NO. 22-2970

In The

# United States Court Of Appeals
# For The Third Circuit

**CHILDREN'S HEALTH DEFENSE, INC.; PETER CORDI; RAELYNNE MILLER; KAYLA MATEO; ADRIANA PINTO; JAKE BOTHE; ANTHONY LAMANCUSA; JESSICA MOORE; RYAN SANDOR; GIANNA CORALLO; RYAN FARRELL; SEBASTIAN BLASI; MAGGIE HORN; LINDSAY MANCINI,**

***Appellants,***

**v.**

**RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY; BOARD OF GOVERNORS; RUTGERS SCHOOL OF BIOMEDICAL AND HEALTH SCIENCES; CHANCELLOR BRIAN L. STROM; PRESIDENT JONATHAN HOLLOWAY, in their official capacities,**

**ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY**

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# BRIEF OF APPELLANTS

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**UNITED STATES COURT OF APPEALS**
**FOR THE THIRD CIRCUIT**

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| CHILDREN'S HEALTH DEFENSE, INC., PETER CORDI, RAELYNNE MILLER, KAYLA MATEO, ADRIANA PINTO, JAKE BOTHE, ANTHONY LAMANCUSA, JESSICA MOORE, RYAN SANDOR, GIANNA CORALLO, RYAN FARRELL, SEBASTIAN BLASI, MAGGIE HORN, LINDSAY MANCINI,<br><br>*Appellants*,<br>-against-<br><br>RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY, BOARD OF GOVERNORS, RUTGERS SCHOOL OF BIOMEDICAL AND HEALTH SCIENCES, CHANCELLOR BRIAN L. STROM, PRESIDENT JONATHAN HOLLOWAY, in their official capacities.<br><br>*Appellees* | **No. 22-2970**<br><br>**DISCLOSURE STATEMENT** |

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned counsel for Plaintiff Children's Health Defense, Inc. (a private non-governmental party) certifies that it has no corporate parents, affiliates and/or subsidiaries which are publicly held.

Dated: November 7, 2022

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## INTRODUCTION

This appeal raises a very important question: Does a university have the legal authority to coerce a student's consent to a highly invasive injection of a yet-to-be fully investigated *experimental* vaccine that does not prevent the spread of disease and poses risk of serious harm?

Appellants Peter Cordi, Raelynne Miller, Kayla Mateo, Adriana Pinto, Jake Bothe, Anthony Lamancusa, Jessica Moore, Ryan Sandor, Gianna Corallo, Ryan Farrell, Sebastian Blasi (formerly Doe 3), Maggie Horn (formerly Doe 6), Lindsay Mancini (formerly Doe 9) are students at Rutgers University and members of Children's Health Defense ("CHD"), an established non-profit that advocates for vaccine safety and informs its members and the public at large about the harm and injury vaccines may cause. Together, the students and CHD brought this action to challenge Rutgers University's requirement that all students be vaccinated against COVID-19 for the start of the 2021 Fall semester (the "Rutgers Policy"). At present, Rutgers Policy still requires full vaccination and boosters for students, faculty and staff.

This suit was filed against Rutgers University, its Board of Governors, the Rutgers School of Biomedical and Health Sciences, President Jonathan Holloway and Chancellor Brian L. Storm (collectively, "Rutgers") seeking declaratory judgment, injunctive relief and damages.

At all times relevant to this appeal, all currently available COVID-19 vaccines remain under clinical study. They remain in every legal and practical sense *experimental.* Further these vaccines are now generally known not to prevent infection or transmission, and to pose significant risks (e.g. myocarditis).

Rutgers made the decision to mandate these experimental vaccines on students (not faculty or staff) only four months after they were made available under an Emergency Use Authorization ("EUA"), a mechanism purposely intended to bypass the rigorous safety and efficacy testing that the Food and Drug Administration ("FDA") typically requires for drugs and biologics. The Vaccine Adverse Event Reporting System ("VAERS"), operated by the FDA and the Centers for Disease Control and Prevention ("CDC"), is the primary national repository of adverse event information. As of November 4, 2022, VAERS showed 1,458,322 reports of adverse events from all age groups following COVID-19 vaccination, including 31,961 deaths and 265,274 serious injuries.[1] The district court as well as this Court are required to accept these allegations as true.

[1] *See* Megan Redshaw, *10-Year Old Boy Died of Cardiac Arrest 7 Days After Moderna Shot, VAERS Data Show,* The Defender (November 14, 2022), available at https://childrenshealthdefense.org/defender/covid-vaccine-injury-vaers-data/ (last visited January 2, 2023).

This Court is also required to accept that COVID-19 vaccines were not designed nor shown to prevent transmission, ever. There were no data demonstrating these vaccines prevented transmission when Rutgers mandated them. To this day these injections have not been tested to prove that they minimize outbreaks. Rutgers knows this well as Rutgers is carrying out clinical trials for all three vaccine manufacturers, Pfizer, Moderna and Johnson & Johnson. As Plaintiffs alleged in 2021, these vaccines cannot reduce the spread of COVID-19. If this is true, then it is irrational for Rutgers to mandate them to prevent transmission. Furthermore, these experimental vaccines pose a serious risk of injury and even death. As a result, any purported benefit to students is outweighed by the constitutionally guaranteed right to informed consent and to refuse unwanted medical treatment. State colleges and universities must not be permitted to mandate experimental vaccines that are still under investigation for efficacy and safety. The lack of information makes it impossible to weigh benefit against risk in order to mandate them for any specific public health benefit. If vaccines do not prevent transmission, the argument that they are necessary to protect others has no basis in fact and deserves no legal weight.

Additionally, since these vaccines admittedly do not prevent transmission, Rutgers cannot lawfully treat vaccinated and unvaccinated students differently. Discrimination between these two groups is unreasonable and arbitrary.

Finally, the law has not remained static since *Jacobson v. Massachusetts* was decided more than 100 years ago. Since then, the Supreme Court has recognized that the right to informed consent and to refuse unwanted medical treatment is deeply rooted in our nation's history, making that right fundamental and requiring strict scrutiny to override, or a heightened standard when it is balanced against a state interest. The Supreme Court's doctrine of unconstitutional conditions, also developed post-*Jacobson,* requires courts to intervene when government coerces a person to forfeit constitutional rights for a public benefit.

Our rights to Due Process and Equal Protection mean we must all be allowed to choose freely, without coercion, whether to consent to *experimental* COVID-19 vaccines and to subject ourselves to their unknown risks. Those who refuse should not be treated differently – as outcasts, shunned from civil society, from public gatherings and public places, fired from jobs, and banned from schools, or in this case, a public university. We should be treated equally, without discrimination.

## JURISDICTIONAL STATEMENT

The district court had subject matter jurisdiction under 28 U.S.C. §1331 because this case concerns questions of federal law, namely the Fourteenth Amendment of the United States Constitution, 42 U.S.C. §1983, and 21 U.S.C. §360bbb-3. (JA180-181). The district court also had supplemental jurisdiction under 28 U.S.C. §1367(a) because it concerns related questions of state law under

certain statutes and regulations that form part of the same case or controversy (e.g. N.J.S.A. 18A:61D-1, *et seq*., N.J.A.C. 8:57-6.1, *et seq*.). (JA180-181).

This Court has appellate jurisdiction under 28 U.S.C. §1291 because on September 22, 2022, the district court entered an Order rendering a final judgment dismissing all of Plaintiffs' claims (JA4), and Plaintiffs filed a timely notice of appeal one month later, on October 19, 2022. (JA1).

## STATEMENT OF THE ISSUES

1. Did the district court err by misapplying the applicable standard of review and failing to accept as true all the allegations in the Amended Complaint? Students stated the correct standard of review in their brief opposing Rutgers' motion to dismiss. (JA317-316).

2. Did the district court err by ruling that students who received religious exemptions lacked standing to challenge Rutgers Policy and that their claims were moot? Students raised this issue in their brief opposing Rutgers' motion to dismiss. (JA318-320).

3. Did the district court err by ruling that Rutgers has been delegated police power to mandate *experimental* COVID-19 vaccines during a pandemic? Students raised this issue in their brief opposing Rutgers' motion to dismiss. (JA339-347).

4. Did the district court err by applying rational basis review to students' Due Process and Equal Protection challenges to Rutgers Policy, and by otherwise dismissing these claims? Students raised this issue in their brief opposing Rutgers' motion to dismiss. (JA320-335).

5. Did the district court err by misinterpreting and dismissing students' Equal Protection claims? Students raised this issue in their brief opposing Rutgers' motion to dismiss. (JA334-335).

6. Did the district court err by ruling that Rutgers Policy is not preempted by federal law? Students raised this issue in their brief opposing Rutgers' motion to dismiss. (JA335-339).

## STATEMENT OF RELATED CASES AND PROCEEDINGS

This case has not been before this Court previously, and Appellants are not aware of any other cases in any court or agency relating to the Rutgers Policy or actions at issue in this case.

## STATEMENT OF THE CASE

### Relevant Facts

CHD's mission is to end childhood chronic health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and to establish safeguards so that such epidemics never recur in the future. (JA160). The harm and injury caused by vaccines has been a focus of CHD for many years. (JA160).

Originally, CHD and eighteen students filed this action. (JA42). During the course of this case, several students withdrew fearing ostracism and retaliation if their identities and views became public. Thirteen of those students are now pursuing this appeal. (JA1). These students maintain a variety of objections to COVID-19 vaccination: religious, medical, and practical. All of the students requested and received a religious exemption, except Adriana Pinto. (JA161-177). Ms. Pinto would have been a senior at Rutgers in the 2021 Fall semester shortly after this action was filed. (JA165-166). Ms. Pinto objects to COVID-19 vaccination because COVID-19 vaccines would alter her body's natural immunity with unknown and untested chemical substances and technologies that have not been proven safe or effective long-term. Since she has struggled with her health as a young adult and must adhere to strict requirements to remain healthy, she does not want to be injected with an experimental vaccine. (JA165). She was unable to obtain a medical exemption from a doctor and has not objected to immunization on religious grounds. For the 2021 Fall semester Ms. Pinto was registered solely for on-line coursework, nevertheless Rutgers informed her that she could not attend even remote classes without taking the vaccine. (JA165-66). Additional to their religious objections and medical concerns (exercising their right to informed consent), all of these students reached the conclusion that the unknown risks of COVID-19 vaccination outweigh the known risks of the disease for each of them

personally and refused COVID-19 vaccination. (JA161-177). Their decisions were based on varied information about COVID-19 disease and vaccines from official sources, including the CDC, FDA and vaccine manufacturers. (JA161).

Rutgers is not an elected body or a board of health. Rutgers mandated COVID-19 vaccines after they were on the market for only a few months. (JA217-218; JA223-224). All COVID-19 Vaccines widely available in the United States were authorized under Section 564 of the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §360bbb-3, which empowers the FDA to issue an "Emergency-Use Authorization" ("EUA") for a medical drug, device or biologic, such as a vaccine, under certain emergency circumstances; the mechanism allows the FDA to make vaccines available to the public that have not gone through FDA's full approval process; all COVID-19 vaccines, PCR testing and even masks are authorized for emergency use pursuant to Section 564. (JA185-186). Section 564 requires the FDA to establish certain required conditions; among them the requirement that individuals to whom the product is administered are informed of "the option to accept or refuse administration of the product." (JA186-187). FDA imposes and enforces the "option to accept or refuse" conditions by requiring the distribution to potential vaccine recipients of Fact Sheets that state, "It is your choice to receive or not receive [the vaccine]" and this statement appears in the EUA Fact Sheet for each of the three EUA COVID-19 vaccines. (JA187).

The FDA and the National Institutes of Health ("NIH") refer to EUA products as both "investigational" and "experimental" and use those terms interchangeably to describe them. (JA20, JA216-219).[2] COVID vaccines employ a novel technology that has never been put in widespread use in humans ever before. (JA207). According to the FDA, there are insufficient data to know whether the vaccines actually prevent asymptomatic infection or prevent transmission of the disease. (JA209). Therefore these vaccines cannot promise herd immunity to any population; and their effectiveness which remains an open question is vastly overstated. (JA209). COVID-19 vaccines skipped testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity – these vaccines were never tested to establish if they will change human genetic material, reduce fertility, cause birth defects or cause cancer. (JA211). Plaintiffs alleged the novelty and risks of COVID-19 vaccines (JA211-213; JA219-220). Plaintiffs alleged increasing reports of vaccine injuries (JA213-214).

Rutgers is engaged in the investigational study of all three experimental COVID-19 vaccines and thus has financial ties to the three COVID-19 vaccine manufacturers: Pfizer, Moderna and Johnson & Johnson. Rutgers is a clinical trial

[2] *See* FDA, *Understanding the Relevant Terminology of Potential Preventions and Treatment for COVID-19,* FDA.gov. (Oct. 2020) ("an investigational drug can also be called an experimental drug") at https://www.fda.gov/media/138490/download (last visited Jan. 9, 2023).

site for all three vaccines. (JA203-207); Plaintiffs alleged that Rutgers had a conflict of interest in making any decision to impose a COVID-19 vaccine mandate on its campuses. (JA206).

Rutgers has required COVID-19 student vaccination since the start of the 2021 Fall semester. Despite telling the public that it would not require COVID-19 vaccines for students to return on campus on January 22, 2021, Rutgers reversed course and announced its mandate on March 25, 2021, and formally adopted it on April 13, 2021. (JA223-226). Rutgers Policy permits students to request medical and religious exemptions, however, exempted students are subject to masking, mandatory weekly or bi-weekly testing, and are excluded from university housing. (JA232). The current and revised Rutgers Policy requires students to receive at least one COVID-19 booster.

Since briefing the motion to dismiss, a number of developments bolster Plaintiffs' allegations about the lack of safety and effectiveness of COVID vaccines. Freedom of Information Act ("FOIA") requests[3] led to the release of an unredacted Pfizer pharmacovigilance safety analysis collecting 42,086 adverse event reports in the first three months of the vaccine rollout: including 1,223

[3] *Public Health and Medical Prof. for Transparency v. F.D.A.*, No. 4:21-cv-1058-P, 2022 WL 90237 (N.D. Tex. Jan. 6, 2022)

deaths.[4] In another FOIA document release CDC admitted it never monitored VAERS for COVID-19 vaccine safety signals.[5] On October 10, 2022, Pfizer's Janine Small, President of International Developed Markets, told the European Parliament that before Pfizer released its COVID-19 vaccine into the market, neither she nor other Pfizer officials knew whether the vaccine would prevent transmission because the drugmaker had not tested for it.[6]

Although Rutgers Policy no longer requires masking, it continues to require exempted students to test weekly or twice-weekly and to exclude them from university housing.[7] Most recently, Rutgers was selected to conduct clinical trials

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[4] *See* 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021 at https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf ; *see also* Michael Nevradakis, *Pfizer hired 600+ People To Process Vaccine Injury Reports, Documents Reveal*, The Defender (April 5, 2022) at https://childrenshealthdefense.org/defender/pfizer-hired-600-people-vaccine-injury-reports/ (last visited Jan. 9. 2023).

[5] *See* Josh Guetzkow, *CDC Admits It Never Monitored VAERS For COVID Vaccine Safety Signals*, The Defender (June 21, 2022) at https://childrenshealthdefense.org/defender/cdc-vaers-covid-vaccine-safety/ (last visited Jan. 9. 2023).

[6] Jack Phillips, *Pfizer Exec Admits COVID Vaccine Was Not Tested For Preventing Transmission*, The Defender (Oct. 12, 2022) at https://childrenshealthdefense.org/defender/pfizer-covid-vaccine-never-tested-prevent-transmission-et/ (last visited Jan. 9, 2023).

[7] *See* https://coronavirus.rutgers.edu/important-updates-and-changes-to-rutgers-covid-19-protocols/ (current Rutgers COVID-19 requirements);

on children for a COVID-19 bivalent vaccine.[8] Despite recent academic studies concerning the risks associated with COVID-19 vaccination,[9] Rutgers Policy continues its trajectory.

## Proceedings Below

Plaintiffs filed this action against Rutgers in the United States District Court for the District of New Jersey on August 16, 2021 seeking a declaratory judgment, injunctive relief and damages. (JA42). Plaintiffs challenged Rutgers Policy as preempted by federal law and *ultra vires* under state law; they claimed that it violated the right to informed consent and to refuse unwanted medical treatment under the Due Process Clause and the Equal Protection Clause of the Fourteenth Amendment; and sought damages under Section 1983 and the New Jersey Civil Rights Act, among other claims not on appeal.

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http://health.rutgers.edu/medical-counseling-services/medical/immunization-requirements-allergy-shots/ (current Rutgers university housing requirements).

[8] *See* Patti Zielinski, *Rutgers Recruiting Participants for Pfizer COVID-19 Pediatric Bivalent Vaccine Clinical Trial* (Nov. 4, 2022), at https://www.rutgers.edu/news/rutgers-recruiting-participants-pfizer-covid-19-pediatric-bivalent-vaccine-clinical-trial (last visited Jan. 9, 2023).

[9] *See* K. Bardosh, et al., *COVID-19 Vaccine Boosters for Young Adults: A Risk-Benefit Assessment and Five Ethical Arguments against Mandates at Universities* (Aug. 31, 2022), at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4206070 (last visited Jan. 9, 2023).

On August 30, 2021, student Adriana Pinto sought an injunction. (JA64). The district court denied her motion. (JA134-149). Plaintiffs did not appeal.

On October 19, 2021, Plaintiffs amended their Complaint. (JA150). Rutgers moved to dismiss the Amended Complaint on November 19, 2021. (JA271); Plaintiffs opposed on January 11, 2022 (JA309); Rutgers filed its reply on January 31, 2022. (JA417). Subsequently both parties filed letters with the district court citing supplemental authority and changed circumstances, (JA 433-446), most notably CDC's decision to give the same guidance to people regardless of vaccination status and Governor Murphy's Order ending the COVID test mandate for unvaccinated teachers, childcare workers and state workers in August 2022. (JA449). Rutgers Policy was not modified accordingly.

Rulings Presented for Review

On September 22, 2022, the district court issued its Opinion and Order dismissing Plaintiffs' complaint with prejudice and instructing the Clerk to close the matter. (JA4-5). The district court ruled that students who received religious exemptions to Rutgers Policy, and challenged it, lacked standing as a result of their exemptions and that their claims were moot. (JA13-16). The district court also held that *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) requires the use of rational basis review to assess challenges to Rutgers Policy. (JA12-13). Concluding that Plaintiffs' claims did not involve fundamental rights or a suspect

classification, the district court applied rational basis review to rule that Rutgers Policy was rationally related to a legitimate government interest of protecting the members of its community from COVID-19 disease and preventing disruptions that COVID-19 caused for three semesters. (JA14-17). Presuming that COVID-19 vaccines are safe and effective, and that despite conducting clinical trials for all three vaccine manufacturers, Pfizer, Moderna, and Johnson & Johnson, "Rutgers' financial interests could not have played a role in the implementation of the Policy," – a fact that is specifically controverted by Plaintiffs' allegations – the district court ruled that Rutgers Policy satisfied rational basis review. (JA19). The district court also ruled that unvaccinated students are not members of a protected class and that their claims of disparate treatment satisfy rational basis. (JA15-17). The district court found no conflict between Rutgers Policy and 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III), requiring informed consent for the administration of COVID vaccines. (JA25-26). The district court also found that Rutgers had legal authority under state law and regulations, N.J.S.A. 18A:61D-1, N.J.A.C. §8:57-6.4(c), to mandate these experimental COVID vaccines as a condition of enrollment during an outbreak, and under N.J.A.C. §8:57-6.14(d), -6.15(c) to exclude unvaccinated students from university housing. (JA26-27). The remainder of the district court's rulings is not the subject of this appeal.

## SUMMARY OF THE ARGUMENT

The district court failed to accept as true all of the allegations in the Amended Complaint, and that failure taints its legal conclusions. Against the allegations in the complaint, the district court adopted the general view that COVID-19 vaccines are safe and effective, and – more importantly – that COVID-19 vaccines prevent infection and transmission; that COVID-19 is a vaccine-preventable disease; and that Rutgers had no financial incentives to mandate vaccine products. These facts contradicted the allegations that the district court was bound to accept as true, and this Court should remand for further proceedings.

The district court also erred by holding that students who received religious exemptions lacked standing to challenge Rutgers Policy because their religious exemptions rendered their claims moot. That decision constituted legal error because it contradicted the district court's own precedent, failed to follow controlling Third Circuit and Supreme Court precedents, and mischaracterized the nature of the exempted students' claims.

The district court further erred by holding that Rutgers Policy is subject to rational basis review. The district court reached that conclusion by ignoring well-settled Supreme Court and Third Circuit precedents, establishing that the right to informed consent and the corollary right to refuse unwanted medical treatment are fundamental rights and therefore should be subject to a heightened standard of

review, if not strict scrutiny. More than 100 years have passed since *Jacobson v. Massachusetts* was decided in 1905, and *Jacobson* should not be applied in a vacuum but read in conformity with modern jurisprudence. *Jacobson* must also be applied in conformity with the unconstitutional conditions doctrine developed by the Supreme Court in the last half century: "the government may not deny a benefit to a person because he exercises a constitutional right."

Alternatively, even if rational basis review were to apply to challenges against experimental vaccine mandates, the district court failed to consider that mandating a vaccine that does not prevent transmission of disease is not rationally related to the purpose of preventing transmission on a university campus; and it is even less rational to mandate remote students to take it. Further, if the university curried favor with vaccine manufacturers, then Rutgers had no legitimate state interest.

The district court misunderstood Plaintiff's equal protection claims and failed to analyze them correctly.

Lastly, the district court's ruling that Section 564 does not preempt Rutgers Policy is clearly erroneous. Federal law requires informed consent freely given for emergency-use authorized vaccines; Rutgers Policy conflicts with that law by coercing consent.

## ARGUMENT

### Standard of Review

This Court exercises "plenary review over the grant of a motion to dismiss." *Brown v. Card Service Center*, 464 F.3d 450, 452 (3d Cir. 2006). "When considering an appeal from a Rule 12(b)(6) dismissal," this Court "must accept all well-pled allegations in the Complaint as true and draw all reasonable inferences in favor of the non-moving party." *Id.* (citing *In re Rockefeller Ctr. Props. Sec. Litig.*, 311 F.3d. 198, 215 (3d Cir. 2002). "In doing so, we must determine whether the plaintiff may be entitled to relief under any reasonable reading of the Complaint." *Id.* (citing *Pinker v. Roche Holdings, Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002).

When reviewing a district court's Rule 12(b)(1) dismissal for mootness, this Court "review[s] the district court's factual findings for clear error and its legal conclusions de novo." *Hartnett v. Pennsylvania State Education Assoc.*, 963 F.3d 301, 305 (3d Cir. 2020). "[T]he standard for reviewing a Rule 12(b)(1) motion is lower than that for a Rule 12(b)(6) motion," however, and "[a] claim may be dismissed under Rule 12(b)(1) only if it 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or is wholly insubstantial and frivolous'." *See Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176-77 (3d Cir. 2000).

## I. THE DISTRICT COURT ERRED BY FAILING TO ACCEPT AS TRUE THE ALLEGATIONS IN THE AMENDED COMPLAINT.

All of the district court's rulings rest on facts and assumptions that contradict Plaintiffs' allegations in the Amended Complaint. For example, the district court assumed that Rutgers was capable of making the determination that COVID-19 vaccines are safe and effective in order to mandate them. Read in the light most favorable to the non-moving party, Plaintiffs alleged numerous facts that Rutgers could not make that assessment. More specifically, the district court assumed, against Plaintiffs' allegations, that COVID-19 vaccines prevent infection and transmission. Citing the vaccine manufacturers and the FDA, there are insufficient data available to show that these vaccines prevent infection or transmission. As a result, the district court cannot assume that they do, or that Rutgers logically came to such a determination, or that Rutgers was even capable of making any analysis of benefit versus risk when it decided to mandate COVID-19 vaccines on the student population of almost 70,000. Based on the lack of information at the time these vaccines were mandated (and lasting until today), Plaintiffs allege that it is not possible to make that assessment given the current state of knowledge and science. (JA139). Similarly, the district court assumes, contrary to Plaintiffs' allegations, that COVID-19 is a *vaccine-preventable* disease. (JA27). It is not. These facts may remain in dispute but at the pleading stage, Plaintiffs' version of the facts must be accepted as true. Finally, without any

explanation or basis, the district court ruled "that Rutgers' financial interests could not have played a role in the implementation of the Policy." (JA19). Plaintiffs alleged numerous facts that, as a research university, working hand-in-glove with Pfizer, Moderna and Johnson & Johnson, Rutgers had conflicts of interest in making the decision to mandate COVID-19 vaccines. (JA206). Rutgers' complete reversal that it would not mandate vaccines, its decision to mandate vaccines at first only upon students (not faculty or staff), its ongoing involvement in the clinical trials, and its receipt of multimillion dollar grants and programs from these companies all suggest that Rutgers' financial interests influenced its decision to mandate a vaccine that does not work. Since those facts are necessary to a court's analysis whether Rutgers' mandate is sufficiently associated (e.g. rationally related or narrowly tailored) to a legitimate interest, a record on those facts must be developed before the district court can render judgment on the students' claims.

Students are not asking for this Court to determine the most *effective* method to protect the public against COVID-19. Their claim is more modest – they are asking this Court to determine that an experimental vaccine, whose safety and efficacy is not fully understood, that has not been proved to prevent infection or transmission, cannot be mandated to stop disease spread. If allowed at the district court, students could have actually proved that Rutgers did not know if COVID-19 vaccines could prevent transmission at the time Rutgers Policy began. Rutgers

continues to mandate vaccines it now knows cannot prevent transmission since Rutgers is involved in the clinical trials, rendering its mandate clearly not rationally related to its express purpose to prevent the spread of COVID-19 on campus. The relationship between the vaccine, its ineffectiveness at preventing the spread of COVID-19, and Rutgers' purported objectives are even more irrational as applied to Ms. Pinto, a student who enrolled in remote classes only. There is no rational basis for requiring a student enrolled in remote classes and not physically present to vaccinate with an experimental vaccine that does not prevent disease against her constitutional right to informed consent and to refuse unwanted medical treatment, especially when unvaccinated faculty and staff were permitted on campus freely when she was deregistered. The district court's failure to accept these facts is reversible error.

## II. THE DISTRICT COURT ERRED BY HOLDING THAT STUDENTS WITH RELIGIOUS EXEMPTIONS LACKED STANDING.

Rutgers conceded that student Adriana Pinto and CHD had standing to assert claims. (JA287). Ms. Pinto did not request a medical or religious exemption and as a result of Rutgers Policy was deregistered from her remote classes that would have permitted her to complete her degree and graduate in 2022. (JA165-166). Ms. Pinto is a member of CHD, a non-profit organization. (JA165). Since Ms. Pinto is a member, the district court held "CHD's standing mirrors hers." *See*

*Friends of the Earth Inc. v. Laidlaw Environmental Services, Inc.*, 528 U.S. 167, 181 (2000) ("[a]ssociation has standing to bring suit on behalf of its members").

The remaining students received religious exemptions. (JA161-177). However, those exemptions came with the conditions that they were required to submit to weekly testing, to mask, and withdraw from university housing – while vaccinated students were not subject to these conditions. Rutgers also reserved the right to impose additional conditions upon exempted students at any time. (JA161). Exempted students alleged that these were unconstitutional conditions because the vaccine did not prevent infection or transmission, and vaccinated students could spread the disease as easily as unvaccinated students. Therefore, vaccinated and unvaccinated students were not distinct cohorts, and any disparate treatment between them required legal justification. Nevertheless, as a result of their exemptions, the district court held that those students lacked standing because the exemptions mooted their claims. (JA13-16). The district court reached this conclusion by ignoring its own precedent (same judge) in a similar case, misapplying precedent from this Circuit and others, ignoring Supreme Court precedent, and mischaracterizing the exempt students' claims.

First, in *Messina v. College of New Jersey*, the district court (same judge) held twice that college students exempt from a COVID-19 vaccine mandate had standing to pursue similar claims against the College of New Jersey. *See* 566 F.

Supp. 3d 236, 250 n. 2 (D.N.J. 2021) (In *Messina* "Plaintiffs have standing to bring this action because they allege the Mandate places several unconstitutional requirements on exempt students such as themselves. Plaintiffs have alleged an 'invasion of a legally protected interest' that is concrete, particularized and imminent.") (citing *Spokeo, Inc. v. Robins*, 578 U.S. 330 (2016) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) and *In re Nickelodeon Consumer Privacy Litig.*, 827 F.3d 262, 272 (3d Cir. 2016)); *see also* Civ. No. 21-17576, 2021 WL 4786114 (D.N.J. Oct. 14, 2021) at n.2. The district court (same judge) provided no explanation for reaching the opposite conclusion in this case.

When the district court issued its decision, only unvaccinated students were subject to routine (weekly) testing and barred from university housing. Although it is true that Rutgers at one point required everyone to mask regardless of vaccination status, the Court only mentioned that condition to conclude that there was no disparate treatment, (JA20-21), ignoring the other conditions that Rutgers continues to impose on exempt students and faculty. These conditions have not expired; exempt students are still subject to disparate conditions.

The district court's reliance on *Wade v. Univ. of Conn. Bd. of Trs.*, 554 F. Supp. 3d 366 (D. Conn. 2021) and *Pelekai v. Hawai'i*, Civ. No. 21-343, 2021 WL 4944804 (D. Haw. Oct. 22, 2021), is erroneous. The exempt plaintiffs in these cases were challenging only the vaccine mandate, not conditions imposed upon

them as a result of their exemptions. *See Wade* at 368 ("[h]aving received exemptions, their claims are moot because they are unlikely to face any continuing injury from the vaccination requirement"); *Pelekai* at *4 ("Plaintiffs no longer assert any claim premised upon or challenging testing").

That Rutgers ultimately required everyone to mask does not change the fact that only exempt unvaccinated students (and faculty) are still to this day required to test and are still excluded from university housing when they can transmit the virus as easily as vaccinated students (and faculty) – these conditions constitute a "live controversy" that unvaccinated students should be able to pursue: Due Process challenges to mandatory testing and masking and Equal Protection Challenges to disparate conditions placed upon them as a result of claiming an exemption.

During the course of the proceedings below, Rutgers broadened its vaccine mandate to cover faculty and staff, not just students, as a result of President Joseph R. Biden, Jr.'s Executive Order 14042 (JA288-289), and later broadened it further to apply to visitors. Plaintiffs' claims are not moot simply because everyone was required to mask or because unvaccinated faculty and staff were later subject to a federal mandate. Rutgers Policy "is subject to change based on factors such as the progress of the COVID-19 pandemic and guidance from governmental authorities." (JA351). *N.J. Turnpike Auth. v. Jersey Cent. Power & Light*, 772 F.2d 25, 31 (3d Cir. 1985) ("a matter is not necessarily moot simply because the

order attacked has expired; if the underlying dispute between the parties is 'one capable of repetition, yet evading review,' it remains a justiciable controversy"). Rutgers did not lift all restrictions imposed upon unvaccinated students or subject all persons on campus to the same conditions they are still subjected to. Thus, substantive issues remained justiciable (e.g. disparate treatment concerning mandatory testing and exclusion from university housing) and because Rutgers continues to reserve the right to modify its policies further and impose additional disparate conditions on unvaccinated students these issues are capable of repetition. *Id.* at 32 (3d Cir. 1985) ("…if there is a likelihood that the acts complained of will be repeated, the substantive issues remain justiciable, and a declaratory judgment could be rendered to define the rights and obligations of the parties."). Exempt students seek remedies of declaratory relief, injunctive relief and monetary damages which were never mooted by Rutgers' modified policies or the exemptions. Exempt students were entitled to a declaratory judgment since their rights were violated during the period that Rutgers' mandate did not apply to faculty and staff. *See Messina*, Civ. No. 21-17576, 2022 WL 4078501, at *5 n. 2 (D.N.J. Aug. 31, 2022) (holding that distinctions between claims concerning the vaccine requirement and restrictions imposed on exempt students are "inconsequential"). Like the students in *Messina*, "[b]ut for" Rutgers' vaccine mandate the exempt students in this case would not have had to choose between

complying with the requirement or applying for an exemption. *Id.* ("an invasion of a legally protected interest").

## III. THE DISTRICT COURT ERRED BY RULING THAT RUTGERS HAS POLICE POWER TO MANDATE AN EXPERIMENTAL VACCINE DURING A PANDEMIC.

Since "[t]he authority of the state to enact" a vaccine mandate emanates from its "police power" and "the state may invest local bodies called into existence… with authority" to safeguard public health and safety," *Jacobson* at 24-25, a court must first assess whether the entity that ordered the mandate was empowered to do so. *See National Fed. Ind. Bus. v. Dept. Labor Occupational Safety and Health Administration*, 142 S. Ct. 661, 665 (2022) (Occupational Health and Safety Act does not authorize the Secretary of Labor to enact a vaccine mandate on all employers with at least 100 employees); *see also Biden v. Missouri*, 142 S. Ct. 647, 652 (2022) (Congress authorized Secretary of Health and Human Services to condition receipt of Medicaid and Medicare funds upon facilities ensuring that their employees be vaccinated against COVID-19).

The district court ruled that "N.J.S.A. §18A:61D-1 and N.J.A.C. §8:57-6.4(c) *require* Rutgers to obtain proof from students of certain immunizations and authorize Rutgers to require other ACIP-recommended vaccinations." (JA26-27). The district court also ruled that N.J.S.A. §8:57-6.14(d) and -6.15(c) permit Rutgers to exclude exempt students "from classes and from participating in

institution-sponsored activities during a vaccine-preventable disease outbreak or threatened outbreak." (JA27). The district court reached these conclusions with no analysis or consideration of the entire statutory scheme, ignoring the plain language of these codes, and assuming facts contrary to Plaintiffs' allegations in error.

First, the district court ignored that N.J.S.A. 18A:61D-1 has no language delegating police powers to Rutgers to mandate anything. This statute's plain text requires Rutgers to collect from students "as a condition of admission or continued enrollment" their valid immunization record, "which documents the administration of all required immunizations against *vaccine-preventable disease*, or evidence of immunity from these diseases, in accordance with regulations promulgated by the Department of Health." (emphasis added). The district court ignored that this statute only allows Rutgers to collect such records from a student who is "30 years of age or less." Reading this statute plainly, if Rutgers has no authority to collect an immunization record from any student 30 years of age or older, it has no authority to enforce any vaccine mandate as to them. Accepting Plaintiffs' allegations as true, this statute is wholly inapplicable since Plaintiffs are alleging that COVID-19 vaccines do not prevent infection or transmission (JA208-210), and if true, COVID-19 vaccines are not "immunizations against *vaccine-preventable diseases*" that would trigger authority under this statute. As a result,

N.J.S.A. 18A:61D-1 is not a statutory delegation of police power to Rutgers to mandate any experimental vaccines.

The district court also totally ignored New Jersey's well-defined statutory scheme for mandating vaccines. *Jacobson, National Fed.,* and *Biden* require a clear delegation of police power to mandate vaccines. *See National Fed.*, at 667 (Gorsuch, J.) ("The central question we face today is: Who decides?"). In New Jersey, Rutgers does not decide.

New Jersey's Department of Health has the power to mandate vaccines: acting through New Jersey's Public Health Council, the Department of Health can mandate vaccines *but only* if it publishes the proposed regulation, holds a public hearing, and gives the public the opportunity to comment – none of which Rutgers can do. *See* N.J.S.A. 26:1A-7 (power to establish State Sanitary Code, including immunization against disease); *see also* N.J.S.A. 26:4-2 (general powers).

The Commissioner of Health can mandate vaccines unilaterally, *but only* during a public health emergency. *See* N.J.S.A. 26:13-14. Most recently, the Governor may also mandate COVID-19 vaccines, but that authority is tightly controlled by the state legislature. *See* N.J.S.A. 26:13-36.

More importantly, higher education administrative code section titled, "Modifications in the event of an outbreak or vaccine shortage" identifies only the Commissioner of Health or local health officers (which Rutgers is not) "may

modify the immunization requirements as set forth in this subchapter to meet the emergency." N.J.A.C. 8:57-6.21. "These modifications may include obtaining immunization documentation *or requiring **specific** immunizations for each student not covered by this subchapter*." N.J.A.C. 8:57-6.21(a)(1)(emphasis added). Thus, for higher education, only the Commissioner and local health officers may act in the event of an outbreak to mandate "***specific*** immunizations" that are not already set forth in the regulations "to meet the emergency." There is no express provision that Rutgers, or any other institution of higher education in New Jersey, has this authority and can take action "in the event of an outbreak" to mandate novel experimental vaccines for college attendance. There is good reason for that: in the event of an outbreak, it makes no sense for public or private institutions to have discretion about what vaccines to mandate or when; moreover, N.J.A.C. 8:57-6.21 gives only the Commissioner the power to temporarily suspend an immunization requirement for higher education in the event of a national or state "vaccine shortage." The Commissioner's power to coordinate a uniform response to an outbreak would be meaningless if colleges and universities have independent authority to mandate vaccines. To date, none of the government officials in New Jersey who are expressly empowered to mandate vaccination in response to an outbreak of COVID-19 have mandated any such vaccines for college attendance. The Department of Health has not promulgated any regulations requiring COVID-19 vaccines for attendance at public institutions of higher education either.

Without explanation or analysis, the district court ruled that N.J.A.C. 8:57-6.4(c) "authorize[s] Rutgers to require other ACIP-recommended vaccinations." (JA26-27). However, N.J.A.C. 8:57-6.4(c) (formerly N.J.A.C. 8:57-6.2(c), and before 1995, N.J.A.C. 9:2-14.2(b)) does not authorize Rutgers to do anything "during an outbreak"; at most, it only permits colleges and universities to establish "additional *requirements* for student immunizations and documentation recommended by the ACIP [Advisory Committee on Immunization Practices]" (emphasis added) not *additional* immunizations or *specific* immunizations (the language used by N.J.A.C. 8:57-6.21), and certainly not additional *experimental emergency use authorized* vaccines. Read in conjunction with New Jersey's legal framework, this regulation only means that colleges and universities can impose additional requirements and documentation on immunizations that are already required by existing statutes or regulations, if ACIP recommends it; this could include for example, changes in the types of documentation accepted as proof of vaccination or a particular brand of hepatitis B vaccine, since hepatitis B vaccine is statutorily required. *See* N.J.S.A. 18A:61D-8. Plaintiffs' interpretation of N.J.A.C. 8:57-6.4(c) is supported by the history of this regulation which the district court also ignored.

N.J.A.C. 8:57-6.4(c) was first proposed in 1989; the administrative history of this regulation[10] does not support the district court's conclusion the state gave Rutgers *carte blanche* authority to unilaterally impose any new vaccine on its student body 30 years ago. *See* 21 N.J.Reg. 3605-3607 (1989) (original version of rule proposed for N.J.A.C. 9:2-14.2(c)); 22 N.J.Reg. 1137-1140 (1990) (original version of rule adopted and codified at N.J.A.C. 9:2-14.1(b)). (JA406-416). Nowhere in the administrative history of this regulation going back to 1989 is there any discussion or suggestion that Rutgers (and every other college in New Jersey) was delegated police power to unilaterally increase the types of vaccines that students must take to attend. Absent an express delegation of police power, this regulation should not be read to give Rutgers, an unelected body, unprecedented power during an outbreak.

When N.J.A.C. 8:57-6.4(c) was originally proposed, Rutgers lodged a public comment to express its concerns that "standards within the rules and the underlying legislation are inadequate as approximately 10% of those individuals vaccinated prior to 1980 are not adequately protected due to vaccine failure." 22

[10] *See* 21 N.J.Reg. 3605 (1989) (original rule proposal for N.J.A.C. 9:2-14(c)); 22 N.J.Reg. 1137-1140 (original rule codified at N.J.A.C. 9:2-14.1(b)); 27 N.J.Reg. 3631(a) (1995) (recodified at N.J.S.A. 8:57-6.2(c)); 27 N.J.Reg. 4701(a) (1995); 33 N.J.Reg. 2752(a) (2001); 34 N.J.Reg. 3023(a) (2002); 36 N.J.Reg. 3335(a) (2004); 37 N.J.Reg. 3037(b) (2005); 40 N.J.Reg. 1962(a) (2008) (proposal to recodify at N.J.S.A. 8:57-6.4(c)); 41 N.J.Reg. 1419(a) (2009) (recodified at N.J.A.C. 8:57-6.4(c)).

N.J.Reg. 1138 (1990) (JA414). In response to Rutgers' comment, the Board of Higher Education at the time consulted with the Department of Health, which did not "recommend a change in the rules with regard to vaccine requirements at this time." *Id.* Back then, the only immunizations required by state law for college attendance were for measles, mumps and rubella. *Id.* Rutgers' concern that the rules being proposed did not require proof of such vaccination post-1980 would be unfounded if Rutgers could simply mandate such immunizations under these new regulations, especially when the original formulation of the regulation did not require a supporting ACIP recommendation to do so. (JA414-§9:2-14.2). When this regulation was promulgated, Rutgers did not believe that it had unilateral authority to mandate new vaccines. Rutgers' comment to the 1989 rule proposal would be superfluous if the regulation, N.J.A.C. 8:57-6.4(c), meant that a university had the authority to require more specific vaccinations unilaterally on its student body. It does not. Despite this administrative history, the district court ruled incorrectly that N.J.A.C. 8:57-6.4(c) gives Rutgers unilateral authority to impose whatever new vaccine Rutgers deems appropriate upon the student body with no restrictions (other than a recommendation by the ACIP).

In sum, N.J.A.C. 8:57-6.4(c), is not a delegation of police power to mandate vaccines, and it is certainly not an authorization to mandate *experimental* vaccines during a public health emergency. If colleges and universities could simply add

new vaccines to those required by the state Department of Health to attend college, then there would be no need for the State Legislature to devote effort to passing statutes requiring additional vaccines for college attendance since the adoption of this regulation in 1990. *See e.g.* N.J.S.A. 18A:61D-8 (adding hepatitis B vaccine in 2002); N.J.S.A. 18A:62-15.1 (2019 meningococcal vaccine amendment).

The district court's interpretation that N.J.A.C. §8:57-6.14(d) and N.J.A.C. §8:57-6.15(c) allow Rutgers to exclude unvaccinated students from university housing is similarly erroneous. First, the express language of these regulations does not give Rutgers the power to ban students from dormitories or evict them when an outbreak arises – they only allow exclusion of students from "classes" and "from participating in institution-sponsored activities."[11] Second, Rutgers' authority to exclude students from classes under these regulations only arises during "a *vaccine-preventable disease* outbreak." The district court failed to accept as true Plaintiffs' allegations that COVID-19 is not a vaccine-preventable disease because there is no vaccine that prevents COVID-19. (JA27; JA208-210). If COVID-19 vaccines do not prevent infection or transmission, then COVID-19 cannot be a "vaccine-preventable disease," and Rutgers cannot exclude students under these rules.

[11] N.J.A.C. §8:57-6.15(c)(1) requires Rutgers consult with the Health Commissioner in deciding to exclude religiously exempt students; there is no indication Rutgers ever did so.

Additionally, *Jacobson* stands for the proposition that a state legislature makes the determination that vaccination is necessary and can delegate that authority to a board of health. 197 U.S. at 27 ("appropriate for the legislature to refer that question… to a Board of Health"). *Jacobson* stands for the proposition that the power to mandate vaccines is a police power to be exercised or delegated by the State Legislature. In *Jacobson*, Massachusetts delegated that authority to local boards of health. New Jersey has delegated that authority to the Department of Health and under more limited circumstances, to the Governor, the Commissioner of Health or local health officers. New Jersey has not delegated such authority to private and public institutions of higher education, and therefore Rutgers lacks the prerequisite authority to mandate vaccines as *Jacobson,* and now the *National Fed.* and *Biden* Supreme Court precedents require. And since none of the government actors who are truly empowered to mandate compulsory vaccination in New Jersey have mandated COVID-19 vaccines for college attendance, Rutgers cannot do so. The district court considered none of these arguments.

Finally, in the alternative, if this Court were to find that Rutgers has authority under N.J.A.C. 8:57-6.4(c) to mandate vaccines, then this Court must consider the text of that regulation which tethers Rutgers' authority to an ACIP recommendation; any vaccine that a college or university may require under N.J.A.C. 8:57-6.4(c) must follow ACIP recommendation dictates.

The ACIP recommendations that Rutgers relies upon to mandate COVID-19 vaccines under N.J.A.C. 8:57-6.4(c) require compliance with 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), the requirement that recipients of these vaccines have a right to accept or refuse administration. The ACIP's recommendations expressly require a recipient to receive Fact Sheets stating that she has the option to refuse.[12] Rutgers cannot claim it has authority to require new vaccines on students "recommended by the ACIP" and then impose a mandate that conflicts with that very same ACIP recommendation. *Assuming arguendo*, that N.J.A.C. 8:57-6.4(c) gives Rutgers authority to mandate any new vaccine the ACIP recommends, whatever immunization requirement it adopts must comply fully with the ACIP's recommendation. In this case, Rutgers Policy violates the ACIP recommendation which requires informed consent.

The district court considered none of these matters in its conclusory determination that Rutgers Policy is authorized by state law. *Cf. Biden v. Missouri,* 142 S. Ct. 647, 654 (2022) ("The challenges posed by a global pandemic do not allow a federal agency to exercise power that Congress has not conferred upon it").

[12] *See e.g.* https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7044e2-H.pdf ("Before vaccination providers should provide the EUA Fact Sheet for the vaccine being administered…")

## IV. THE DISTRICT COURT ERRED BY HOLDING THAT STUDENTS' DUE PROCESS AND EQUAL PROTECTION CLAIMS WERE SUBJECT TO RATIONAL BASIS REVIEW.

Relying on *Jacobson v. Massachusetts,* 197 U.S. 11 (1905), the district court concluded that the constitutionality of Rutgers Policy was subject to rational basis review. (JA16-17). That ruling constitutes legal error because it ignores decades of binding precedents under the Due Process Clause and the unconstitutional conditions doctrine that modify *Jacobson*. The district court's decision is also erroneous because it misreads *Jacobson* and misapplies it to the facts in this case, which command a different result.

### A. Informed Consent is A *Fundamental* Right.

The district court completely ignored a line of cases decided since *Jacobson*, examining the right to informed consent and its corollary right to refuse unwanted medical treatment under the Due Process Clause of the Fourteenth Amendment. *See Washington v. Glucksberg*, 521 U.S. 702 (1997); *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 269 (1990); *Washington v. Harper*, 494 U.S. 210 (1990); *Youngberg v. Romeo*, 457 U.S. 307 (1982); *Ingraham v. Wright*, 430 U.S. 651, 673 (1977); *White v. Napoleon*, 897 F.2d 103 (3d Cir. 1990); *Rennie v. Klein*, 653 F.2d 836, 844 (3d Cir. 1981). Since *Jacobson*, the Supreme Court and this Court have come to recognize the right to informed consent and to refuse unwanted medical treatment is "deeply rooted in this Nation's history and constitutional

traditions." *Glucksberg,* at 725, *see also Cruzan,* at 269 ("The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions"). As a result, these rights must be regarded now as "fundamental" and these precedents require a court revisiting vaccine challenges today to employ a heightened standard of review if not strict scrutiny – but definitely not "rational basis". *See Washington v. Glucksberg*, 521 U.S. 702 (1997) (examining the right to informed consent); *Washington v. Harper,* 494 U.S. 210 (1990) (the significant liberty interest in avoiding unwanted administration of antipsychotic drugs); *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 269 (1990) (the constitutionally protected right to refuse lifesaving hydration); *see also Youngberg v. Romeo,* 457 U.S. 307, 316 (1982) (liberty from bodily restraints); *Ingraham v. Wright*, 430 U.S. 651 673 (1977) (freedom from unjustified intrusions into the body); *White v. Napoleon*, 897 F.2d 103 (3d Cir. 1990) (the right to information necessary to exercise informed consent); *Rennie v. Klein*, 653 F.2d 836, 844 (3d Cir. 1981) (the right to refuse unwanted medical treatment).

The district court also ignored the now well-settled unconstitutional conditions doctrine that "the government may not deny a benefit to a person because he exercises a constitutional right." *See Koontz v. St. Johns River Water Mngmt. Dist.*, 570 U.S. 595, 604 (2013); *Rumsfeld v. Forum for Academic and*

*Institutional Rights, Inc.*, 547 U.S. 47 (2006); *Rutan v. Republican Party of Ill.*, 497 U.S. 62 (1990); *Regan v. Taxation with Representation of Wash.*, 461 U.S. 540 (1983); *Memorial Hospital v. Maricopa County*, 415 U.S. 250, 269 (1974). This doctrine applies in the university context. *See Perry v. Sindermann*, 408 U.S. 593 (1972) (public college violates a professor's freedom of speech if it declined to renew his contract because he was an outspoken critic of the college's administration). "Those cases reflect an overarching principle, known as the unconstitutional conditions doctrine, that vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz*, at 604 (citing *Perry v. Sindermann*, 408 U.S. 593 (1972). "[R]egardless of whether the government ultimately succeeds in pressuring someone into forfeiting a constitutional right, the unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them." *Koontz*, at 606. The district court ignored all of these precedents.

*Jacobson* cannot be read in isolation, as though none of this jurisprudence exists. In *Cruzan*, the Supreme Court cited *Jacobson v. Massachusetts*, 197 U.S. 11, 24-30 (1905) (balancing individual liberty interest against State's interest in preventing disease), *Breithaupt v. Abram*, 352 U.S. 432, 439 (1957) ("As against the right of an individual that his person be held inviolable…"), *Washington v.*

*Harper*, 494 U.S. 210, 229 (1990) ("The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty"), *Vitek v. Jones*, 445 U.S. 480, 495-496 (1980) (transfer to a mental hospital coupled with mandatory behavior modification treatment implicated liberty interests), and *Parham v. J.R.*, 442 U.S. 584, 600 (1979) ("[A] child, in common with adults, has a substantial liberty interest in not being confined unnecessarily for medical treatment"), to recognize the "liberty interest in refusing medical treatment." *Cruzan*, at 278-79. According to the Supreme Court, that liberty emanates from the common law principle that "even touching of one person by another without consent and without legal justification was a battery." *Id.* at 269. "Before the turn of the century, [the Supreme Court] observed that no right is held more sacred, or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Id.* (citing *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891). Since *Jacobson*, "[t]his notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Id.* (quoting *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129-130 (1914) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an

operation without his patient's consent commits an assault, for which he is liable in damages."). Hence, the Supreme Court concluded "[t]he informed consent doctrine has become firmly entrenched in American tort law." *Id.*

In *Cruzan,* the Supreme Court further held, "[t]he right to refuse unwanted medical treatment" – to not consent – is "the logical corollary of the doctrine of informed consent." *Id.* at 270. It also held that "[a] person's liberty interest under the Due Process Clause in avoiding unwanted medical treatment must be determined by balancing his liberty interests against the relevant state interests." 497 U.S. at 278-79 (internal quotation marks admitted).

Following *Cruzan*, the Supreme Court went even further in *Washington v. Glucksberg,* 571 U.S. 702 (1997), and settled the question that the right to informed consent and refuse unwanted medical treatment is fundamental. In *Glucksberg,* the Supreme Court held that the Due Process Clause "protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition," and "implicit in the concept of ordered liberty," such that "neither liberty nor justice would exist if they were sacrificed." *Glucksberg*, at 721. Holding that substantive due process requires a "careful description" of the asserted fundamental liberty interest, the Supreme Court in *Glucksberg* concluded that "the right assumed in *Cruzan*" (the right to informed consent) was not "simply deduced from abstract concepts of personal autonomy

but rather "the common law rule that forced medication was a battery, and the long tradition protecting the decision to refuse unwanted medical treatment." *Id.* at 725. As a result, the Supreme Court held that the right recognized in *Cruzan* "was entirely consistent with this Nation's history and constitutional traditions." *Id.* at 724-25. The only conclusion that can be drawn from these holdings is that *Glucksberg* stands for the proposition that the right to informed consent and to refuse unwanted medical treatment is a ***fundamental*** right. *Id.* at 725 (distinguished from the right to die which has not enjoyed similar protection). The district court failed to weigh the effect of these binding precedents.

The district court also ignored the express command of this Court:

> The Due Process clause of the Fourteenth Amendment substantively protects certain ***fundamental*** rights. Among these are the right to be free from unjustified intrusions into the body, *Ingraham v. Wright*, 430 U.S. 651, 673 (1977), the related right to refuse unwanted medical treatment, *Rennie v. Klein*, 653 F.2d 836, 844 (3d Cir. 1981), and as we decide today, the right to sufficient information to intelligently exercise those rights.

*White v. Napoleon*, 897 F.2d 103, 111 (3d Cir. 1990) (emphasis added); *see also Leapheart v. Prison Health Services, Inc.*, No. 3:10-cv-1019, 2010 WL 5391315 (M.D. Pa. Nov. 22, 2010) at *6 ("[I]t is well-settled the Due Process Clause of the Fourteenth Amendment substantively protects certain fundamental rights").

The district court was bound by this Court's precedent to view Plaintiffs' rights to informed consent and to refuse unwanted medical treatment as

***fundamental***. Accordingly, Rutgers Policy must be "narrowly tailored to a compelling state interest," and rational basis is the wrong test. *See Burson v. Freeman*, 504 U.S. 191, 198 (1992) (when fundamental rights are at stake, "the state must show that the regulation is necessary to serve a compelling state interest and that it is narrowly drawn to achieve that end").

Alternatively, the district court was required to follow *Jacobson* conservatively and employ a *balancing* test – not a rational basis test – to determine whether Rutgers Policy violates constitutional rights by balancing the students' liberty interests against the relevant state interests. *See Cruzan,* 497 U.S. at 278 (holding that *Jacobson* employed a balancing test and balanced an individual's interest in declining an unwanted smallpox vaccine against the State's interest in preventing disease.). In other words, rational basis review does not apply.

In the current judicial landscape, Plaintiffs' claims here merit strict judicial scrutiny or at least heightened review among tiers of constitutional adjudication. Plaintiffs' liberty interests have gained weight in the balance against Rutgers' purported interest. *Jacobson* recognized "a sphere within which the individual may assert the supremacy of his own will and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will." 197 U.S. 11, 24-30 (1905).

Experimental vaccines that do not prevent infection or transmission fall within this inviolate "sphere" because they have "no real or substantial relation" to Rutgers' express purpose of preventing the spread of disease and vitiate the argument that these vaccines are necessary for the protection of others.

### B. Unconstitutional Conditions Doctrine Prohibits Coercion.

The district court in this case turned a blind eye to Rutgers' coercion. (JA22) ("Rutgers has not mandated any medical products"). However, the unconstitutional conditions doctrine compels a court to acknowledge it. *Koontz,* 570 U.S. at 606 ("we have recognized that regardless of whether the government ultimately succeeds in pressuring someone into forfeiting a constitutional right, the unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them.") Challenges to vaccine mandates must consider the unconstitutional conditions doctrine. "As in other unconstitutional conditions cases in which 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." *See Koontz*, 570 U.S. at 607. "A predicate for any unconstitutional conditions claim is that the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure that person into doing." *Id.* at 612. If Rutgers cannot order students to get vaccinated with experimental vaccines, it cannot pressure them to do so either.

Forcing a student to choose between an experimental vaccine or forfeiting her college enrollment is extortion. College students are at the pinnacle stage of their educational careers; achieved by years of study, toil, dedication and significant financial investment. Discharge from college enrollment is devastating and poses life altering, career jeopardizing consequences. Ms. Pinto, for example, needed two classes to graduate from Rutgers when she filed her claims in 2021; she was not able to graduate and remains deregistered. Rutgers knows the power it wields by threatening to deregister students, suspending their educational careers indefinitely. Would members of this Court have felt uncoerced if asked to choose between a vaccine or law school? Would members of this Court feel free to choose between your judicial appointments and an experimental vaccine if that choice were forced upon you? *See Biden v. Missouri*, 142 S. Ct. 647, 658 (Thomas, J., dissenting) (describing a mandate as "the statutory authority to force healthcare workers, by coercing their employers to undergo a medical procedure they do not want and cannot undo."). If Plaintiffs' allegations are true, then Rutgers Policy coerces students to forfeit their fundamental right to informed consent (and refuse unwanted medical treatment) by threatening to withhold the benefit of attending Rutgers. Courts can no longer turn a blind eye to this coercion because of the Supreme Court's unconstitutional conditions doctrine.

### C. Rutgers Policy Requires Heightened Scrutiny.

*Jacobson* was decided before courts articulated tiers of judicial scrutiny, before the doctrine of unconstitutional conditions, before the right to informed consent, and the right to refuse unwanted medical treatment were recognized as fundamental. Therefore, *Jacobson* is somewhat instructive but most certainly not dispositive. *See Halgren v. City o Naperville*, No. 21-cv-05039, 2021 WL 5998583 (N.D. Ill. Dec. 19, 2021) ("[M]odern courts cannot adopt a blunt application of *Jacobson's* 'substantial relation' deference test. Instead courts must interpret *Jacobson* through the lens of constitutional analysis."); *see also Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 74 (2020) (Kavanaugh, J., concurring) (addressing *Jacobson*, cautioned: "judicial deference in an emergency or crisis does not mean wholesale abdication, especially when important questions of religious discrimination, racial discrimination, free speech or the like are raised."); *see also Calvary Chapel Dayton Valley v. Sisolak*, 140 S. Ct. 2603, 2608 (2020) (Alito, J., dissenting) ("[I]t is a mistake to take the language in *Jacobson* as the last word on what the constitution allows public officials to do during the COVID-19 pandemic.").

*Jacobson* dealt with a nearly 100-year old smallpox vaccine and a $5 fine. 197 U.S. at 23-24 and footnotes. This case is not *Jacobson*. COVID-19 vaccines existed for only four months before Rutgers mandated them. Accepting as true the

allegations in the Complaint, where Plaintiffs allege so many unknowns about the efficacy and safety of novel COVID-19 vaccines, (JA207-223), the district court was not in a position to assess the relationship between an experimental vaccine, Rutgers' purported interests and Plaintiffs' fundamental liberties without a more developed adversarial record.

*Jacobson* holds that government action to mandate established vaccines must be subject to "reasonable conditions," "necessary for the public health or public safety," and proportional to the "necessity of the case." 197 U.S. at 26-28. Thus, *Jacobson* requires vaccines to be efficacious, safe, necessary, proportional and to accord with fundamental rights. 197 U.S. at 27-33 ("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, it is the duty of the courts to so adjudge, and thereby give effect to the Constitution."). These requirements must be harmonized with the current view that the right to informed consent and refuse unwanted medical treatment is now "fundamental," and that plaintiffs' coerced liberty interest is entitled to greater protection.

In the current judicial landscape, *Cruzan* and its progeny bestow greater weight to the liberty that was at stake in *Jacobson* a hundred years ago. Courts must now examine the decision to mandate vaccines with more exacting scrutiny:

How much did Rutgers know about the safety and efficacy of these vaccines? Was Rutgers capable of analyzing benefit versus risk, harm or injury to the student body? How did Rutgers manage its conflict of interests working for all three vaccine manufacturers? The district court never answers these questions.

Instead, the district court ignored these precedents and misread the substance of Plaintiffs' Due Process Claims. Students are not arguing against any and all vaccine requirements, (JA326), but rather against the mandate of an *experimental* vaccine, with no evidence that it prevents infection or transmission, with so many unknowns about safety or long-term health effects and thousands of reports of serious adverse reactions and deaths. Those facts cannot be discounted, ignored, or not accepted as true on a motion to dismiss. If it can be proven that FDA and the manufacturers said there was no data then (and no data exist now) that COVID-19 vaccines prevent infection or transmission, then Plaintiffs have stated a claim for a violation of Due Process.

In sum for COVID-19 experimental vaccines to satisfy the requirements of *Jacobson, Cruzan, Gluksberg, Napoleon* and *Koontz* today, COVID-19 vaccines must be proven to prevent infection and transmission; their risks and safety profile must be known; and a mandate must be narrowly tailored (or real and substantially related) to its purpose, so that individuals and the entities that mandate them can assess whether the benefits truly outweigh the risks and the mandate is necessary.

Students maintain that Rutgers has never had the information to make these assessments and never tried. Consistent with these precedents strict scrutiny or at least a heightened review should be applied to their claims, not a rational basis review that is essentially a foregone conclusion of constitutionality.

**D. Rutgers Policy Fails Even Rational Basis.**

In the alternative, if this Court affirms rational basis review, at this stage, on the current record, assuming Plaintiffs' facts are true, Rutgers Policy does not meet the requirements of rational basis because there are too many unknowns about COVID-19 vaccines. The expressed purpose of Rutgers Policy is to "minimize outbreaks of COVID-19" and to "prevent and reduce the risk of transmission of COVID-19" on campus. (JA253). These are legitimate state interests. However, Plaintiffs have also alleged that Defendants' financial relationships with COVID-19 vaccine manufacturers create conflicts of interest that may explain its initial decision to reverse course and issue a mandate. (JA202-207). Reading these facts in the light most favorable to Plaintiffs and drawing all reasonable inferences from them, Rutgers may not have pursued a legitimate interest, and did so arbitrarily (first mandating only students, then faculty and staff, and later visitors). This Court is also required to accept the following facts in Plaintiffs' First Amended Complaint which make Rutgers Policy more irrational:

First, and foremost, according to the FDA, there are insufficient data to know the efficacy of currently available COVID-19 vaccines or boosters in preventing asymptomatic infection or transmission of SARS-CoV-2. (JA151;207-223). It is irrational to mandate a vaccine that does not work.

Second, according to the FDA, there are insufficient data to know that COVID-19 vaccines as safe. (JA202-203). There are absolutely no data or information concerning whether COVID-19 vaccines pose any long-term risks. (JA212, JA219l; JA255-256). With this information lacking, whether the benefits of COVID-19 vaccines outweigh their risks is unknown. (JA156). It is irrational to mandate a vaccine without a full safety profile.

FDA permits use of all currently available COVID-19 vaccines under Section 564 of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3, which is an "emergency use authorization" ("EUA"), whose purpose is to make products available that have not gone through FDA's full safety and efficacy review process. (JA184-186). All currently available COVID-19 vaccines, testing and even masks are made available under EUA. (JA186). FDA is required to ensure that individuals are informed of "the option to accept or refuse administration" of EUA products. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). Even clinical studies for Pfizer's "Comirnaty" vaccine are ongoing, (JA189), and in any event, Pfizer's licensed vaccine is not currently available. (JA202).

As a result of their status as EUA products, COVID-19 vaccines are deemed by the FDA and the NIH as "experimental" vaccines, and these agencies use those terms interchangeably to describe them. (JA202-203). These vaccines were only tested on human subjects for six (6) months before release, and clinical studies for these vaccines are ongoing and will not be completed for several years. (JA203, JA212). Rutgers is engaged in clinical studies on all three vaccines, has multimillion dollar financial ties to all three COVID-19 vaccine manufacturers, and those relationships pose conflicts of interest when deciding to mandate. (JA203-207). EUA testing and masking are in the same investigational position. There is no test to determine if individuals are infectious. (JA194). FDA has never approved any face mask as being effective against COVID-19. (JA191)

Significantly, if Plaintiffs' allegations are accepted as true, COVID-19 vaccines cause injury and death. In less than a year, COVID-19 vaccines were reported to kill and injure more people than all other vaccines tracked in the government's VAERS since its inception in 1989. (JA155-156). Allegedly Rutgers did not consider this information. (JA215, JA224)

Rates of COVID-19 were lower when vaccines were unavailable. (JA183-184). Studies suggest that COVID-19 vaccines do not work, and whatever benefit they impart wanes or boosters would not be needed. (JA196). These are not "labels and conclusions," a "formulaic recitation of the elements of a cause of

action," or even "naked assertions devoid of further factual enhancement." *Ashcroft*, 556 U.S. at 678. These allegations are based on statements from the FDA. (JA151, JA191, JA208-209, JA212-213, JA216-218).

Plaintiffs pled that there are insufficient data to know that COVID-19 vaccines prevent infection or transmission, no data of long-term health risks, and increasing data about death and injury caused by these vaccines. (JA207-216). Construing these facts in the light most favorable to Plaintiffs, there is no method for an institution mandating these vaccines to reasonably weigh the risk and benefits, and no way to assess how to mandate these vaccines in a reasonable manner to reduce the spread of contagious disease. The lack of knowledge and information as to whether these vaccines prevent transmission makes it impossible for any college or university to say reasonably that mandating them is rationally related to a reduction in transmission. Because of the alleged unknowns surrounding COVID-19 vaccines, mandating them is not sufficiently related to Rutgers' express purpose to reduce transmission on campus. As a result, against the weight of a person's right to refuse in light of so many unknowns about the risks and safety of these COVID-19 vaccines, the state's interest must yield, especially while these vaccines remain "experimental." Plaintiffs are not asking the Court to make its own judgments about effectiveness; Plaintiffs allege that the FDA already determined there was insufficient data to confirm COVID-19

vaccines prevented transmission.[13] Accepting Plaintiffs' allegations, colleges and universities cannot mandate these vaccines or make distinctions between vaccinated and unvaccinated students. In view of Plaintiffs' allegations, Rutgers' requirement that students with fully remote schedules like Ms. Pinto must also vaccinate is particularly irrational since students like her would not attend class in-person – and she was deregistered when Rutgers allowed unvaccinated faculty and staff on campus freely.

Plaintiffs have alleged that breakthrough infections of the Delta variant demonstrate the ineffectiveness or waning efficacy of COVID-19 vaccines. (JA208-210). The emergence of the Omicron variant confirmed that fact in spades. Even though Rutgers claimed that vaccines were necessary and boasted the vast majority of its community are vaccinated, it decided to start the 2022

[13] The Amended Complaint cites FDA Briefing Documents that set forth all of the unknowns about these EUA COVID-10 vaccines. (JA151). For example, FDA's Briefing Document on the Pfizer BioNTech COVID-19 vaccine sets out the unknown benefits and data gaps associated with this vaccine: "Duration of protection" (unknown past two months); "Effectiveness in certain populations at high risk of severe COVID-19" (unknown for immunocompromised); "Effectiveness in individuals previously infected with SARS-CoV-2" ("data are insufficient"); "Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections" ("uncertainties"); "Vaccine effectiveness against asymptomatic infection" ("data are limited to assess the effect"); "Vaccine effectiveness against long-term effects of COVID-19 disease" ("not possible to assess"); "Vaccine effectiveness against mortality" ("Benefits in preventing death should be evaluated in large observational studies following authorization"); "Vaccine effectiveness against transmission of SARS-CoV-2." ("Data are limited to assess the effect."). (JA398-400).

Spring semester remotely.[14] That decision was made because these experimental vaccines do not work, and if they do not work, they cannot survive judicial scrutiny to be mandated. The district court considered none of this.

## V. THE DISTRICT COURT ERRED BY RULING THERE WERE NO EQUAL PROTECTION CLAIMS.

The district court erred in its analysis of students' equal protection claims by misunderstanding the nature of those claims. Contrary to the Court's conclusions, students alleged distinct violations of equal protection. Students alleged that Rutgers' initial decision to mandate vaccines upon them, but not faculty or employees, treated them differently from others similarly situated. (JA259). The district court resolved this classification as moot. (JA12). But, students also alleged that Rutgers Policy unlawfully discriminates against them for invoking their Due Process rights (JA260), which should be subject to a heightened standard of review as discussed *supra*. Students further alleged that naturally-immune students (who recovered from a COVID infection) are similarly situated to vaccinated students and should be treated similarly. (JA259)[15]. The district court did not rule or otherwise address those two particular claims of disparate treatment, so those claims must survive.

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[14] *See* https://coronavirus.rutgers.edu/significant-changes-related-to-covid-19/

[15] Plaintiffs Miller, Mancini, Corallo, and Pinto alleged natural immunity (JA161-177).

Additionally, Plaintiffs alleged that Rutgers' decision to require only exempt students to wear masks, test weekly and withdraw from university housing is another example of different treatment from similarly situated students (JA260-261). If the vaccines do not prevent transmission, as alleged, then vaccinated and unvaccinated students are similarly situated because they can spread the virus equally – and Rutgers' intentional policy of treating them differently has no rational basis (or would not satisfy the requirements of heightened review or strict scrutiny). The district court did not consider this disparity.

Instead, the district court erroneously concluded that by treating all unvaccinated persons at the university the same (subjecting all unvaccinated persons to mandatory testing and banning them from university housing), the students failed to plead disparate treatment. However, the unvaccinated students' claims concern disparate treatment from vaccinated students (not unvaccinated faculty) because the vaccine is ineffective at stopping transmission. Such claims are recognized as "class of one" equal protection claims, governed by the Supreme Court's holding in *Village of Willowbrook v. Olech*, 528 U.S. 562 (2000). This Court acknowledges "class of one" equal protection claims: "a plaintiff must allege that (1) the defendant treated him differently from others similarly situated; (2) the defendant did so intentionally, and (3) there was no rational basis for the difference in treatment." *Phillips v. County of Allegheny*, 515 F.3d 224, 243 (3d Cir. 2008);

*Hill v. Borough of Kutztown*, 455 F.3d 225 (3d Cir. 2006); *see also DeMuria v. Hawkes*, 328 F.3d 704 (2d Cir. 2003). The district court did not conduct a "class of one" analysis between unvaccinated and vaccinated students or between vaccinated students and naturally-immune students because it assumed facts that COVID-19 vaccines work, and natural immunity does not exist.

Accepting Plaintiffs' allegations as true, these "class of one" equal protection claims were properly pled because Rutgers Policy did not impose mandatory testing or housing bans on vaccinated students. Plaintiffs alleged that they are similarly situated to vaccinated students because vaccinated students are just as capable of spreading COVID-19. Thus, vaccinated and unvaccinated students are similarly situated and requiring only the unvaccinated students to test or to be excluded from dormitories is an arbitrary classification. The distinction between vaccinated students and naturally-immune students is just as arbitrary for the same reasons.

Due Process and Equal Protection claims would support violations of Section 1983 and the New Jersey Civil Rights Act ("NJCRA"). Since Plaintiffs have pled deprivations of underlying constitutional rights by Defendants, acting *under color of state law*, their claims for money damages under 42 U.S.C. § 1983 and the NJCRA, N.J.S.A. 10:6-2(c), should survive.

## VI. THE DISTRICT COURT ERRED BY RULING THERE IS NO CONFLICT BETWEEN RUTGERS POLICY AND FEDERAL LAW.

The district court ruled that there is no conflict between Rutgers Policy and federal law because "Rutgers has not mandated any medical products… Instead, it has simply made adherence to the mandate a condition to its enrollment at the university." (JA22). As argued, that conclusion is erroneous because making adherence to a mandate a condition to enrollment violates the unconstitutional conditions doctrine. Additionally, such action is preempted by federal law.

The Supremacy Clause establishes that federal law is supreme. U.S. Const., Art. VI, cl. 2. Pre-emption analysis requires a comparison of federal and state law. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 611 (2011). "State law is naturally preempted to the extent of any conflict with a federal statute." *Crosby v. National Foreign Trade Council*, 530 U.S. 363 (2000). The Supreme Court has held that "state and federal law conflict where it is 'impossible for a private party to comply with both state and federal requirements'." *PLIVA, Inc.*, 564 U.S. at 618 (quoting *Freightliner, Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (finding impossibility where it was not lawful under federal law for drug manufacturers to do what state law required of them).

The principle that it is illegal to coerce an individual to accept an experimental medical product is incorporated into the United States Code, the Code of Federal Regulations and guidance from health agencies. *See e.g.* 21

U.S.C. §360bbb-0a (investigational drugs for use by patients with a life-threatening disease or conditions require written informed consent); 42 U.S.C. §9501 (requiring same for mental health patients); 38 U.S.C. §7331 (same for veterans); 42 U.S.C. §300ff-61 ("in testing an individual for HIV/AIDS, the applicant will test an individual only after the individual confirms that the decision of the individual with respect with respect to undergoing such testing is voluntarily made."); 21 C.F.R. §50.20 (establishing conditions for obtaining informed consent for unlicensed medical product in research including that consent should be free from "coercion or undue influence"); 45 C.F.R. §46.116 (for unlicensed products in research "basic elements of informed consent" include a "statement that participation is voluntary" and "refusal to participate will involve no penalty or loss of benefits," and investigators must "minimize the possibility of coercion or undue influence"); FDA's *Information Sheet: Informed Consent* ("Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance… Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.")[16]. *See also Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 184 (2d Cir. 2009) ("The Nuremberg Code, Article 7 of the ICCPR, the

[16] *See* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#coercion (last visited January 11, 2022).

Declaration of Helsinki, the Convention on Human Rights and Biomedicine, the Universal Declaration on Bioethics and Human Rights, the 2001 Clinical Trial Directive, and the domestic laws of at least eighty-four States all uniformly and unmistakably prohibit medical experiments on human beings without their consent, thereby providing concrete content for the norm."). That near universal principle applies to the EUAs for COVID-19 vaccines which were issued pursuant to 21 U.S.C. §360bbb-3, and which, as a condition of emergency use authorization, requires the Secretary to establish "appropriate conditions designed to ensure that individuals to whom the product is administered are informed" of, *inter alia*, "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)(III). Read together these federal statutes and regulations require individuals to exercise informed consent and to choose freely whether to accept or refuse an experimental COVID-19 vaccine under EUA, or, EUA PCR testing or EUA practices (e.g. masking). Conditioning a benefit, or threatening the loss of a benefit to gain consent to administration of an unlicensed product is precisely the type of "coercion" or "undue influence" that is contemplated and forbidden by the federal statutory scheme governing such products. Rutgers Policy conflicts with the right to informed consent reflected in Section 564 because it renders it

impossible for students who object to EUA vaccines, tests and masks to exercise that right freely.

Rutgers Policy makes it impossible for students to exercise informed consent under federal law because it subjects them to coercion or undue influence. It is impossible for students who object to COVID-19 vaccination to simultaneously exercise the informed consent required by 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) and comply with Rutgers Policy. In other words, students coerced by Rutgers Policy, cannot give the informed consent that federal EUA law requires. If a student surrenders informed consent to comply with Rutgers Policy his decision does not comply with federal law; if the same student exercises informed consent under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) and refuses COVID-19 vaccination he violates Rutgers Policy. *See PLIVA, Inc.*, 564 U.S. at 620 ("[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it"). Plaintiffs can present evidence that they were coerced by Rutgers Policy, as alleged, (JA204); and will be in a position to prove impossibility and preemption.

## CONCLUSION

This Court should reverse the district court's rulings as a matter of law. It should also remand for further proceedings and a full adversarial record to adjudicate Plaintiffs' claims.

## STATEMENT REGARDING ORAL ARGUMENT

Appellants respectfully request oral argument concerning all issues that form the subject matter of this Appeal.

Respectfully submitted,

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## COMBINED CERTIFICATIONS

I, the undersigned, hereby certify the following:

1. I am a member of the Bar of the United States Court of Appeals for the Third Circuit.

2. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 12,992 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

3. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. 32(a)(6) because it uses a proportionally spaced typeface: Microsoft Word in 14 point Times New Roman.

4. The text of the electronic and paper versions of the foregoing brief are identical.

5. A virus check was performed on this brief using Avast Antivirus Software and that no virus was indicated.

6. On January 10, 2022, I caused the foregoing to be electronically filed with the Clerk of Court using the CM/ECF System, which will send notice of such filing to all registered users.

Dated: January 10, 2022

Respectfully submitted

*/s/ Julio C. Gomez*
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