

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

CATALINA MESSINA, KATHERINE DIEKER, )  
CHRISTOPHER JACOB, ANNA ZIMBERG, )  
AND ISABELLA WALZ )  
 )  
Plaintiffs, )  
 )  
vs. ) Civil Action  
 )  
THE COLLEGE OF NEW JERSEY )  
THE BOARD OF TRUSTEES OF THE )  
COLLEGE OF NEW JERSEY )  
 )  
 )  
 )  
Defendants. )  
\_\_\_\_\_ )

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BRIEF IN SUPPORT OF APPLICATION FOR A TEMPORARY RESTRAINING  
ORDER AND/OR PRELIMINARY INJUNCTION

Oral Argument Requested if opposed.

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## STATEMENT OF FACTS

### **A. The TCNJ mandate**

Defendant Board of Trustees of the College of New Jersey is the governing body of The College of New Jersey ("TCNJ"). TCNJ is a state school. Verified Complaint ("Verif. Compl.") at ¶8.

On May 10, 2021, TCNJ announced that all students would be required to receive a "Covid-19 vaccination" to attend school ("the Mandate"). *Id.* at ¶9. Students were given a deadline of August 9, 2021 to have received a first injection and uploaded proof to the Online Wellness Link ("OWL"), a TCNJ web application used to digitally track student medical information. *Id.* at ¶11. Students who missed this deadline were subject to deregistration and ineligible to participate in academic or extracurricular activities in the 2021 Fall Term. *Id.* at ¶12.

Students "may be considered" for an exemption if it conflicts with their sincerely held religious beliefs or if they have a medical contraindication. "Personal discomfort" with the pharmaceuticals is not a valid reason to decline one. *Id.* at ¶¶13-14. Natural immunity through recovery from Covid-19 does not exempt a student from The Mandate. *Id.* at ¶15.

Students granted an exemption from the Mandate are subject to a myriad of intrusive and discriminatory requirements and restrictions. These students are banned from: living on campus,

traveling overnight with varsity athletic teams, participating in non-varsity athletic clubs, and participating in all other activities that, in TCNJ's determination, "involve high contact with others." They are prohibited from being physically close to other people. They must submit to tracking and monitoring of their health with twice-weekly medical testing and daily health reports to TCNJ. They must quarantine if they are identified as a "close contact" of someone who tested positive for Covid-19, even if they themselves are healthy, have tested negative, or are immune. Their medical information is shared with their professors and they may be dropped from classes if "too many" exempted students are enrolled. *Id.* at ¶18(a)-(j).

All exemptions are placed in a student's file and are periodically reviewed by a health professional to "determine whether the exemption shall remain in effect and whether additional restrictions shall apply." If TCNJ determines that an exemption no longer applies, the student will be required to receive one of the mandated injections to continue school. This can apparently happen at any time. *Id.* at ¶¶16-17.

#### **B. Nature of the Mandated Pharmaceuticals**

It is simpler to define something by what it is rather than by what it is not. In the case of the products mandated by TCNJ, they do not fit easily within the definition of "vaccine," as

discussed within, but they do fit clearly within the definition of gene therapy products.

The FDA Office of Cellular, Tissue, and Gene Therapies defines gene therapy products as ones that are "administered as nucleic acids, viruses or genetically-engineered microorganisms," and which "mediate effects via: transcription or translation of the transferred genetic material, or integration into the genome."<sup>1</sup>

The products required under the Mandate all meet this definition. They are all composed of nucleic acids. The Pfizer and Moderna products mediate effects by translation of the transferred mRNA into the coronavirus spike protein while the Johnson and Johnson ("J&J") product mediates effects by transcription of the DNA product in the spike protein.<sup>2</sup> The Pfizer, Moderna, and J&J products (hereafter "the Gene Therapy Products" or "the GTPs") all meet the composition and mechanism of action for the gene therapy definition.<sup>3</sup> See also Moderna's S-1 form (FDA

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<sup>1</sup>Andrew Byrnes, "The Chemistry, Manufacturing and Controls (CMC) Section of a Gene Therapy IND" (undated) <https://fda.yorkcast.com/webcast/Play/efe41dc555fb4b2eab8f1ce5bb2ce023> (last accessed September 7, 2021)

<sup>2</sup> Jonathan Corum and Carl Zimmer, *How the Johnson & Johnson Vaccine Works*, New York Times, Updated May 7, 2021 ("The Johnson & Johnson vaccine is based on the virus's genetic instructions for building the spike protein. But unlike the Pfizer-BioNTech and Moderna vaccines, which store the instructions in single-stranded RNA, the Johnson & Johnson vaccine uses double-stranded DNA.") (last accessed September 16, 2021)

<sup>3</sup>Notably, the genetic material in the Pfizer, Moderna, and J&J products are not exact copies of SARS-Cov2's genetic material. The J&J product uses DNA while the genetic material of SARS-Cov2 is RNA. The Pfizer and Moderna genetic material encodes for the



regulates mRNA products as "gene therapy"), Exhibit E to Verif. Compl.

### **C. The Plaintiffs**

Plaintiffs are all current TCNJ students subject to the Mandate. Plaintiffs Catalina Messina, Christopher Jacob, Katherine Dieker, and Isabella Walz have religious exemptions to the Mandate for the Fall 2021 semester. Ms. Dieker, who has Type I diabetes, was advised by her doctor not to get the GTP, but TCNJ rejected her doctor's request for an exemption. Verif. Compl. at ¶53. Plaintiff Anna Zimberg has a medical exemption for the Fall 2021 semester.

Ms. Messina has been forced to defer this semester because she cannot and will not undergo the medical procedures TCNJ is requiring of exempt students. Messina Aff at ¶¶45-46. She will not get the GTP because of her religious beliefs and her right to exercise control over her own body. *Id.* She cannot undergo medical testing every 3-4 days because it would be detrimental to her physical and mental well-being. *Id.*

All Plaintiffs who are attending TCNJ this semester are suffering the inconvenience and indignity of undergoing a medical testing procedure twice a week and having their health status surveilled by school. They each must take time out of their day

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spike protein of SARS-Cov2, but is not an exact copy of the genetic code. Instead, the RNA is "nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 f." FDA letters to Pfizer and Moderna, Exhibits A and B to Declaration of Dana Wefer.

twice a week to submit to an uncomfortable medical procedure or they may be disciplined.<sup>4</sup> Ms. Messina cannot undergo the procedure at all. Ms. Dieker has already suffered two nosebleeds after the procedures. Verif. Compl. at ¶60. Ms. Zimberg has had to have the procedure done by a fellow student she knows, not a medical professional. Verif. Compl. at ¶70. The students are even required to continue the medical testing procedures if they are away from campus. Verif. Compl. at ¶20. In the case of Ms. Walz and Ms. Zimberg, this is particularly absurd because they are immune by having contracted and recovered from Covid. All Plaintiffs assert that the testing and medical surveillance is an invasion of their liberty and privacy rights to exercise autonomy over their bodies.

All Plaintiffs are suffering the indignity and unequal treatment of being placed on a list according to their medical status and having their medical status shared with their professors. As a consequence of this, Ms. Dieker, Ms. Zimberg, and Ms. Walz have each been singled out and treated differently by their professors due to their medical status. Ms. Dieker was told by one professor that she should discretely segregate herself from other students due to her medical status. Verif. Compl. at ¶58.

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<sup>4</sup>TCNJ, "Student Conduct and Off Campus Services, last updated by TCNJ August 30, 2021, available at <https://conduct.tcnj.edu/covid-19-resources/> (last accessed September 19, 2021) ("Failure to complete required testing may be referred to Student Conduct for disciplinary action.")

Ms. Zimberg was asked to sit near a window. Zimberg Aff. at ¶73. All were told to be mindful of their physical proximity to others.

Ms. Dieker and Mr. Jacob are also affected by the school's arbitrary policies concerning club sports. Ms. Dieker is captain of the Women's Club Lacrosse team and Mr. Jacob plays on the Men's Soccer Club. Verif. Compl. at ¶¶64-65. Neither of them are clear on how much they are allowed to participate in their sports because it depends on the club's executive board having submitted special practice plans to ensure that Ms. Dieker and Mr. Jacob do not get too physically close to others. However, if Ms. Dieker and Mr. Jacob played varsity instead of club, these restrictions would apparently not apply and they would be free to participate fully, except for travel.

#### **LEGAL ARGUMENT**

#### **THE MANDATE SHOULD BE ENJOINED BECAUSE IT VIOLATES THE 14<sup>TH</sup> AMENDMENT TO THE U.S. CONSTITUTION**

A temporary injunction should be granted if (1) the plaintiff is likely to succeed on the merits; (2) denial will result in irreparable harm to the plaintiff; (3) granting the injunction will not result in irreparable harm to the defendant; and (4) granting the injunction is in the public interest. *Maldonado v. Houstoun*, 157 F.3d 179, 184 (3d Cir. 1998).

Plaintiffs fulfill each element. The facts of this case demonstrate a shocking overreach of government power in clear violation of the United States Constitution. The Mandate violates

the Due Process and Equal Protection clauses of the 14<sup>th</sup> Amendment in multiple and layered ways including: the liberty and privacy to decline medical procedures, the liberty and privacy to be free of government medical testing, the liberty and privacy to be free from government medical surveillance, and the right to participate equally in campus activities.

**I. JACOBSON IS DISTINGUISHABLE FROM TCNJ'S MANDATE**

The right of a free and mentally competent person to decline unwanted medical procedures is well-established as essential to the ordered concept of liberty and the individual right to privacy. People have the right to decline even lifesaving medical care. This applies to taking things out of a person's body against their will. *In re A.C.*, 573 A.2d 1235 (D.C. Court of Appeals 1990) (c-section cannot be performed without consent, even to save life of baby); *Lane v. Candura*, 376 N.E.2d 1232 (Mass. App. Ct. 1978) (patient cannot be forced to undergo amputation even if they will likely die without it). It applies to putting things into a person's body against their will. *Zant v. Prevatte*, 286 S.E.2d 715 (Ga. 1982) (prisoner right to refuse food), *Erickson v. Dilgard*, 252 N.Y.S. 2d 705 (Special term 1962) (competent adult has liberty to refuse blood transfusion even if it may cause their death). It applies no matter how unreasonable or illogical the refusal. It applies even if children will be left without their parent. *In re Osborne*, 294 A.2d 372 (D.C. Court of Appeals 1972). It is a

fundamental right and to intrude on this right the state's action must be narrowly tailored to achieve a compelling government interest.

The only exception is vaccines. This exception is based on the precedent of *Jacobson v. Massachusetts* in which the Supreme Court upheld a legislative enactment that authorized a \$5 fine for people who declined the smallpox vaccine. *Jacobson*, 197 U.S. 11 (1905). Specifically, the Court held that the right to decline the smallpox vaccine is not a liberty secured by the Constitution. *Id.* at 38 (stating "we do not perceive that this legislation has invaded any right secured by the Federal Constitution"). The Court did not engage in balancing because tiered constitutional analysis had not yet been invented. *Jacobson* has birthed a line of cases in which "vaccines" stand outside traditional constitutional analysis. Under an expansive reading of *Jacobson* there is no liberty right to decline any medical procedure categorized as a "vaccine."

The Supreme Court addressed vaccine mandates just one other time, in 1922. That case, *Zucht v. King*, upheld a San Antonio ordinance that excluded children from school if they had not received the smallpox vaccine. The policy was upheld because declining the smallpox vaccine was not a right guaranteed by the 14<sup>th</sup> Amendment based on the precedent set in *Jacobson*. *King*, 260 U.S. 174 (1922).

Together, *Jacobson* and *King* take pharmaceuticals labeled as "vaccines" outside another tenet of constitutional analysis- the unconstitutional conditions doctrine. In 1926, four years after *King* was decided, the Supreme Court articulated for the first time the doctrine of unconstitutional conditions, which prohibits the government from conditioning a benefit or privilege on the surrender of a constitutional right. *Frost v. Railroad Commission of State of California*, 271 U.S. 583 (1926). The doctrine has been applied to a myriad of government benefits like tax exemptions, unemployment benefits, welfare, and public employment. *Perry v. Sindermann*, 408 U.S. 593, 59 (1972) (internal citations omitted).

Because declining a vaccine is not a liberty right under *Jacobson*, the unconstitutional conditions doctrine has not been applied to vaccines. Consequently, any government benefit or privilege can theoretically be linked to a person's agreeing to take a vaccine, including tax exemptions, unemployment benefits, welfare, public employment, driving, or even using the local playground. Thus far this has been applied to public education, but there are already attempts all over the country to expand it to public employment, private employment, and travel.

Because "vaccines" are privileged to be outside traditional constitutional analysis, the threshold inquiry in every case related to a "vaccine" mandate must be whether the mandated pharmaceutical is a "vaccine." If it is not, then then it is

outside the scope of *Jacobson* and *King* and strict scrutiny applies because declining medical procedures is a fundamental right.

*Jacobson* is also distinguishable because it is not a legislative enactment, the GTPs do not have a century of medical data and century of scientific consensus as the smallpox vaccine did, and the consequence of declining the "vaccine" is far more serious than in *Jacobson*, where it was a \$5 fine.

**A. The GTPs are not vaccines under a statutory or dictionary definition of the word**

As a threshold matter, *Jacobson* is inapplicable because it applies to vaccines and the GTPs are not vaccines. They do not fall under any relevant statutory definition and they are excluded from most dictionary definitions due to their composition.<sup>5</sup>

The word "vaccine" is not defined in the Vaccination Assistance Act of 1962 ("the VAA"), the first federal program to provide funding for vaccination<sup>6</sup>, or the National Childhood Vaccine Injury Act ("NCVIA"), the most prominent federal statute relating to vaccines. Since the VAA, Congress has passed other laws concerning vaccine distribution and government appropriations, but

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<sup>5</sup>There is a statutory definition for the word "vaccine" in the tax code. 26 U.S.C.A. § 4132(a)(2) defines "vaccine" as "any substance designed to be administered to a human being for the prevention of 1 or more diseases." However, this definition is so broad it could include any prophylactic drug. The statute does not concern vaccination, it concerns taxation.

<sup>6</sup>Notably, Congress took care to safeguard choice when it came to immunization stating that the law should not be construed to require a vaccination program that would "require any person who objects to immunization to be immunized." Pub.L. 87-868 (1962).

the word does not appear to be defined in any of these laws either. See e.g., 42 U.S.C. 245. Instead, Congress's inclusion of a "vaccine" in an appropriation or program follows the designation of a pharmaceutical as a "vaccine" by executive branch agencies.

The NCVIA sets forth that new vaccines are added to the Vaccine Injury Table when the Centers for Disease Control ("CDC") recommends a vaccine to the Secretary of Health and Human Services. 42 USC §300aa-14(e(2)). However, classification of a pharmaceutical as a vaccine likely happens earlier than that. The FDA assigns vaccines to a review group specifically designated for them- The Vaccines and Related Biologics Committee. There does not appear to be public information available about how the FDA determines whether a drug application belongs in the Vaccine Committee or another committee. It is even possible that pharmaceutical manufacturers themselves set the process in motion by categorizing their product as a vaccine on the application.

Because there is no statutory definition for the word "vaccine" in federal statutes concerning vaccination, dictionary definitions and other sources may be instructive. A review of the definition of "vaccine" over the last 116 years shows that the word's meaning was once fixed, but has now become unsettled with no agreed-upon definition; in fact, dictionaries contradict each other. Even the CDC website contradicts itself in defining "vaccine," as discussed within.



In 1905 and 1916, when *Jacobson* and *King* were decided, the definition of vaccine was fixed and narrow:

of or pertaining to cows; pertaining to, derived from, or caused by, vaccinia; as, vaccine virus; the vaccine disease. -  
- n. The virus of vaccinia used in vaccination.<sup>7</sup>

The word describes one specific virus and the use of that virus to inoculate against smallpox. The Court's opinions in *Jacobson* and *King* related only to the smallpox vaccine, though at the time the term "smallpox vaccine" would have been redundant.

The dictionary definition of "vaccine" remained largely the same in the fifty years following *Jacobson*. In 1954, it was still related only to smallpox:

The substance taken from a cow with cowpox and the fluid used in inoculating the body against smallpox.<sup>8</sup>

Jumping forward 40 years, an archive<sup>9</sup> of Webster's Dictionary Online 2006 definition for "vaccine" shows that the word made it through the digital revolution intact. The first definition still related only to smallpox, as it had for the past century. A second

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<sup>7</sup> Vaccine, *The Webster's Revised Unabridged Dictionary* (editor Noah Porter, Springfield, MA: C. & G. Merriam Co., 1913), available at <https://www.websters1913.com/words/Vaccine>

<sup>8</sup> Vaccine, *Webster's Illustrated Dictionary*, 1954, Exhibit C to Declaration of Dana Wefer.

<sup>9</sup> Archived webpages throughout were taken from archive.org, a 501(c)(3) organization "building a digital library of Internet sites and other cultural artifacts in digital form" since 1996. The website allows users to save a screenshot of a webpage in time. The about section for the organization is here: <https://archive.org/about/>

definition expanded the category of vaccines to include:

a preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms that is administered to produce or artificially increase immunity to a particular disease.<sup>10</sup>

This definition ("the Microorganism Definition") became dominant and is still found in other dictionaries such as Collins English Dictionary<sup>11</sup> and Random House Kernerman Webster's College Dictionary (2010).<sup>12</sup>

Few courts have grappled with the question of what constitutes a "vaccine," but of those that have, most have used the Microorganism Definition. See *Blackmon v. American Home Products Corp.*, 267 F.Supp.2d 667, 674 (S.D. Tex. 2003) (relying on definition of vaccine in *Dorland's Medical Dictionary* 1799 (27th ed.1988) ("a suspension of attenuated or killed microorganisms") and *Webster's 9th New Collegiate Dictionary* 1301 (9th ed.1991) ("a preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms"); see

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<sup>10</sup> Vaccine, Merriam-Webster online as of February 12, 2006 available at <https://web.archive.org/web/20060212064058/https://www.merriam-webster.com/dictionary/vaccine>

<sup>11</sup> Vaccine, Collins English Dictionary - Complete and Unabridged, 12<sup>th</sup> Edition (2014), available at <https://www.collinsdictionary.com/dictionary/english/vaccine> (last accessed September 25, 2021).

<sup>12</sup> Random House Kernerman Webster's College Dictionary (2010) (defining vaccine as "any preparation of weakened or killed bacteria or viruses introduced into the body to prevent a disease by stimulating antibodies against it").

also *Owens Ex Rel. Schafer v. American Home Prod.*, 203 F. Supp. 2d 748, 755 (S.D. Tex. 2002) (citing the same dictionary definitions).

Technology advanced again last year with the invention of "Subunit, recombinant, polysaccharide, and conjugate vaccines," which contain "specific pieces of the germ—like its protein, sugar, or capsid (a casing around the germ)."<sup>13</sup> Some dictionaries expanded the definition of "vaccine" to include this new technology and others have not. See e.g., *Dorland's Illustrated Medical Dictionary*, 1767 (32d ed 2012) (defining "vaccine" as "a suspension of attenuated or killed microorganisms. . . .or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases") (as quoted in *Dean v. Secretary of Health and Human Services*, United States Court of Federal Claims, No. 16-1245V (May 29, 2018)).

Washington State, which appears to be the only state that has defined the word through legislation, uses a similar definition:

a preparation of killed or attenuated living microorganisms, or fraction thereof, that upon administration stimulates immunity that

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<sup>13</sup> The U.S. Department of Health and Human Services breaks "vaccines" down into many different sub-categories including: inactivated vaccines, live-attenuated vaccines, Messenger RNA (mRNA) vaccines (like Moderna and Pfizer), Subunit, recombinant, polysaccharide, and conjugate vaccines, Toxoid vaccines, and viral vector vaccines (like Johnson and Johnson). See U.S. Department of Health and Human Services, "Vaccine Types," last reviewed by HHS April 29, 2021, available at <https://www.hhs.gov/immunization/basics/types/index.html> (last accessed September 7, 2021).

protects against disease and is approved by the federal food and drug administration as safe and effective.

RCW 70.290.010(10).

The technology advanced again with the advent of mRNA and DNA “vaccines” and in a testament to how fluid the definition is, some online dictionaries changed the definition for “vaccine” just in the last few months to bring the GTPs within its ambit. For example, on January 18, 2021, the Webster Online Dictionary’s definition of vaccine was:

A preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms that is administered to produce or artificially increase immunity to a particular disease.<sup>14</sup>

Eight days later the definition was expanded such that the GTPs, which were excluded under the old definition because they do not contain microorganisms, now qualified as vaccines. Specifically, a secondary definition was added to include:

A preparation of genetic material (such as a strand of synthesized messenger RNA) that is used by the cells of the body to produce an antigenic substance (such as a fragment of virus spike protein).<sup>15</sup>

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<sup>14</sup> Vaccine, *Merriam-Webster Dictionary* as of January 18, 2021 archived <https://web.archive.org/web/20210118194713/https://www.merriam-webster.com/dictionary/vaccine> available at

<sup>15</sup> Vaccine, *Merriam-Webster Dictionary*, as of January 26, 2021, archive available at <https://web.archive.org/web/20210126065143/https://www.merriam-webster.com/dictionary/vaccine>. Interestingly, on or around August 21, 2021, Merriam-Webster updated the definition *again*, this time to include non-infectious agents, which brings

Cambridge Dictionary did the same thing. Four months ago, the GTPs were excluded from the Cambridge Dictionary definition of "vaccine" because they do not contain a virus or bacteria:

A substance containing a virus or bacterium in a form that is not harmful, given to a person or animal to prevent them from getting the disease that the virus or bacterium causes.<sup>16</sup>

But by August the definition was changed, bringing the GTPs within its ambit:

A substance that is put into the body of a person or animal to protect them from a disease by causing them to produce antibodies (=proteins that fight diseases).<sup>17</sup>

The definition has followed the technology, resulting in a hodgepodge of definitions as technology has moved faster than language. Even the CDC has fallen into this trap. On the CDC webpage titled "Glossary of Vaccine Terms," the CDC defines "vaccine" as

A suspension of live (usually attenuated) or inactivated microorganisms (e.g. bacteria or viruses) or fractions thereof administered to induce immunity and prevent infectious

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pharmaceuticals like "cancer vaccines" and "ricin vaccines" under the ever-expanding vaccine umbrella.

<sup>16</sup>Vaccine, *Cambridge Dictionary*, as of June 23, 2021 available at <https://web.archive.org/web/20210623084055/https://dictionary.cambridge.org/dictionary/english/vaccine>

<sup>17</sup>Vaccine, *Cambridge Dictionary*, as of August 2, 2021 available at <https://web.archive.org/web/20210802213130/https://dictionary.cambridge.org/dictionary/english/vaccine>

diseases and their sequelae.<sup>18</sup>

This definition excludes the GTPs. However on another webpage the definition drops any reference to composition and instead defines “vaccine” by its function: “[a] preparation that is used to stimulate the body’s immune response against diseases.”<sup>19</sup>

The split in definitions on the CDC website illustrates a larger trend and demonstrates that the word “vaccine” is expanding in two different directions to the same result. On one hand the definition is expanded to include new technology. Thus the definition has gone from: the vaccinia virus → microorganisms → microorganisms or parts of microorganisms → modified genetic material that encodes for a viral protein.

Other definitions, like the second CDC one, have dropped the composition part of the definition altogether so that *anything* that “stimulates” an immune response is a “vaccine.” In that case, the definition went from the vaccinia virus →

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<sup>18</sup> CDC, *Glossary*, last reviewed by CDC July 2020, available at <https://www.cdc.gov/vaccines/terms/glossary.html> (last accessed September 7, 2021)

<sup>19</sup> CDC, *Immunization: The Basics*, last reviewed by CDC September 1, 2021 <https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm> (last accessed September 7, 2021). It’s worth noting that this definition is also undergoing its own expansion. On or around September 7, 2021, the CDC changed the definition of vaccine on its website from a product that stimulates the immune system to “produce immunity” to one that just stimulates the body’s immune response. An archive of the original is available here: <https://web.archive.org/web/20210826113846/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm>

microorganisms generally → microorganisms or parts of microorganisms → anything that stimulates immunity.

Whether the composition part is expanded by adding new technologies as they are invented or whether its dropped altogether, the result is the same: anything that stimulates immunity is being *de facto* treated as a "vaccine."

Thus, in 116 years the definition of "vaccine" has made the drastic move from the specific "virus called vaccinia" to anything that stimulates immunity. This change happened without Congress ever defining the word. Instead, the change has been driven by the advancement of technology and a federal agency's discretion to create sub-categories of "vaccines" rather than calling them by a new word. And it is on this that Plaintiffs' liberty rests.

The expansion of the word "vaccine" would be nothing more than a cultural curiosity, like how the word "phone" has come to encompass smartphones, except that if *Jacobson* applies to all vaccines without any balancing required, every expansion of the word "vaccine" triggers an accompanying expansion of government power and diminution of individual liberty for every American.

Here, the GTPs just do not fit under the traditional meaning of the word vaccine. Even using an expanded definition from the last ten years, the GTPs do not qualify as "vaccines" under most dictionary definitions because they do not contain microorganisms

or pieces of microorganisms.

The GTPs are excluded from traditional dictionary definitions of the word "vaccine." They are outside the definition of "vaccine" from when *Jacobson* was decided and all dominant definitions since then. They can possibly be shoehorned into the broad definition on the CDC website, but even that broad definition is contradicted by another CDC definition, which excludes the GTPs. It is impossible to determine that Plaintiffs have no liberty right to decline the GTPs under *Jacobson* because they are "vaccines" when there is no agreement on what constitutes a "vaccine." Consequently, strict scrutiny applies because the GTPs are a medical procedure.

**B. *Jacobson* is distinguishable from the TCNJ mandate because *Jacobson* involved a legislative enactment while TCNJ's mandate is bureaucratic.**

*Jacobson's* outcome was highly dependent on the fact the challenged statute was a legislative enactment. *Jacobson*, 197 U.S. at 11. (holding that "[t]he police power of a State embraces such reasonable regulations relating to matters...established directly by legislative enactment" and "it is for the legislature, and not for the courts, to determine in the first instance whether vaccination is or is not the best mode for the prevention of smallpox and the protection of the public health"). The ordinance in *King* was also legislative.



In contrast, the TCNJ Board is not a legislature and the Mandate is not the result of a legislative process. Thus, it is outside the ambit of *Jacobson* and strict scrutiny applies.

**C. *Jacobson* involved a minor fine while TCNJ's mandate imposes an invasive system of ongoing medical testing, medical surveillance, and segregation.**

The consequences for declining the smallpox vaccine in *Jacobson* was a \$5 fine, equivalent to about \$140 today. It was a light intrusion on Mr. Jacobson's liberty. Justice Gorsuch noted how light this intrusion was just last year in his concurring opinion in *Roman Cath. Diocese of Brooklyn v. Cuomo*. 141 U.S. 63, 70 (2020) (noting that "[t]he imposition on Mr. Jacobson's claimed right to bodily integrity, thus, was avoidable and relatively modest") (Gorsuch, J., concurring).

In contrast, the TCNJ Mandate does not lightly impinge on liberty. Instead, it derails a person's plotted course in life by banning them from continuing their education at TCNJ despite years of investment and considerable expense. This is an unconstitutional condition under traditional constitutional analysis. See *Dolan v. City of Tigard*, 512 U.S. 374, 385, 114 S. Ct. 2309, 2317 (1994) (explaining that under the "well-settled doctrine of 'unconstitutional conditions,' the government may not require a person to give up a constitutional right...in exchange for a discretionary benefit conferred by the government where the benefit sought has little or no relationship to the property").

Exempt students must undergo twice weekly medical testing procedures and daily medical reporting and surveillance. Their medical status is reported to their teachers and they are banned or highly limited from partaking in regular campus activities. The consequences of declining the vaccine is a massive intrusion on the students' lives that is ongoing and indefinite. The alternative to TCNJ's mandated medical procedures is other medical procedures in the form of testing and medical surveillance. This is a wholly different circumstance from the \$5 fine in *Jacobson*.

This massive intrusion is so far outside of *Jacobson's* fact pattern that *Jacobson* is distinguishable and not controlling.

**D. Even if the GTPs are vaccines, their novelty and experimental nature is so drastically different from the vaccines in *Jacobson* that *Jacobson* is distinguishable and does not apply**

The smallpox vaccine and information concerning its safety existed for more than 100 years at the time *Jacobson* was decided, and the Court took this historical data into consideration. *Jacobson*, 197 U.S. at 23-24 (holding that expert testimony concerning the smallpox vaccine was not necessary because there was a century of data and century of medical consensus concerning it).

In contrast, the GTPs are novel medical products themselves, and also novel technologies (the gene therapy and the nanolipid delivery system for the mRNA products). The GTPs have existed less than 2 years, have been administered to the general population for

less than a year, and are still in clinical trials. There was never a GTP tested in a healthy population until last year. Comirnaty, Pfizer's GTP, is the first GTP ever approved for widespread use, and there is considerable controversy over the approval process.<sup>20</sup>

Knowledge concerning the GTPs' efficacy and safety is evolving in real time. This is completely different from *Jacobson* where the vaccine had a century of historical data on which the legislatures and Court could and did rely. The difference between the smallpox vaccine in *Jacobson* and the GTPs is a material difference so great *Jacobson* cannot apply.

Because the GTPs are not vaccines, because the Mandate is not legislative, because the consequences for declining the vaccine are so extreme, and because the GTPs are so materially different from the smallpox vaccine, *Jacobson* is distinguishable and not controlling.

**II. Because *Jacobson* is not controlling, strict scrutiny applies and the TCNJ Mandate is plainly unconstitutional**

Strict scrutiny applies to state action affecting fundamental rights. The right to decline medical procedures is fundamental. Both the GTPs and the medical testing are medical procedures, so

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<sup>20</sup> See e.g., Peter Doshi, *Does the FDA think these data justify the first full approval of a covid-19 vaccine?*, BMJOpinion, August 23, 2021, available at <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/> (last accessed September 7, 2021).

both are subject to strict scrutiny.<sup>21</sup> The additional requirement that Plaintiffs submit to ongoing medical surveillance and the disclosure of personal medical information to their professors also implicates fundamental rights because they fall within the privacy interests rooted in the Fourteenth Amendment, namely “the individual interest in avoiding disclosure of personal matters and the interest in independence in making certain kinds of important decisions.” *Doe by & through Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518, 527 (3d Cir. 2018) (citing *Doe v. Luzerne County*, 660 F.3d 169, 175 (3d Cir. 2011)).

TCNJ’s asserted interests must be balanced and weighed against the seriousness of these intrusions on liberty and privacy. *Wisconsin v. Yoder*, 406 U.S. 205, 214 (1972) (stating that with balancing, state interest must be “of sufficient magnitude to override the interest claiming protection”). The policy also must be narrowly tailored to advance TCNJ’s asserted interests. *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997) (stating that “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”) (quoting *Reno v. Flores*, 507 U.S. 292, 301 (1993)).

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<sup>21</sup> The medical testing also violates the privacies protected by the 4<sup>th</sup> Amendment to the Constitution.

The below factors should be considered in balancing TCNJ's interests against all the fundamental liberties intruded upon by the Mandate.

**A. The factors that make *Jacobson* distinguishable also favor striking down the Mandate under strict scrutiny analysis**

The facts that the Mandate is not a legislative enactment, that the GTPs are experimental, and that the alternative to receiving a GTP is invasive testing procedures and medical surveillance instead of a modest fine all weigh in favor of striking down the Mandate.

**B. The uncertainty concerning the GTPs' ability to stop infection and transmission weighs against the Mandate**

Much is unknown concerning the GTPs' efficacy. The "Fact Sheets for Recipients and Caregivers" for each GTP states that "the product may not protect everyone" and "the duration of protection is currently unknown." Exhibits F, G, and H to Verf. Compl. It is increasingly clear that "breakthrough" infections are fairly common.

The government does not know how long immunity from the GTPs lasts or its efficacy against new variants. Information is coming out in real time and government officials are even issuing conflicting information at times. For example, in April CDC Director Dr. Rochelle Walensky stated that data suggests

"[v]accinated people do not carry the virus – they don't get sick."<sup>22</sup> However, a CDC spokesperson walked back the claim later that day stating "[i]t's possible that some people who are fully vaccinated could get Covid-19. The evidence isn't clear whether they can spread the virus to others. *We are continuing to evaluate the evidence.*"<sup>23</sup> Three months later, this past July, the CDC announced that more recent data shows vaccinated and unvaccinated people carry similar viral loads, which "suggest[s] an increased risk of transmission."<sup>24</sup>

The fact that GTP efficacy is unsettled weighs heavily in favor of students' right to decline it. The fact that people who have received the GTPs may still get and transmit Covid-19, undermines any state interest in Mandating students to take the GTP. This is especially true when viewed in tandem with the next factor: the Mandate does not account for natural immunity.

**C. The Mandate's failure to account for natural immunity shows that the Mandate is not narrowly tailored**

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<sup>22</sup> Paola Rosa-Aquino, *CDC Data Suggests Vaccinated Don't Carry, Can't Spread Virus*, *New York Magazine, The Intelligencer* (April 1, 2021) available at <https://nymag.com/intelligencer/2021/04/cdc-data-suggests-vaccinated-dont-carry-cant-spread-virus.html> (last accessed September, 7 2021).

<sup>23</sup> *Id.* (emphasis added)

<sup>24</sup> CDC, *Statement from CDC Director Rochelle P. Walensky, MD, MPH on Today's MMWR (Media Statement (July 30, 2021) available at <https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html> (last accessed September 7, 2021).*

People who recover from Covid-19 develop robust and broad immunity that protects them from reinfection.<sup>25</sup> A study funded by the National Institute of Health and National Cancer Institute and published in the journal Science found that “more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection.”<sup>26</sup> Another study published in Science found that the naturally immune produce an array of antibodies that are resistant to every Sars-Cov2 variant currently in circulation.<sup>27</sup>

The fact that the Mandate does not account for those who are immune through recovery demonstrates that the Mandate is not narrowly tailored under equal protection and due process analysis.

**D. The wide range of treatments available for Covid-19 undermines TCNJ’s interests and shows the Mandate is not narrowly tailored**

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<sup>25</sup> Turner, J.S., Kim, W., Kalaidina, E. et al. *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*. Nature 595, 421-425 (2021). (“Overall, our results indicate that mild infection with SARS-CoV-2 induces robust antigen-specific, long-lived humoral immune memory in humans”) available at <https://doi.org/10.1038/s41586-021-03647-4> May 24 (last accessed September 7, 2021)

<sup>26</sup>NIH, *Lasting immunity found after recovery from COVID-19*, (January 26, 2021) available at <https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19> (last accessed September 7, 2021).

<sup>27</sup> Lingshu Wangu, *Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants* Science, Vol. 373 Issue 6556 (August 13, 2021) available at <https://science.sciencemag.org/content/373/6556/eabh1766>

Most people who contract Covid-19 require no treatment and are given no treatment. For people who need treatment, there are no fewer than eight FDA authorized treatments available.<sup>28</sup> The wide range of treatments undermine TCNJ's interest in mandating a prophylactic pharmaceutical of questionable efficacy. This is especially true when viewed in tandem with the next factor: Covid-19's low infection fatality rate.

**E. Covid-19's low infection fatality rate even without treatment weighs in favor of the students' liberty and privacy rights to decline the medical procedure**

To balance the state and individual interests, it is not necessary to know the exact infection mortality rate. Viruses have a range of mortality rates ranging from 100% fatal (rabies)<sup>29</sup> to essentially zero. Smallpox had a mortality rate of up to 30%.<sup>30</sup> The government's interest in stemming the spread of viruses through coerced medical procedures is logically more compelling with more fatal viruses and less compelling with less fatal viruses.

The CDC has not released an estimated infection fatality rate for Covid-19 or, if it has, it's very hard to find. However, the

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<sup>28</sup> FDA, Emergency Use Authorization (listing authorized therapeutics under Drug and Biological Therapeutic Products, available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs> (last accessed September 7, 2021))

<sup>29</sup> Pieracci EG, Pearson CM, Wallace RM, et al. Vital Signs: Trends in Human Rabies Deaths and Exposures – United States, 1938–2018. *MMWR Morb Mortal Wkly Rep* 2019;68:524–528, available at <https://www.cdc.gov/mmwr/volumes/68/wr/mm6823e1.htm>.

<sup>30</sup> CDC, *What is Smallpox?* (last reviewed June 7, 2016) available at <https://www.cdc.gov/smallpox/about/index.html>



World Health Organization Bulletin, a peer reviewed journal, published a study that found that “the infection fatality rate of COVID-19...ranged from 0.00% to 0.31% (median 0.05%)” for people under 70.<sup>31</sup> Even if these numbers are not exact, it is clear Sars-Cov2 is on the low end of virus mortality, which weighs in favor of the students’ right to decline the GTPs. This is especially true when viewed in tandem with the next factor: the medical procedure carries risks.

**F. The fact that the mandated medical procedure carries risk weighs in favor of the individual liberty to decline it**

As part of informed consent, people receiving a GTP are given a “Fact Sheet for Recipients and Caregivers.” The Fact Sheets for the Pfizer and Moderna GTPs list several risks, including myocarditis and pericarditis, which the CDC has stated is elevated in young men.<sup>32</sup> The Fact Sheet for the J&J GTP warns that “[b]lood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets,” and Guillian Barre syndrome have occurred in some people. The fact sheets all state that “other serious and unexpected side effects may occur.”

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<sup>31</sup>John P A Ioannidis, *Infection fatality rate of COVID-19 inferred from seroprevalence data*, Bull World Health Organ 2021;99:19-33F (October 14, 2020) available at <https://www.who.int/bulletin/volumes/99/1/20-265892.pdf>

<sup>32</sup> Berkeley Lovelace Jr, *CDC safety group says there’s a likely link between rare heart inflammation in young people after Covid shot* (June 23, 2021) available at <https://www.cnbc.com/2021/06/23/cdc-reports-more-than-1200-cases-of-rare-heart-inflammation-after-covid-vaccine-shots.html> (last accessed September 7, 2021)

Exhibits F, G, and H to the Verif. Compl.

Notably, the serious injuries of myocarditis, pericarditis, and blood clots were discovered *after* the GTPs had already been administered to people and people had suffered those injuries. The “other serious side effects [that] may occur” will be discovered in the same manner. There are known and unknown physical risks.

There have also been many reports of girls and women experiencing abnormal vaginal bleeding after receiving the GTPs. The NIH is researching the cause.<sup>33</sup> Currently the cause is unknown because the GTPs are experimental.

Finally, because the government is treating the GTPs as “vaccines,” adverse events are subject to the Vaccine Adverse Event Reporting System (“VAERS”) reporting. VAERS was created by Congress in 1990 as “a national early warning system to detect possible safety problems in U.S.-licensed vaccines.”<sup>34</sup> The early warning system is throwing up red flags. People have reported more injuries to VAERS from the GTPs than all other injuries combined for the entire 21 year history VAERS has existed, more than 650,000 reports as of September 3, 2021.<sup>35</sup> Moreover, due to underreporting,

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<sup>33</sup> National Institute of Health, *COVID-19 Vaccines and the Menstrual Cycle: NIH encourages researchers to investigate reported changes in menstruation after COVID-19 vaccination* (last updated August 2, 2021) available at <https://covid19.nih.gov/news-and-stories/covid-19-vaccines-and-menstrual-cycle> (last accessed September 7, 2021)

<sup>34</sup> <https://vaers.hhs.gov/about.html>

<sup>35</sup> <https://www.openvaers.com/>

these numbers are likely low.<sup>36</sup>

There is clearly some risk to these injections. The only other instance in which the government can force free people to risk the well-being of their body to further a state interest is explicitly granted to the government in the Constitution. Specifically, Congress has the power to raise an army and send that army to war. Other than that, there is no other authority granted to government to intrude on the liberty of a free citizen, not accused of any crime, and require them to do something with their body that carries a risk of death or permanent disability. If a government entity wishes to compel people to take a risk with their body the interest must be compelling enough to override the individual liberty and privacy interest to decline the risk.

Here, it is not. Moreover, the urgency of the individual liberty to avoid this risk is heightened because individuals have no recourse against the product manufacturers if they are injured. This is because the manufacturers have been granted legal immunity for harm caused by their product.<sup>37</sup>

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<sup>36</sup> Department of Health and Human Services, *Guide to interpreting VAERS data*, (undated) available at <https://vaers.hhs.gov/data/dataguide.html> (last accessed September 7, 2021) (stating that "'Underreporting' is one of the main limitations of passive surveillance systems, including VAERS. The term, underreporting refers to the fact that VAERS receives reports for only a small fraction of actual adverse events")

<sup>37</sup>HHS, PREP Act Immunity from Liability for COVID-19 Vaccinators, (last reviewed April 2021) available at <https://www.phe.gov/emergency/events/COVID19/COVIDvaccinators/Pa>

**G. The fact that the medical procedure TCNJ wishes to compel is likely to make individuals ill in the short term weighs in favor of students' liberty to decline the procedure**

Most people experience short-term symptoms of illness after the injections including headache, fatigue, fever, muscle ache and chills. 82.8% of the participants in Pfizer's clinical trials experienced at least one of these symptoms,<sup>38</sup> along with 61.5% of the J&J participants,<sup>39</sup> and 81.9% of the Moderna.<sup>40</sup>

The fact that an individual is more likely than not to experience symptoms of illness after the procedure favors the individual right to decline the procedure. It is impossible that the Constitution forbids the government from forcing an ill person to take something that will make them well, but permits the government to force someone who is well to take something that will make them ill. That would be a logical and moral absurdity.

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ges/PREP-Act-Immunity-from-Liability-for-COVID-19-Vaccinators.aspx

<sup>38</sup>CDC, *Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine*, (last reviewed May 14, 2021) available at <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html#18-systemic-reactions> (last accessed September 7, 2021).

<sup>39</sup>CDC, *The Janssen COVID-19 Vaccine's Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events*, (last reviewed August 12, 2021) available at <https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/reactogenicity.html> (last accessed September 7, 2021).

<sup>40</sup>CDC, *The Moderna COVID-19 Vaccine's Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events*, (last reviewed August 9, 2021) <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html> (last accessed September 7, 2021).

**H. The fact that TCNJ has navigated similar viruses without mandating medical procedures and medical surveillance undermines TCNJ's interests and shows the Mandate is not narrowly tailored**

There is ample precedent for protecting college campuses from respiratory viruses with measures that do not violate the Constitution. In 2009/2010, colleges navigated the H1N1 pandemic, which disproportionately killed young people, without mandating medical procedures or medically surveilling individual students. CDC issued guidance included things like: *encouraging* flu vaccines, facilitating isolation of *sick* students, and encouraging people to cover their faces when they are sneezing, coughing or actually sick.<sup>41</sup> TCNJ's Mandate is not narrowly tailored because these measures are available and have a proven record of working.

**I. The fact that the medical product TCNJ wishes to mandate is manufactured by corporations with a shocking range of criminal convictions and deceptive practices relating directly to the safety of their products weighs in favor of the individual right to decline the medical procedure.**

Of the three corporations manufacturing the GTPs, two (Pfizer and J&J) have extensive track records of criminality, fraud, and product safety issues.<sup>42</sup> The third, Moderna, has no track record at all having never brought a product to market.

Pfizer, J&J and their subsidiaries have pled guilty to felony

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<sup>41</sup> CDC, CDC Guidance for Responses to Influenza for Institutions of Higher Education during the 2009-2010 Academic Year, February 22, 2010, available at <https://www.cdc.gov/h1n1flu/institutions/guidance/> (last accessed September 19, 2021).

and misdemeanor criminal violations of an astonishing range of statutes including the Food, Drug and Cosmetics Act, the False Claims Act, and the Foreign Corrupt Practices Act. A jury also found that Pfizer violated the Racketeering Influenced and Corrupt Organizations Act. Pfizer's underlying criminal and unethical actions include (but are not limited to): feloniously misbranding drugs with intent to defraud or mislead,<sup>43</sup> illegally promoting drugs, submitting false claims to the government, paying kickbacks to doctors, withholding evidence about faulty medical products, falsifying records to cover up unsafe manufacturing practices, and testing an experimental drug on children in Nigeria.<sup>44</sup> In addition to criminality, Pfizer has been the subject of many high-profile drug safety scandals, most famously Bextra and Celebrex.

J&J and its' subsidiaries' records of criminality and

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<sup>43</sup> <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>

<sup>44</sup> United States Department of Justice ("DOJ"), Justice Department Announces Largest Health Care Fraud Settlement in Its History Pfizer to Pay \$2.3 Billion for Fraudulent Marketing (September 2, 2009) available at <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>; DOJ, Pfizer to Pay \$14.5 Million for Illegal Marketing of Drug Detrol: Settlement Involves False Claims Act Lawsuit Not Resolved at the Time of the Government's \$2.3 Billion Dollar Settlement with Pfizer in 2009 (October 22, 2011) available at <https://www.justice.gov/opa/pr/pfizer-pay-145-million-illegal-marketing-drug-detrol>; U.S. Securities and Exchange Commissions, SEC Charges Pfizer with FCPA Violations, (August 7, 2012) available at <https://www.sec.gov/news/press-release/2012-2012-152htm>; Joe Stephens, Pfizer to Pay \$75 Million to Settle Nigerian Trovan Drug-Testing Suit, (July 31, 2009) available at <https://www.washingtonpost.com/wp-dyn/content/article/2009/07/30/AR2009073001847.html>

deception may exceed Pfizer's. Highlights include: causing children's medicine contaminated with metal to enter commerce and attempting to cover up the contamination without informing the public, obstructing justice and "corruptly persuading others" to shred evidential documents, numerous instances of illegally marketing drugs, submitting false claims to the government, and paying kickbacks to doctors, pharmacists, and nursing homes.<sup>45</sup> J&J

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<sup>45</sup> DOJ, McNeil-PPC Inc. Pleads Guilty in Connection with Adulterated Infants' and Children's Over-the-Counter Liquid Drugs (March 10, 2015) available at <https://www.justice.gov/opa/pr/mcneil-ppc-inc-pleads-guilty-connection-adulterated-infants-and-childrens-over-counter-liquid>; The Associated Press, Ortho Fined \$7.5 Million in Retin-A Case (April 11, 1995) available at <https://www.nytimes.com/1995/04/11/business/ortho-fined-7.5-million-in-retin-a-case.html>; DOJ, Two Johnson & Johnson Subsidiaries to Pay Over \$81 Million to Resolve Allegations of Off-Label Promotion of Topamax (April 29, 2010) available at <https://www.justice.gov/opa/pr/two-johnson-johnson-subsidiaries-pay-over-81-million-resolve-allegations-label-promotion>; DOJ, Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations: Allegations Include Off-label Marketing and Kickbacks to Doctors and Pharmacists, November 4, 2013 available at <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations>; Iowa Attorney General, *AGs reach \$116.9 million settlement with Johnson & Johnson: Ethicon Surgical mesh devices caused serious complications for women* (October 17, 2019) available at <https://www.iowaattorneygeneral.gov/newsroom/settlement-johnson-ethicon-vaginal-mesh>; DOJ, *Johnson & Johnson Agrees to Pay \$21.4 Million Criminal Penalty to Resolve Foreign Corrupt Practices Act and Oil for Food Investigations* (April 8, 2011) available at <https://www.justice.gov/opa/pr/johnson-johnson-agrees-pay-214-million-criminal-penalty-resolve-foreign-corrupt-practices-act>; DOJ, *Johnson & Johnson Medical, Inc. Agrees to Pay U.S. \$3.9 Million to Resolve Claims of Overcharging VA for Medical Supplies*, (September 21, 2001) available at <https://www.justice.gov/archive/opa/pr/2001/September/488civ.htm>; DOJ, *Lifescan, Inc. Agrees to Pay United States \$15 million*

has also been the subject of several high profile drug safety scandals, the most recent involving billions of dollars in civil awards for plaintiffs alleging that J&J knew its baby powder might be contaminated with cancer-causing asbestos and covered it up.<sup>46</sup>

The shocking backgrounds of these corporations weighs in favor of the individual liberty to decline being injected with products they manufacture.

**J. The fact that the federal agency tasked with ensuring pharmaceutical safety is plagued by scandals and failures directly related to the agency's ability to protect the public from unsafe pharmaceuticals favors the individual liberty to decline the GTPs.**

Whistleblowers, industry experts, and even U.S. Senators have been warning the public for more than a decade that the FDA is not working properly.

In 2007, Senator Chuck Grassley testified before the House Oversight Committee concerning what he had learned in his oversight of the FDA while Chairman of the Senate Finance Committee. His testimony details ineptitude and perversion of purpose. He identified four "systemic" problems with the FDA:

First, scientific dissent is discouraged, quashed, and sometimes muzzled inside the Food

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*for overcharging veterans affairs department*, (November 14, 2001) available at [https://www.justice.gov/archive/opa/pr/2001/November/01\\_civ\\_590.htm](https://www.justice.gov/archive/opa/pr/2001/November/01_civ_590.htm)

<sup>46</sup>Roni Caryn Rabin and Tiffany Hsu, *Johnson & Johnson Feared Baby Powder's Possible Asbestos Link for Years*, New York Times (December 14, 2018) available at <https://www.nytimes.com/2018/12/14/business/baby-powder-asbestos-johnson-johnson.html>



and Drug Administration. Second, the FDA's relationship with drug makers is too cozy. The FDA worries about smoothing things over with industry much more than it should with its regulatory responsibilities. Third, inside the FDA there's widespread fear of retaliation for speaking up about problems. And fourth, the public safety would be better served if the agency was more transparent and forthcoming about drug safety and drug risks.<sup>47</sup>

Scientists within the FDA reflect these same sentiments. A 2006 survey of FDA scientists by the Union of Concerned Scientists calls into question the FDA's commitment to its mission and honesty with the public. Less than half of the respondents agreed that the "FDA routinely provides complete and accurate information to the public" and nearly 20% reported that they had been explicitly asked by FDA decision makers to "provide incomplete, inaccurate, or misleading information to the public, regulated industry, media, or elected/senior government officials." Only 49% agreed that "FDA leadership is as committed to product safety as it is to bringing products to market" and just half felt that the "FDA is acting effectively to protect public health."

There have also been several high-profile FDA scandals and failures that add to the well of public distrust, most notably FDA actions and inactions that helped fuel the opioid epidemic. The

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<sup>47</sup> Ranking Member's News | Newsroom | The United States Senate Committee on Finance <https://www.finance.senate.gov/ranking-members-news/-senator-grassleys-testimony-to-house-oversight-hearing-on-the-adequacy-of-fda-efforts-to-assure-the-safety-of-the-drug-supply>

FDA's failures on this front are well-publicized and chronicled, including in the opinion pages of the AMA Journal of Ethics where Dr. Andrew Kolodny charged the FDA with failing to obtain evidence of long-term safety and effectiveness of opioids, regulatory failures, failure to manage conflicts of interest,<sup>48</sup> and failure to properly enforce marketing regulations.<sup>49</sup>

This is a sampling of FDA failures to protect the public from dangerous drugs. Many more instances are documented and enough information has percolated to the surface of public awareness that it is reasonable for people to have a distrust of the agency's ability to keep people safe from harmful pharmaceuticals.

This is a different world from *Jacobson* where the vaccine had been around for a century and was a product entirely of science, not government. The GTPs are a novel technology being manufactured by criminal corporations that were committing crimes right under the nose of the FDA. The urgency of the individual liberty to decline a medical procedure involving novel technology is

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<sup>48</sup> One disturbing conflict of interest has recently caught the attention of a bipartisan group of Senators. See "Markey Joins Senators Hassan, Grassley, and Whitehouse In Call to FDA to Provide Answers on Potential Conflicts of Interest with Consulting Firm McKinsey in Relation to Opioid Crisis" available at <https://www.markey.senate.gov/news/press-releases/markey-joins-senators-hassan-grassley-and-whitehouse-in-call-to-fda-to-provide-answers-on-potential-conflicts-of-interest-with-consulting-firm-mckinsey-in-relation-to-opioid-crisis>

<sup>49</sup> Andrew Kolodny, MD, How FDA Failures Contributed to the Opioid Crisis, *AMA J Ethics*. 2020;22(8):E743-750 (August 2020) (available at <https://journalofethics.ama-assn.org/article/how-fda-failures-contributed-opioid-crisis/2020-08>)

heightened when the government agency charged with ensuring its safety has this track record and reputation.

**III. Plaintiffs are likely to succeed on the merits concerning the medical testing and surveillance**

Testing for Covid-19 is a medical procedure that implicates fundamental liberty and privacy interests, so strict scrutiny applies. The medical surveillance through the testing and daily checkups also implicates privacy and liberty rights, so strict scrutiny applies. Thus, the Court must balance TCNJ's asserted interests against the individual liberty to decline medical testing procedures and to be free from medical surveillance.

Here, the privacy and liberty rights are so deeply rooted in our national history and traditions that there is *no precedent* historically or legally to which TCNJ can point to justify its policies. It is plainly unconstitutional.

**IV. Denying an injunction will result in irreparable harm to Plaintiffs**

The Mandate is unconstitutional. As long as the Mandate stands, Plaintiffs will have to rely on TCNJ's allowing an "exemption" to the Mandate. TCNJ has been very clear that the exemptions are discretionary, subject to "periodic" review, and can be withdrawn at any time. Verif. Compl. at ¶16; Exhibit A to Verif. Compl. The Mandate is the sword of Damocles hanging over Plaintiffs heads, ready to fall if they miss a testing appointment or get too close to another student. Moreover, the existence of

the Mandate is the basis upon which Plaintiffs are being segregated and subjected to additional restrictions and requirements that intrude on their rights to liberty, privacy, and equal protection.

The restrictions and requirements put on exempt students are also unconstitutional incursions on Plaintiffs' liberty and privacy rights. As long as these conditions continue, Plaintiffs are subject to repeated violations of their rights and bodily autonomy. For Ms. Messina, it means a total derailment of her education because she cannot attend school. For the other Plaintiffs, it means they must indefinitely undergo twice weekly medical testing procedures, continue under intrusive medical surveillance of their private health information, and continue to be singled out and treated in a discriminatory manner that operates on a presumption that Plaintiffs may be infected with a communicable disease despite being healthy or even immune to the disease. These constitutional violations are without precedent in history or law and Plaintiffs will be irreparably injured by their continuing while litigation proceeds.

**V. Granting the injunction will not result in irreparable harm to Defendant**

There is no irreparable harm to Defendant in striking down the Mandate. There are many alternative and constitutional methods that TCNJ has at its disposal to control the spread of communicable disease on campus.

**VI. Granting the injunction is in the public interest**

The public interest is served in enjoining unconstitutional policies that intrude on people's liberty and privacy rights in unprecedented and extraordinarily intrusive ways.

**CONCLUSION**

For the foregoing reasons, it is respectfully requested that the Court enter an order enjoining TCNJ's Mandate.

Respectfully submitted,

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