a pandemic. These actions should be proportionate to the transmissibility and severity of the emerging virus. The intervals are further stratified into eight domains so that the trajectory of planning and response activities for any one domain can be more easily followed. The eight domains are incident management, surveillance and epidemiology, laboratory, community mitigation, medical care and countermeasures, vaccine, risk communications, and state/local coordination. The intervals also might be valuable as a common reference point because they can be used to link the status of a pandemic with specific interventions.

U.S. experiences during recent novel influenza events were useful for testing the concepts in the proposed intervals and the decisions and actions that were implemented during those intervals. The public health impact of novel influenza virus strains can differ substantially, both in geographic spread and mortality. For example, the 2009 H1N1 outbreak was caused by a highly transmissible novel influenza virus that emerged in North America and resulted in a pandemic (2), whereas the H3N2v virus, which also emerged in North America, caused approximately 300 cases in humans and limited outbreaks involving domestic animal-to-human transmission (3). The H7N9 outbreak was caused by a novel influenza virus that emerged outside of U.S. borders and had high mortality but has not spread to other countries thus far (5). These experiences have provided opportunities to test the validity and

usefulness of the intervals and the recommendations for public health actions triggered by each interval to ensure that they are applicable in a diverse range of scenarios.

Pandemic Interval Definitions

To define the intervals, the relationship between the timing of the broad WHO phases and the more detailed planning intervals was examined (Figure). In addition to the relationship to the WHO phases, the intervals are characterized by specific transmission-related indicators (Table) and by the types of response activities that should occur within each interval (Appendix).

Progression through the intervals is not exclusively linear. For example, identification of a novel influenza A virus does not necessitate progression to the next interval (the recognition interval) if the virus does not demonstrate the potential for ongoing transmission. Similarly, after the preparation interval, subsequent waves of outbreaks will prompt federal, state, and local public health officials to reenter the acceleration, deceleration, and preparation intervals. The duration of each pandemic interval might vary from weeks to months depending on the characteristics of the virus and the public health response.

Investigation Interval: Investigation of Novel Influenza Cases

The investigation interval is initiated by the identification and investigation of a novel influenza A infection in humans or animals anywhere in the world that is judged by subject-matter experts to have potential implications for human health (Appendix [Table 1]). Public health actions focus on targeted surveillance and epidemiologic investigations to identify human infections and assess the potential for the virus to cause severe disease in humans, including person-to-person transmission, co-investigations of animal outbreaks with animal health representatives, and consideration of case-based control measures (i.e., antiviral treatment and antiviral postexposure prophylaxis of contacts for infected humans and isolation of humans and animals who are infected). After recognition of a case of novel influenza infection in a human, as occurred with the H7N9 and H3N2v viruses, animal investigations subsequently identified circulation of influenza viruses in birds and swine, respectively, and identified the reservoir of these previously unrecognized novel influenza viruses. CDC conducts an IRAT assessment during the investigation interval to characterize the potential for emergence, and if the virus does emerge, the severity of human infection (*12*). Generally, identification of human cases of novel influenza A infection are reported to WHO in accordance with the International Health Regulations (*15*).

Recognition Interval: Recognition of Increased Potential for Ongoing Transmission

The recognition interval is initiated when increasing numbers of human cases or clusters of novel influenza A infection are identified anywhere in the world, and the virus characteristics indicate an increased potential for ongoing human-to-human transmission (Appendix [Table 2]). Public health actions concentrate on control of the outbreak, with a focus on potential use of case-based control measures, including treatment and isolation of ill persons and voluntary quarantine of contacts.

Initiation Interval: Initiation of the Pandemic Wave

The initiation interval begins when human cases of a pandemic influenza virus infection are confirmed anywhere in the world with demonstrated efficient and sustained human-to-human transmission (Appendix [Table 3]). The definition of efficient and sustained transmission is established during an event based on the epidemiologic characteristics of the emerging virus. For example, efficient transmission could be defined as a household or an institutional attack rate of ≥20% in more than two communities, and sustained could be defined as transmission of virus for three or more generations in more than one cluster. Continued implementation of case-based control measures and routine personal protective measures (e.g., hand hygiene) is essential, as is enhanced surveillance for detecting additional cases of the novel virus to determine when community mitigation measures will be implemented. If

possible, PSAF results (*13*) should be used to ensure that actions are proportional to the severity of the disease caused by the virus.

Acceleration Interval: Acceleration of the Pandemic Wave

The acceleration interval is indicated by a consistently increasing rate of pandemic influenza cases identified in the United States, indicating established transmission (Appendix [Table 4]). Consideration of immediate initiation of appropriate community mitigation measures such as school and child-care facility closures and social distancing (*16*) in addition to the efficient management of public health resources (including medical countermeasures and vaccines, if available) are of primary importance in this interval (*17*) and are guided by PSAF results. Isolation and treatment of ill persons and voluntary quarantine of contacts continue as key mitigation measures. Historical analyses and mathematical modeling indicate that early institution of combined, concurrent community mitigation measures might maximize reduction of disease transmission and subsequent mortality in the affected areas (*18–21*).

Deceleration Interval: Deceleration of the Pandemic Wave

The deceleration interval is indicated by a consistently decreasing rate of pandemic influenza cases in the United States (Appendix [Table 5]). During this interval, planning for appropriate suspension of community mitigation measures and recovery begins. State or local health officials might rescind community mitigation measures in certain regions within their jurisdiction when no new cases are occurring or are occurring infrequently.

Preparation Interval: Preparation for a Subsequent Pandemic Wave

The preparation interval is characterized by low pandemic influenza activity, although outbreaks might continue to occur in certain jurisdictions (Appendix [Table 6]). Primary actions focus on discontinuing community mitigation measures; facilitating the recovery of the public health, health-care, and community infrastructure; resuming enhanced surveillance protocols to detect subsequent waves; evaluating the response to the initial wave; and preparing for potential additional waves of infection. Because this interval can last from weeks to months, planning and preparation for a subsequent pandemic wave should reflect this variability. A pandemic is declared ended when evidence indicates that influenza, worldwide, is transitioning to seasonal patterns of transmission (*8*). Like the 2009 H1N1 strain, pandemic strains might circulate for years after the pandemic, gradually taking on the behavior and transmission patterns of seasonal influenza viruses.

Assessing Risks to Enhance Decision-Making

In addition to describing the progression of a pandemic, certain assessments, interpretations, and findings (i.e., indicators) are used to define the transition points between the intervals (Table). Within each interval, certain actions can be determined for state, local, and federal governments. Each indicator also initiates a set of important decisions that affect actions in the current and subsequent intervals. These decisions can range from formal generation and analysis of options to more informal but equally important discussions among subject-matter experts, pandemic response leaders, and various stakeholders (Appendix).

Decisions about appropriate actions require information regarding the real or potential impact of the novel virus on public health. Within any interval, decisions about which actions should be considered should take into account numerous factors, such as virus transmission parameters, severity of disease among different age and risk groups, availability and effectiveness of control measures and treatment options (e.g., community interventions, antivirals, and vaccines), and impact on health care, schools, businesses, and the community.

Although data needed to make decisions might be limited during the earliest intervals, delaying action might weaken the effectiveness of the response. Therefore, estimating the likelihood of risks, particularly the risks of transmissibility, severity, and antiviral resistance, is critical (*12,13,22*). In addition, certain

actions, such as the decision to produce a pandemic vaccine, require extensive preparation or time to implement, mandating that decision-making be initiated and completed as early as possible before the intervals when those actions need to occur and usually long before adequate data are available to support the need for those actions with certainty.

CDC developed two risk assessment tools for the decision-making framework, IRAT (*12*) and PSAF (*13*). Both are designed to be used during the initial intervals when data are limited, to allow for iterative updates as new information becomes available and to accommodate various potential scenarios. Once completed, results of both tools are communicated to federal, state, and local decision-makers to guide public health actions (Appendix).

Influenza Risk Assessment Tool

When a novel influenza A virus is identified in humans but is not circulating widely in the human population, it is important to evaluate 1) the risk that the virus will develop efficient and sustained human-to-human transmission and 2) the risk that the virus will substantially affect public health. IRAT was developed to facilitate such an assessment (*12*). Therefore, the indicator for the investigation interval, which is a newly identified influenza A virus in animals or identification of a novel influenza A virus recovered from humans, can serve as an initial trigger to conduct IRAT scoring.

IRAT is used by the U.S. government and the WHO Global Influenza Surveillance and Response System as a risk assessment process that involves data gathering, discussion, and consensus building among subject-matter experts to assign a risk score. Ten predefined risk elements are given a risk score. These 10 elements fall into three categories: 1) attributes that pertain to the biologic properties of the virus (four elements), 2) attributes of the population (three elements), and 3) attributes of the ecology and epidemiology of the virus (three elements) (*12*). A team of experts assigned to each particular element provides a risk score for the virus for that element. A weight is then applied to the element scores for each of the two risk questions (i.e., emergence and impact). The results of this process can be used to decide whether and how to act and communicate concerns regarding both emergence and potential public health impact. As new information becomes available, the scoring can be repeated. This process has been used to assess recently emerging viruses such as H3N2v and H7N9 for vaccine development, manufacturing, and stockpile decisions. After a novel virus has achieved efficient and sustained transmission, PSAF can then be used to characterize the potential impact of a pandemic relative to previous influenza epidemic and pandemic experiences.

Pandemic Severity Assessment Framework

Once a novel influenza virus has emerged and is circulating in human populations, the risk posed by the pandemic can be assessed. In 2007, as part of the interim guidance for community mitigation strategies, the Pandemic Severity Index was introduced as a tool to define the severity of a future influenza pandemic. To facilitate risk communication, the index had five categories similar to the hurricane severity scale, ranging in severity from category 1 (moderate severity) to category 5 (most severe) and was based on a hypothetical 30% attack rate and ranges of case-fatality ratios associated with a particular novel influenza virus (*16*). Experiences from the 2009 H1N1 pandemic identified that early data on the less severe but highly transmissible characteristics of the virus in the community were limited. Consequently, the Pandemic Severity Index, which based severity solely on mortality, tended to overestimate severity because more severe cases are likely to be reported at the initiation of a pandemic. Building on those lessons, PSAF was developed to characterize the potential impact of a pandemic relative to previous influenza epidemic and pandemic experiences (*13*). PSAF can be used early in a pandemic and assessments can be repeated as information changes. Although IRAT focuses on risk of emergence and potential for impact if emergence occurs, PSAF focuses on epidemiologic parameters of transmissibility and severity after a virus has emerged with efficient and sustained transmission and requires a sufficient number of cases and clusters in humans to allow for the assessment to be completed. Depending on the number of cases, size of clusters, and the geographic location of outbreaks,

the trigger for using PSAF might be as early in the pandemic as the recognition interval but is more likely to be triggered during the initiation interval and regularly updated as the pandemic progresses.

PSAF is based on transmissibility and clinical severity parameters and uses different scales for initial assessments in an emerging pandemic, and for later, more refined assessments. The initial assessment, performed early in the outbreak when epidemiologic data are limited, uses a dichotomous scale of low-moderate versus moderate-high transmissibility and severity. The later assessment, performed when more reliable data are available, is more refined, using a 5-point scale for transmissibility and a 7-point scale for clinical severity. After available data are assessed on these scales, the overall results are plotted with the measures of transmissibility along a y-axis and the measures of severity along an x-axis and compared with referent points such as previous pandemics or particularly severe influenza seasons (*13*). In the very early stages of an emerging pandemic, public health officials reiterate the importance of early treatment of ill persons as well as community mitigation measures to slow the spread of influenza, including voluntary isolation (i.e., ill persons staying home when sick), respiratory etiquette, hand hygiene, and guidance on treatment with antivirals. The results of PSAF assessments help national, state, and local decision-makers determine whether to implement additional community mitigation measures, including those that can be very disruptive and might have a more serious economic and societal impact on individual persons and communities (e.g., school dismissals or quarantine of contacts).

Using the Intervals, Influenza Risk Assessment Tool, and Pandemic Severity Assessment Framework

The use of transmission-defined intervals and tools such as IRAT and PSAF to assess risks and potential impact provides information that can guide decision-making and actions across different jurisdictions and levels of government and help inform appropriate risk communication strategies. A list of some of the key decisions and options for action that are triggered by progression through each interval are described (Appendix). Planning and response efforts for recent novel influenza A viruses and pandemics have been organized into eight domains to ensure that subject-matter expertise is properly applied to all aspects of the event. The decisions and actions are further stratified into these domains so that the trajectory of planning and response activities for any one domain can be more easily followed. The eight domains are incident management, surveillance and epidemiology, laboratory, community mitigation, medical care and countermeasures, vaccine, risk communications, and state/local coordination. The tables are not meant to be prescriptive or comprehensive but rather to identify numerous priority issues that need to be addressed during each interval. The circumstances of each situation dictate the timing of decisions and actions.

Discussion

The updated influenza pandemic framework provides six intervals and indicators for public health decision-making and actions during the progression of a novel influenza A virus from emergence through pandemic. The intervals are based on events that occur along a hypothetical epidemic curve. Although the actual shape of a future epidemic curve cannot be accurately predicted and might be modified by interventions, the use of an idealized curve permits generally applicable intervals to be defined. The concept of describing intervals of a pandemic can be applied to a single outbreak occurring in an individual state or a community, or information from multiple outbreaks can be aggregated to describe the situation at the national level.

Because the resources and demographics among different regions and states in the United States vary widely, defining detailed indicators that address every potential situation is impossible. Certain indicators might not be scalable to all levels of government, and others do not have corresponding actions from every participant group. However, the proposed intervals, triggers for decision-making, and actions are meant to be flexible enough to allow for the implementation of local, state, and federal actions appropriate to jurisdiction-specific conditions.

This framework is designed to assist with decision-making but does not diminish or replace the role of scientific expertise, particularly as a novel influenza outbreak unfolds. An effective pandemic response is based on numerous assumptions and actions that must be continuously reassessed with accumulated data as the pandemic progresses. The content of this framework is intended to support and organize planning and response efforts at the federal, state, and local levels. The use of common concepts is critical for tracking the course of the pandemic, for communication, and for implementing timely, coordinated response efforts.

Acknowledgments

This report is based, in part, on contributions by subject-matter experts who represented professional societies, including the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, the Association of Public Health Laboratories, the Council of State and Territorial Epidemiologists, and the National Public Health Information Coalition, as well as federal agencies including the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Biomedical Advanced Research and Development Authority, and CDC.

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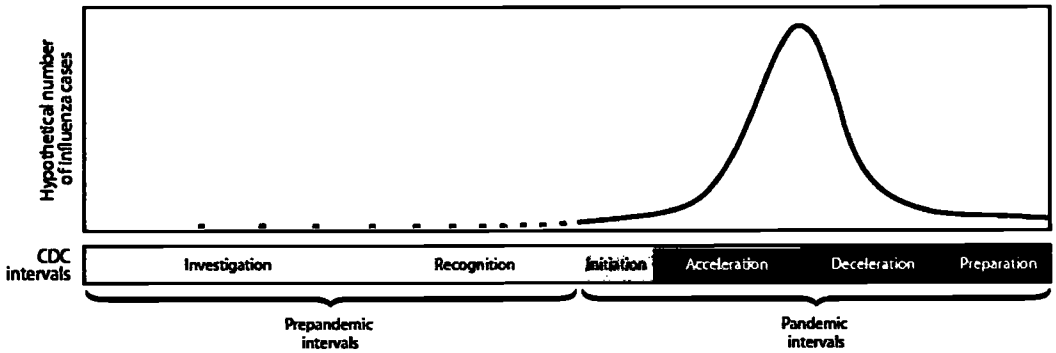
FIGURE. Preparedness and response framework for novel influenza A virus pandemics: CDC intervals



Alternate Text: This figure includes a hypothetical influenza outbreak curve and the corresponding preparedness and response framework for novel influenza A virus pandemics with the World Health Organization (WHO) phases and CDC intervals. The four WHO phases include the interpandemic, alert, pandemic, and transitions phases, and the CDC intervals include the prepandemic intervals (investigation and recognition) and the pandemic intervals (initiation, acceleration, deceleration, and preparation).

TABLE. Preparedness and response framework for novel influenza A virus pandemics: World Health Organization phases and CDC intervals, with federal and state/local indicators

World Health Organization phases	CDC intervals	Federal indicators for CDC intervals	State/Local indicators for CDC intervals
Interpandemic phase: Period between	**Investigation:** Investigation of novel influenza A infection in	Identification of novel influenza A infection in humans or animals anywhere in the world with	Identification of novel influenza A infection in humans or animals in the United States with

influenza pandemics	humans or animals	potential implications for human health	potential implications for human health
Alert phase: Influenza caused by a new subtype has been identified in humans			
	Recognition: Recognition of increased potential for ongoing transmission of a novel influenza A virus	Increasing number of human cases or clusters of novel influenza A infection anywhere in the world with virus characteristics, indicating increased potential for ongoing human-to-human transmission	Increasing number of human cases or clusters of novel influenza A infection in the United States with virus characteristics indicating increased potential for ongoing human-to-human transmission
Pandemic phase: Global spread of human influenza caused by a new subtype	**Initiation:** Initiation of a pandemic wave	Confirmation of human cases of a pandemic influenza virus anywhere in the world with demonstrated efficient and sustained human-to-human transmission	Confirmation of human cases of a pandemic influenza virus in the United States with demonstrated efficient and sustained human-to-human transmission
	Acceleration: Acceleration of a pandemic wave	Consistently increasing rate of pandemic influenza cases identified in the United States, indicating established transmission	Consistently increasing rate of pandemic influenza cases identified in the state, indicating established transmission
	Deceleration: Deceleration of a pandemic wave	Consistently decreasing rate of pandemic influenza cases in the United States	Consistently decreasing rate of pandemic influenza cases in the state
Transition phase: Reduction in global risk, reduction in response activities, or progression toward recovery actions	**Preparation:** Preparation for future pandemic waves	Low pandemic influenza activity but continued outbreaks possible in some jurisdictions	Low pandemic influenza activity but continued outbreaks possible in the state

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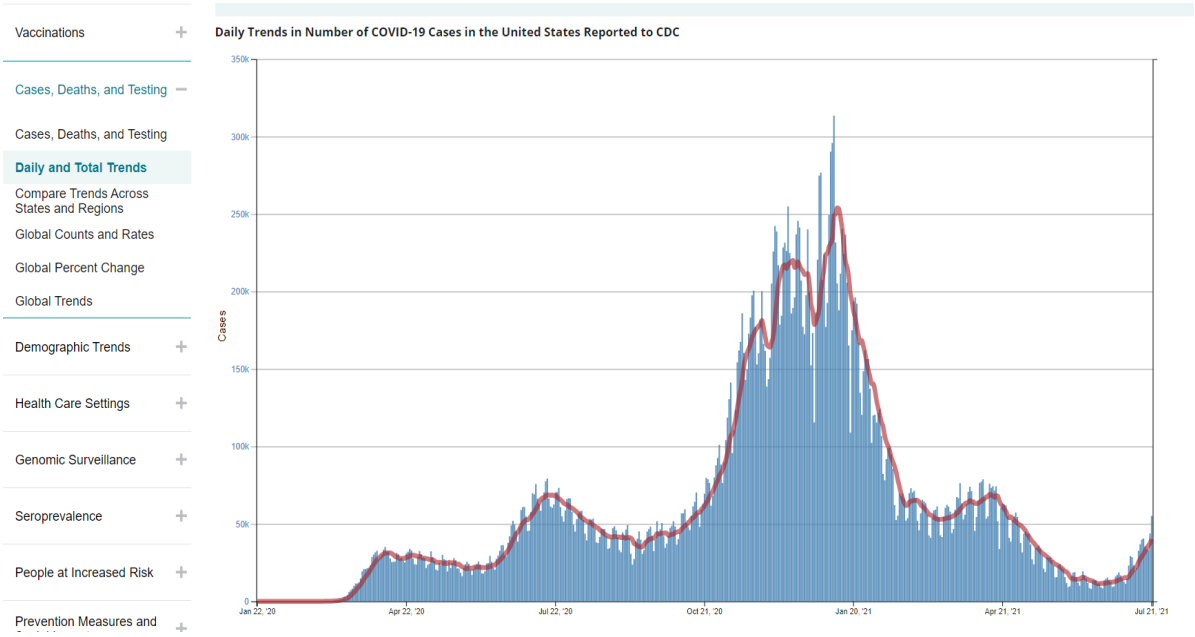
Content source: Centers for Disease Control and Prevention

Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329-4027, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - Contact CDC–INFO

Ex. 3

U.S. Cases Bell Curve

Exhibit 4


Vaccinations
Cases, Deaths, and Testing
Cases, Deaths, and Testing
Daily and Total Trends
Compare Trends Across States and Regions
Global Counts and Rates
Global Percent Change
Global Trends
Demographic Trends
Health Care Settings
Genomic Surveillance
Seroprevalence
People at Increased Risk
Prevention Measures and
Daily Trends in Number of COVID-19 Cases in the United States Reported to CDC
Cases
350k
300k
250k
200k
150k
100k
50k
0
Jan 22, '20
Apr 22, '20
Jul 22, '20
Oct 21, '20
Jan 20, '21
Apr 21, '21
Jul 21, '21

Ex. 4

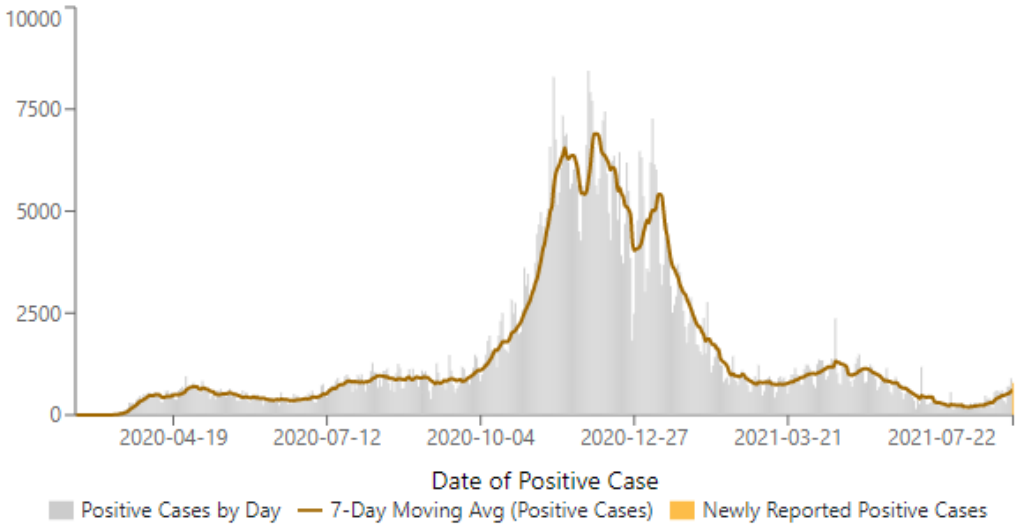
Indiana Cases Bell Curve

Exhibit 5

Positive Cases

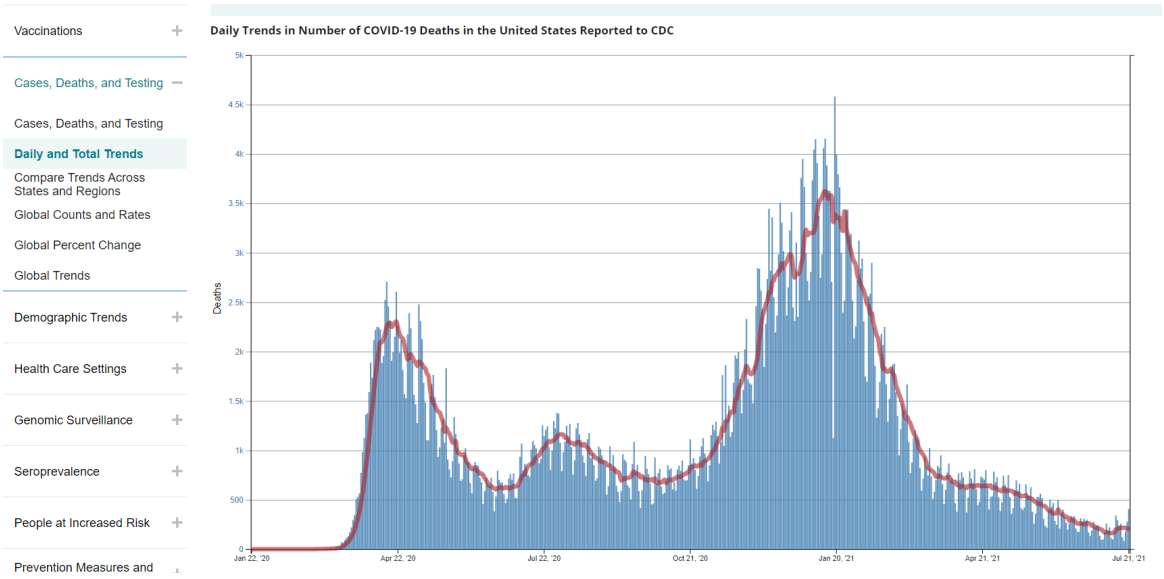
Statewide Positive Cases by Day

All | Newly Reported



U.S. COVID Deaths Bell Curve

Exhibit 6


Vaccinations
Cases, Deaths, and Testing
Cases, Deaths, and Testing
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Global Trends
Demographic Trends
Health Care Settings
Genomic Surveillance
Seroprevalence
People at Increased Risk
Prevention Measures and
Daily Trends in Number of COVID-19 Deaths in the United States Reported to CDC
Deaths
5k
4.5k
4k
3.5k
3k
2.5k
2k
1.5k
1k
500
0
Jan 22, '20
Apr 22, '20
Jul 22, '20
Oct 21, '20
Jan 20, '21
Apr 21, '21
Jul 21, '21

Ex. 6

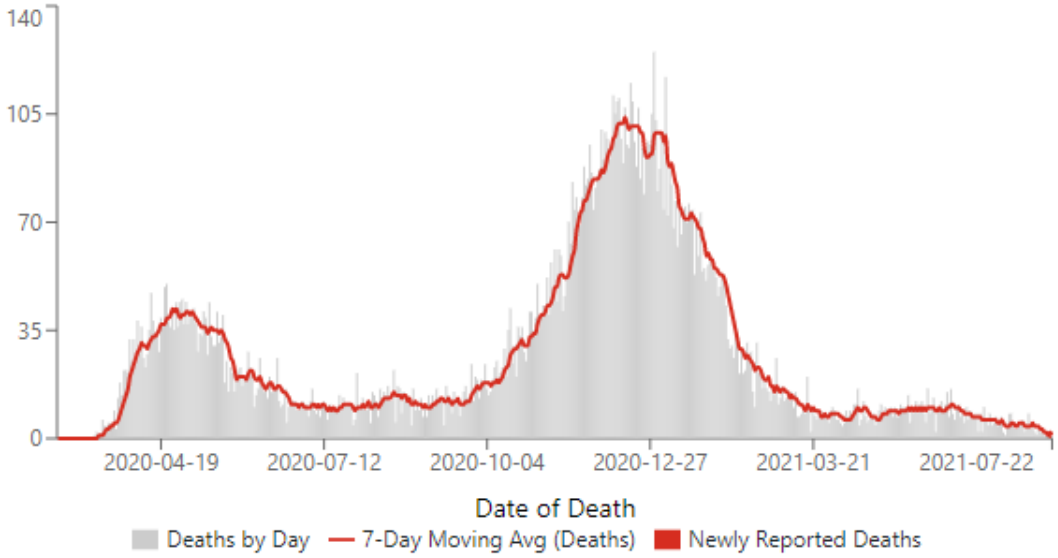
Indiana COVID Deaths Bell Curve

Exhibit 7

Deaths

Statewide Deaths by Day

All | Newly Reported



Email from Indiana University President Whitten

Exhibit 8

Indiana University

Dear IU Community,

Just now I learned that while fully vaccinated for many months, I have tested positive for COVID-19. I began experiencing mild cold symptoms this morning and immediately isolated myself. I got tested shortly thereafter and received the results a few moments ago.

Gratefully, my symptoms are mild, and I will continue to work and lead the university during this time from my home office.

While the vaccine is not 100% effective, I am so grateful to be protected from more serious symptoms.

I encourage everyone to get vaccinated as soon as you can.

I look forward to being back in the office soon and to seeing all of you on campus for the fall semester.

Pamela Whitten

President

Nickie Louise, CDC data shows that COVID-19 survival rate for adults is 99.98%; chances of surviving coronavirus is over 99.9% for most age groups

Exhibit 9

Beeler Ex 4

YOU ARE READING
CDC data shows that COVID-19 survival rate for adults is 99.98%; chances of surviving coronavirus is over 99.9% for most age groups

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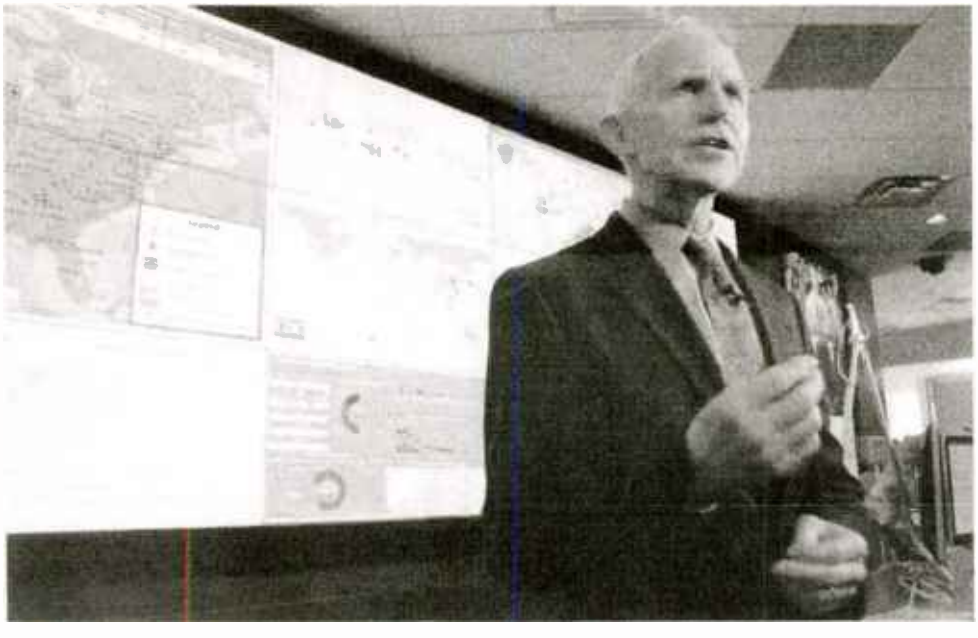
HOME HEALTH

CDC data shows that COVID-19 survival rate for adults is 99.98%; chances of surviving coronavirus is over 99.9% for most age groups

Nickie Louise

POSTED ON NOVEMBER 21 2020



The coronavirus pandemic which started in Wuhan, China in December 2019 has claimed at least 253,600 American lives, according to the latest tracking data from Johns Hopkins University. In September, the Institute for Health Metrics and Evaluation at the University of Washington (IHME) predicted that more than 410 000 Americans could die from COVID-19 by the end of 2020.

Exhibit 14
Witness Beeler
Date 7-1-21

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Ex. 9

deadly is the coronavirus? Who are the most vulnerable and why? To answer some of these questions, researchers and public-health officials use the infection fatality rate to determine how to respond to the deadly virus.

CDC data shows that COVID-19 survival rate for adults is 99.98%; chances of surviving coronavirus is over 99.9% for most age groups

In late August, the U.S. Centers for Disease Control and Prevention (CDC) published its findings on the survival rates for COVID-19 and its controversial provisional death counts. CDC said there is a high survival rate for COVID-19 and individuals are more likely to survive the coronavirus after contracting it. According to the CDC data, 94 percent of all coronavirus deaths, on average, have 2 or more pre-existing conditions or causes per death or co-morbidities.

Based on the stats, it means that less than 10,000 Americans or 6% of the 161,392 US deaths are related to COVID-19 only. Put another way, 94% of Americans who died from COVID-19 had other "types of health conditions and contributing causes" in addition to the virus, the CDC said in the updated report.

The latest CDC data on new survival rates for COVID-19 includes five COVID-19 pandemic planning scenarios "that are designed to help inform decisions by public health officials who use mathematical modeling, and by mathematical modelers throughout the federal government." According to the CDC, each scenario is based on a set of numerical values for biological and epidemiological characteristics of COVID-19 illness, which is caused by the SARS-CoV-2 virus.

The five COVID-19 Pandemic Planning Scenarios also represent a range of possible parameters for COVID-19 in the United States. All parameter values are based on current COVID-19 surveillance data and scientific knowledge. "Scenarios 1 through 4 are based on parameter values that represent the lower and upper bounds of disease severity and viral transmissibility (moderate to very high severity and transmissibility)," the CDC explained. The CDC says that Scenario 5 represents a current best estimate about viral transmission and disease severity in the United States, with the same caveat: the parameter values will change as more data become available.

Below is a quick summary of the CDC COVID-19 Survival Rates.

Age 0-19 — 99.997%

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Ex. 9

Age 50-69 — 99.5%

YOU ARE READING
CDC data shows that COVID-19 survival rate for adults is 99.98%; chances of surviving coronavirus is over 99.9% for most age groups

Age 70+ — 94.3%

Below is Infection Fatality Ratio for **Scenario 5: Current Best Estimate**

R0* 2.5

Age 0-19 years: 0.00003

Age 20-49 years: 0.0002

Age 50-69 years: 0.005

Age 70+ years 0.054

Looking at this data, one can argue that, the most vulnerable age group does (Age 70 and older) does okay with an Infection Fatality Ratio of 0.054. This CDC data should also be sufficient for everyone to feel safe, get the kids back in school, and return back to work. The findings also cast doubts on mainstream media narratives about the potential lockdown later in the year.

Since most in our major news outlets remained silent refuse to cover the news. The state of the media is so bad that it takes a foreign journalist to report the news. Adam Creighton, an Economics Editor. of The Australian and Co-Host of Business Weekend at Sky News Australia, said this on Twitter, *"The US govt last week updated the survival rates (i.e., IF infected) for Covid19: ...Didn't see it reported much."*

Adam Creighton
@Adam_Creighton

The US govt last week updated the survival rates (i.e., IF infected) for Covid19:

0-19 99.997%

Below is a screenshot of Table 1 of the CDC 5 planning scenarios.

In Table 1 below, the Parameter Values that vary among the five COVID-19 Pandemic Planning Scenarios. The scenarios are intended to advance public health preparedness and planning. They are not predictions or estimates of the expected impact of COVID-19. The parameter values in each scenario will be updated and augmented over time, as we learn more about the epidemiology of COVID-19. Additional parameter values might be added in the future (e.g., population density, household transmission, and/or race and ethnicity).

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Ex. 9

R_0*	2.0	4.0	2.5	
Ratio*	20-49 years: 0.00007 50-69 years: 0.0025 70+ years: 0.028	20-49 years: 0.0003 50-69 years: 0.010 70+ years: 0.093	20-49 years: 0.0002 50-69 years. 0.005 70+ years. 0.054	
Percent of infections that are asymptomatic[3]	10-[illegible]	70%	10%	70%	40%
Infectiousness of asymptomatic individuals relative to symptomatic*	25-[illegible]	100%	25%	100%	75%
Percentage of transmission occurring prior to symptom onset**	30-[illegible]	70%	30%	70%	50%

CDC is not alone in predicting a high survival rate for COVID-19 survival rate. Another study conducted by Stockholms Universitet in June 2020, reached a similar conclusion. The study titled, "Predicted COVID-19 Fatality Rates Based on Age, Sex, Comorbidities, and Health System Capacity," found there is a 99.99 percent chance of surviving Covid-19. The study further suggests that the fatality rate from COVID-19 varies greatly across countries.

Chance of Surviving Covid-19 By Age and Sex

	FEMALE		MALE	
AGE	No Underlying Conditions	One or Greater Underlying Conditions	No Underlying Conditions	One or Greater Underlying Conditions
0-9	99.99996	99.9639	99.99996	99.9603
10-19	99.99996	99.9639	99.99996	99.9603
20-29	99.9998	99.9466	99.9997	99.9037
30-39	99.9991	99.8636	99.9986	99.79
40-49	99.998	99.8153	99.9965	99.6943
50-59	99.9888	99.3647	99.9815	99.2135
60-69	99.9562	98.7605	99.8895	97.9992
70-79	99.8251	97.6094	99.5245	95.6517
80+	98.9087	92.8152	96.3318	79.9154

"Predicted COVID-19 Fatality Rates Based on Age, Sex, Comorbidities, and Health System Capacity, Stockholm University", June 2020

Ex. 9

Deposition of Cole Beeler, M.D.

Exhibit 10

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA

RYAN KLAASSEN, JAIME CARINI, D.J.B. by and through his next friend and father, Daniel G. Baumgartner, ASHLEE MORRIS, SETH CROWDER, MACEY POLICKA, MARGARET ROTH, and NATALIE SPERAZZA,	)	
Plaintiffs,	)	
-v-	)	CASE NO. 1:21-cv-238-DRL-SLC
THE TRUSTEES OF INDIANA UNIVERSITY,	)	
Defendant.	)	

The deposition upon oral examination of COLE BEELER, M.D., a witness produced and sworn before me, Patrice E. Morrison, RMR, CRR, Notary Public in and for the County of Marion, State of Indiana, taken on behalf of the Plaintiffs at the offices of Stewart Richardson & Associates, One Indiana Square, Suite 2425, Indianapolis, Indiana, on July 7, 2021, at 1:02 p.m., pursuant to the Federal Rules of Civil Procedure.

STEWART RICHARDSON & ASSOCIATES
Registered Professional Reporters
(800)869-0873

A Which laboratory findings or patient demographic findings.
Q Oh, okay. And what were your conclusions?
A That age and gender may impact outcome in COVID-19. D-dimer, procalcitonin, and lactate dehydrogenase, and BNP may serve as early indicators of disease trajectory.
Q Now, when you say "age," what are you referring to?
A So age, older age, may be associated with worsening outcome.
Q And when you say "older" -- this is becoming personal, but when you say older, what do you mean?
A In general, the risk factors for severe disease increase after 65. Some studies say 60. At this, we found it at 72.7.
Q Okay. Now, did you examine younger people in this study?
A Younger people.
Q Well, let's say college-age people.
A I'd have to look back on what our lowest age group was or what our lowest age individual was. But college, we were just looking at patients who were admitted to the hospital.
Q Oh.
A So that could have been anywhere from, you know, 18

have less chance of mortality than other age groups.

Q Now, the only other age group that has less is, isn't this true, is those younger than people of college age?

A That's my understanding.

Q Okay. And that it goes up, the risk of an adverse effect of a COVID-19 infection goes up as you go through the age groupings toward the highest level, which is people over 85. Is that correct?

A The risk of mortality goes up.

Q Okay. And then what's the relative risk of mortality between college-age students and those over 85?

A Are you looking for an exact number?

Q An estimate.

A The relative risk?

Q Uh-huh.

A Can I say lower?

Q Lower among college age?

A What's the relative risk of a college-age person having a bad outcome versus an elderly person having a bad outcome?

Q Yes. The way I hoped to say it was how much of a greater risk does people over 85 have from a COVID,

adverse effect of a COVID infection than do college-age students?

A The average older individual has a much higher risk of mortality than the average college-age individual.

Q Isn't it true that in the state of Indiana it's 600 times more greater risk of those over 85 than those who are college age?

MS. RICCHIUTO: Object to form.

A That number seems reasonable to me, but I would have to confirm. I don't know that number.

Q And isn't it true that in the United States, as a whole, that the risk of mortality for those over 85 is 800 -- over 800 times more than college-age students?

A I'd have to look at that, those numbers. I don't know it off the top of my head.

Q So what I -- I don't want to know your opinion on this, but the way I look at that is, people who are older -- you have a, what would you call it, a risk profile. The older you are, the greater the risk. And we're talking orders of magnitude greater risk. Hugely greater risks.

Now, are there other diseases that have kind of the reverse? In other words, greater risk the

younger you are?
A Certainly.
Q Okay. And an examples of those would be?
A Sexually transmitted infections, HIV, suicide, car accidents.
Q Polio?
A There's really no polio anymore so I can't speak to that. Potentially back then it was associated with that, but that's multifactorial.
Q All right. Now, when you determine strategies regarding how to deal with infection rates among populations, do you take into account the relative risk?
A Among populations, we take into account the risk to the population that we're serving, yes.
Q Now, is there any governmental agency that is recommending a vaccination mandate for everyone over 85?
A There's no governmental agency that I know of that's recommending for or against a mandate.
Q Has any state or local government imposed a mandate that everyone over 85 get vaccinated?
A Not to my knowledge.
Q What is the survival rate of college-age students who have been infected by COVID-19?

District Court, Order Denying Injunction Pending Appeal

Exhibit 11

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
FORT WAYNE DIVISION

RYAN KLAASSEN *et al.*,

Plaintiffs,

v.

THE TRUSTEES OF INDIANA UNIVERSITY,

Defendant.

CAUSE NO. 1:21-CV-238 DRL-SLC

ORDER

The students move to enjoin Indiana University from enforcing its vaccination policy pending their appeal. *See* Fed. R. Civ. P. 62(d). The court reviews this motion under generally the same analysis governing the preliminary injunction motion. *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Cavel Int'l, Inc. v. Madigan*, 500 F.3d 544, 547-48 (7th Cir. 2007); *see, e.g., Korte v. Sebelius*, 528 F. Appx. 583, 585-86 (7th Cir. 2012).

If the court only had another five days for its preliminary injunction ruling, it would have been shorter. Fair to say the court needn't elaborate on a 101-page opinion. The students never made a strong showing that they were likely to succeed on their constitutional claim's merits. As it turns out, they only made a soft showing.

In this motion, the students posit strict scrutiny by theorizing an expansion of *Roe v. Wade*, 410 U.S. 113 (1973). The court declines to view that theory of error as strong. It stands in contrast to the Constitution, and longstanding precedent from the United States Supreme Court. *See Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997); *Zucht v. King*, 260 U.S. 174, 176-77 (1922); *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 24-25

(1905); *see also Gonzales v. Carhart*, 550 U.S. 124, 163 (2007); *Cruzan v. Director, Missouri Dept. of Health* 497 U.S. 261, 279 (1990); *Washington v. Harper*, 494 U.S. 210, 221-22 (1990).

For any number of reasons articulated in the court's prior opinion, the students lack irreparable harm or an inadequate remedy at law. Indeed, they have many choices available to them that avoid any irreparable harm they perceive in the vaccine policy. Only in the sense of a constitutional violation have they advanced these requirements, albeit again dimly on this record.

The balance of harms and public interest remain undisturbed and now likewise oppose any stay pending appeal. The court addressed these issues in full in its prior opinion. In this motion, the students say their constitutional claim is strong, but it isn't. That low likelihood of success requires from the students a greater showing of the balance of harms. *See Turnell v. CentiMark Corp.*, 796 F.3d 656, 662 (7th Cir. 2015).

For that, the students say the COVID-19 risks have significantly declined, a large measure of the university's population has been vaccinated, and their decision won't harm the university or others. COVID-19 risks are lower than at the pandemic's height because of vaccinations; but viral risks prove ever potent, particularly to those who have awaited or foregone vaccination as variants circle and the pandemic persists. In actuality, at least at last count, many thousands of students remained to be vaccinated at the university. And staying the policy pending appeal risks more harm than not.

Add to what the court said Sunday the additional concern today that a stay introduces greater confusion, not less, as to a student's obligation mere weeks before the fall semester begins in August 2021, particularly given the need to receive the vaccine (if

not exempted) and then to wait two weeks after the last dose for it to take hold. And it risks, on this record, the public's and university's greater interest in health and safety.

Six of eight students have exemptions already. A seventh student qualifies if she would just ask. Almost to a one then, the students need only worry about masking, social distancing, and surveillance testing from here. Any real harm to them is thus quite slight while this case proceeds on appeal.

Only one student has an unexemptible choice; and, given the low likelihood of success, she hasn't shown her interest to outweigh the safety of some 90,000 students, 40,000 faculty and staff, or multiple campus communities. For these reasons, and those given by the court before, the interests align firmly against a stay of this policy pending appeal. The circumstances since Sunday haven't turned materially to the better.

The court DENIES the motion for an injunction pending appeal (ECF 37).

SO ORDERED.

July 21, 2021

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

Ex. 11