Case No. 25-1183

IN THE
UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Beth Boyd, Janet Noland, Michelle Peck, and Carly Robson,

Plaintiffs – Appellants

v.

Shriners Hospitals for Children, Shriners Hospitals for Children – Erie, Beverly Bokovitz, Frances Farley, Jerry Gantt, John McCabe, Phillip Grady, and Mary Antoon

Defendants – Appellees

On Appeal from

United States District Court for the Western District of Pennsylvania
1:23-cv-342

BRIEF OF APPELLANTS AND JOINT APPENDIX
VOLUME I OF II (JA1-JA8)

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JURISDICTIONAL STATEMENT

The United States District Court for the Western District of Pennsylvania, Judge Cathy Bissoon, granted a Rule 12(b)(6) Motion to Dismiss and rendered judgment against the Appellants, Beth Boyd, *et al*, on December 31, 2024. (JA-1, JA-7) The judgment adjudicated all claims as to all parties. The District Court's jurisdiction was established under 28 U.S.C. § 1331 as a civil proceeding arising under the laws of the United States, specifically 42 U.S.C. § 1983 and 1988. The district court also had supplemental jurisdiction under 28 U.S.C. § 1367(a) as it relates to Plaintiffs' wrongful termination and intentional infliction of emotional damage claims under Pennsylvania law.

STATEMENT OF THE ISSUES

1. Did the district court err by failing to accept as true Plaintiffs' factual allegations in the Complaint? Yes, the district court erred by not accepting Plaintiffs' allegations as true and instead accepting Defendants' version of the facts on a Rule 12(b)(6) motion to dismiss. (JA-1-6)

2. Did the district court err by holding that Shriners is not a State Actor? Yes, Shriners, the State, and the USG jointly engaged in the governmental function of distributing and administering EUA/PREP Act investigational drugs under the CDC Program during a declared emergency, and Shriners acted under color of law when it penalized Plaintiffs for exercising the very right Shriners agreed to uphold

on behalf of the State and USG – the right to refuse without penalty or pressure. (JA2)

3. Did the district court err by relying on other district court decisions in similar cases brought by Plaintiffs' counsel, but without stating which parts of which ruling apply to which parts of the case at bar? Yes, the district court erred by dismissing the case for "essentially the same reasons." (JA-2)

4. Did the district court err by ignoring the Legally Effective Informed Consent standard? Yes. Plaintiffs advised the court of the legal standard, its legislative history, and application to their causes of action but the court did not address the issue.(JA-1-6)

5. Did the district court err by dismissing Plaintiffs' counts under Rule 12(b)(6)? Yes, Plaintiffs plausibly alleged causes of action under each count. (JA1-6)

6. Did the district court err by dismissing Plaintiffs' allegations with prejudice? Yes, a dismissal with prejudice without leave to amend was error because amendment at this stage would not be futile, allowing Plaintiffs to focus the state action allegations on the CDC Program and not, as the district court reframed Plaintiffs' arguments, on Shriners "setting internal policies." (JA-2)

STATEMENT OF RELATED CASES AND PROCEEDINGS

Appellants are unaware of any pending related case before this court. In other

courts of appeal, Appellants are aware of the following cases involving the same issues related to Shriners:

Pearson v. Shriners Hosp for Children, 24-40436 (5th Cir., Apr 2, 2025)

Roberts v. Shriners Hosp for Children, 24-1949 (9th Circuit Court of Appeals)

STATEMENT OF THE CASE

This case before this Court presents fundamental questions about who decides to assign drugs their legal indications and who authorizes the conditions under which investigational drugs will be introduced into commerce—the Executive Branch, through Article II, or the Judicial Branch, through judicial preference. The Constitution supplies a clear answer: the Executive Branch. There are no exceptions to that well-settled doctrine.

This case arises from the federal Executive Branch ("Executive Branch") purchasing all COVID-19 investigational drugs in 2020 and establishing the CDC COVID-19 Vaccination Program ("CDC Program") to recruit states and territories to help administer the drugs as an emergency public function, which Pennsylvania recruited Shriners to help it perform its promised obligations to the United States Government ("USG"). (JA-020) Shriners was under a ministerial duty to ensure that Plaintiffs were neither pressured to use the investigational drugs nor punished when exercising the option to refuse, but Shriners deprived Plaintiffs of their right to refuse without penalty when they terminated Plaintiffs. (JA-022)

The district court engaged in Executive Branch powers when holding that the investigational drugs were "effectively FDA approved" and nullifying the CDC Program's regulatory framework by which the Executive Branch introduced the drugs into commerce and under which Program the Plaintiffs held specific programmatic benefits. (JA-001)

On December 11, 2020, the Health and Human Services Secretary ("Secretary") determined that "Pfizer-BioNTech COVID-19 Vaccine," the official name of Pfizer's investigational Covid-19 drug, might be beneficial for preventing infection from and spread of coronavirus and issued it an Emergency Use Authorization ("EUA") but informed the public that it was "an investigational vaccine not licensed for any indication" (i.e., under investigation to become a licensed vaccine). 86 Fed.Reg. 5200 (published Jan. 19, 2021). On December 18, 2020, the Secretary issued to ModernaTX, Inc., an EUA for its investigational drug, Moderna COVID-19 Vaccine, stating it was "an investigational vaccine not licensed for any indication." 86 Fed.Reg. 5200 (published Jan. 19, 2021). On February 27, 2021, the FDA issued to Janssen Biotech, Inc., an EUA for its investigational drug, Janssen COVID-19 Vaccine, stating it was "an investigational vaccine not licensed for any indication." 86 Fed.Reg. 28608 (published May 27, 2021) (JA-064)

These designations reflected the HHS Secretary's recognition that the drugs had not been approved for general commercial marketing within the meaning of 21

U.S.C. § 355, *et seq*., and only introduced them into commerce under emergency expanded access protocols (21 U.S.C. § 360bbb-3) to provide individuals access to the unlicensed drugs should they believe it would benefit their personal health goals during the pandemic.

On August 23, 2021, the FDA approved COMIRNATY® with the licensed legal indication to prevent COVID-19. However, because COMIRNATY® was not ready for manufacturing and thus not available to Plaintiffs at any pertinent time, the Secretary reissued an EUA for Pfizer-BioNTech COVID-19 Vaccine on the same date, August 23, 2021, stating, "There is no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19." The Secretary continued reissuing EUAs for COVID-19 investigational drugs for all times material for various age groups and medical contraindications (e.g., immunocompromised). (JA-204)

On October 29, 2020, the Executive Branch, through the Centers for Disease Control and Prevention ("CDC"), established the CDC COVID-19 Vaccination Program ("CDC Program") to recruit states and territories to help distribute and administer the investigational drugs to volunteering recipients. (JA-024) The CDC provided states with the terms and conditions of the federally funded program, informing them of their legal obligations should they volunteer, under their prerogative, to perform the functions of the Program. (JA-238) The State was

required to "[h]elp the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure)," recruit private parties to help the State perform its promise to the USG under the federal program, and require states to, "monitor activities at the local level **to ensure** the COVID-19 Vaccination Program is implemented throughout the jurisdiction **in adherence** with federal guidance and requirements." (emphasis added). (JA-209-210)

The CDC created the CDC COVID-19 Vaccination Program Provider Agreement that Pennsylvania ("State") incorporated into official State policy because the Program was required to be administered through the State's immunization cooperative agreement, and the USG required the State to ensure that each recruited party's Chief Executive Officer and Chief Medical Officer signed the Agreement. (JA-123)

The CDC Program exclusively relied upon drugs not licensed for any indication, authorized only for emergency use, classified by the Secretary as investigational, and purchased with DoD funds. Additionally, the Program required recipients to voluntarily agree to become human subjects in federally funded research activities, surrender private health information and data collected relating to their reaction to the drugs to unknown persons for unknown reasons and for an unknown length of time, assume more than minimal risk to their safety, and forfeit

the right to seek judicial relief if injured by the Program, its drugs, or persons administering the drugs. (JA-097)

Due to the drug's legal classification as investigational under the CDC Program, the Executive Branch was bound to comply, in part, with the Constitution's 5th and 14th Amendments' due process clauses, the EUA Statute, the PREP Act, 10 U.S.C. § 980, 45 C.F.R. Part 46, the Federal Wide Assurance Program, and the Belmont Report to ensure that the Executive Branch never engaged in human rights abuses when offering humans investigational drugs.

Historical Background

To understand the full intent of Congress to completely prohibit individuals from coming under outside pressure to use investigational drugs or being punished when refusing, it is helpful to review the historical legislative record.

In 1972, the nation became aware of medical research abuses committed against Americans by the Executive Branch known as the Tuskegee Experiment (*The Tuskegee Syphilis Study*, 289 New England Journal of Medicine 730 (1973)). This revelation caused Senator Edward Kennedy to conduct hearings on research abuses committed against minorities, women, the poor, and the uneducated.[1] Congress

[1] Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare United States Senate, titled, 'Quality of Health Care—Human Experimentation,' March 07-08, 1973.

responded by enacting the 1974 National Research Act,[2] requiring a commission to consider "the nature and definition of informed consent in various research settings."[3] On April 18, 1979, the Commission for the Protection of Human Subjects published its findings in "The Belmont Report."[4] (JA-066)

The Commission described the "adequate standards" of informed consent as follows: "An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. 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. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable." The Commission further stated: "Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a

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[2] Title II of the National Research Act, Public Law 93 - 348-July 12, 1974 - https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf

[3] National Research Act Title II - PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVORIAL RESEARCH Part A Section 202. (a)(1)(B)(iv)

[4] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. - Belmont Report. Colorado, DC: U.S. Department of Health and Human Services, 1979

course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled." (JA-027).

Acting on command from Congress under the National Research Act,[5] the Health and Human Services Secretary promulgated regulations to reflect the Commission's findings to end human rights abuses by the Executive Branch involving investigational drugs and related research activities. The regulations are codified at 45 CFR part 46, subparts A through D. The statutory authority for the HHS regulations derives from 5 U.S.C. § 301; 42 U.S.C. § 300v-1(b); and 42 U.S.C. § 289. The regulatory scheme is known as the "Common Rule" within the 600 billion-dollar pharmaceutical industry. (JA-029-032)

The regulations are mandatory for all federal agencies, departments, military, and persons acting on behalf of the USG when presenting humans the opportunity to use investigational drugs (e.g., Pfizer-BioNTech COVID-19 Vaccine) (45 C.F.R.

[5] "The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as may be required to carry out section 474(a) of the Public Health Service Act." PUBLIC LAW 93-348-JULY 12, 1974 p. 353.

§ 46.101(a)). Strict adherence to the Belmont Report is required (§ 46.101(c)), even if the research activity is exempt from regulatory compliance (§ 46.101(i)). Every appropriated dollar authorized by Congress must comply with the Common Rule (§ 46.122), and Congress explicitly requires informed consent relating to investigational drugs and research activities involving DoD-appropriated funding (10 U.S.C. § 980). *Id.*

The primary purpose of the Common Rule is to ensure that no person is subjected to unwanted investigational drugs. This goal is achieved by placing a duty upon persons presenting individuals with an opportunity to use such drugs to ensure they are not pressured to use the drugs or punished for refusing as outlined in exacting detail under 45 C.F.R. § 46.116. *Id.*

The core of the Common Rule stems from 45 C.F.R. § 46.116(a)(1), which requires a potential recipient to be provided with the expected benefit of "legally effective informed consent." Legally effective informed consent is a unique legal standard for investigational drugs and associated activities. It governs all of the USG's uses of investigational drugs without exception. *Id.*

At bottom: Legally Effective Informed Consent, according to the Belmont Report and the Common Rule, can be broken down into its basic formula: (1) individuals must not be under pressure to use investigational drugs, (2) individuals consent for their own personal reasons, and (3) the conditions of 1 and 2 are met

before being administered the drug. Administration of investigational drugs outside this legal standard nullifies legally effective informed consent. (JA-033-035).

In 2001, the Executive Branch established the Federal Wide Assurance ("FWA") program to streamline a mechanism of ensuring compliance with the Common Rule by persons acting on the USG's behalf. The FWA program operates under the Office of Human Research Protection (OHRP), an HHS department under the authority of the Assistant Secretary of Health. The FWA program authorizes persons to access investigational drugs, administer them, and bill the USG for rendering services involving such drugs predicated upon the person submitting a written assurance to HHS that they will adhere to the Common Rule and the Belmont Report anytime they present humans an opportunity to use federally funded or authorized investigational drugs. To date, there are an estimated 30,000 active FWA agreements, including all states, territories, and federal agencies. (JA-077-078)

Therefore, the President is under a constitutional command to "take Care that the Laws be faithfully executed" (U.S. Const. art. II, § 3) by ensuring that no person comes under pressure to use federally funded investigational drugs or punished when exercising the right to refuse.

The Project Bioshield Act of 2004[6], amended 21 U.S.C. § 360bbb-3 (the "EUA Statute"), and empowered the Secretary to authorize the unlicensed use of

[6] Public Law No: 108-276 (07/21/2004)

drugs for emergency use only if no approved or alternative product already existed in the marketplace for that emergency use. Congress requires the Secretary to establish "appropriate conditions" designed to ensure that health care professionals administering the drugs as well as potential recipients are informed that the Secretary has authorized the emergency use of the drugs, of the potential benefits and risks of such emergency use, and of a potential recipient's option to accept or refuse. (21 U.S.C. §360bbb-3(e)(1)(A)(i) and (ii)). However, Congress, mindful of protecting the fundamental right to bodily integrity as expressed in *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 273 (1990), *Washington v. Glucksberg*, 521 U.S. 702 (1997), and *Albright v. Oliver*, 510 U.S. 266, 272 (1994), expressly prohibited the Secretary from having "any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section." One activity that became lawful pursuant to the EUA Statute is to use an unlicensed drug during a declared emergency. Thus, the Secretary has no authority to require any person to use an emergency use drug during a declared emergency. (JA-062-065)

When a person agrees to execute on the Secretary's behalf an EUA's conditions of authorization, they are bound to comply with the EUA's terms. They cannot amend those terms to deprive potential recipients of their constitutional and statutory entitlement rights. All drugs offered under the CDC Program were authorized only for emergency use under the EUA Statute.

Congress was further mindful of the fundamental right to bodily integrity when enacting the Public Readiness and Emergency Preparedness Act (PREP Act), codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e, expressly preempting states and their political subdivisions from establishing, enforcing, or continuing in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or is in conflict with, any requirement applicable under the PREP Act, including its "voluntary nature," (42 U.S.C. § 247d-6e) or to any requirement applicable to a covered countermeasure that is subject to conditions under the Federal Food, Drug, and Cosmetic Act (42 U.S.C. § 247d-6d(b)(8)). Therefore, states and their state actors cannot establish a legal requirement conflicting with the FDCA's option to refuse an EUA drug if it is listed as a countermeasure under the PREP Act, a condition that all drugs under the CDC Program met. (JA-073-075)

The PREP Act is primarily an immunity statute. However, providing immunity to a person who injures another member of society burdens the injured person's right to bring a cause of action for product liability, medical malpractice, fraud, and battery; seek tort remedies for bodily harm caused by another member of society; and be made whole for damages to their finances and emotional well-being, which rights are subject to the Due Process Clause.

The Supreme Court holds that a common law cause of action is a property right, stating: "The hallmark of property is an individual entitlement grounded in state law, which cannot be removed except 'for cause." *Logan v. Zimmerman Brush Company*, 455 U.S. 422 (1992). "The first question, we believe, was affirmatively settled by the *Mullane* case itself, where the Court held that a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause." *Id. See, Tulsa Prof. Collection Svcs. v. Pope,* 485 U.S. 478 (1988)*; Phillips Petroleum Co. v. Shutts,* 472 U.S. 797 (1985).

The PREP Act does not deprive a person of their due process rights because it only requires voluntary use. (42 U.S.C. §247d-6e(c)). It is the government, or the person acting on the government's behalf, that deprives a person of their right to due process when mandating the use of a covered countermeasure as a condition of receiving a benefit to which they are otherwise entitled, which is a violation of the unconstitutional conditions doctrine.

The Supreme Court has long held that "a man may not barter away his life or his freedom, or his substantial rights." *Home Ins. Co. of New York v. Morse*, 87 U.S. 455, 451 (1874). It has also long held that "[t]he state, having power to deny a privilege altogether, may grant it upon such conditions as it sees fit to impose. But the power of the state in that respect is not unlimited, and one of the limitations is that it may not impose conditions which require the relinquishment of constitutional

rights. If the state may compel the surrender of one constitutional right as a condition of its favor, it may, in like manner, compel a surrender of all. It is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence." *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593-94 (1926).

The Supreme Court affirmed its position, stating, "For at least a quarter-century, this Court has made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests." *Perry v. Sindermann*, 408 U.S. 593, 92 S.Ct. 2694, 33 L.Ed.2d 570 (1972).

To ensure that states did not use private parties to avoid constitutional obligations, the Supreme Court held that a state cannot use private parties as a "procedural device" to "produce a result which the State could not command directly." *Speiser v. Randall*, 357 U.S. 513 (1958). It is "axiomatic that a state may not induce, encourage or promote private persons to accomplish what it is constitutionally forbidden to accomplish." *City of Richmond v. J.A. Croson Co*., 488 U.S. 469 (1989), citing *Norwood v. Harrison,* 413 U.S. 455, 465, 93 S. Ct. 2804, 2810, 37 L. Ed. 2d 723 (1973). The State cannot mandate that a person surrender

their due process rights to seek judicial relief if injured by another member of society as a condition of receiving public benefits, and, therefore, it cannot use the PREP Act as a procedural device to achieve that unconstitutional result.

The Executive Branch informed the State and Shriners that "**all COVID-19 vaccine in the United States has been purchased by the U.S. government** (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remains U.S. government property until administered to the recipient." (JA-043) Therefore, because the drugs were classified as investigational, the USG was under a legal obligation to obtain Plaintiffs' legally effective informed consent, which it delegated to the State, which in turn delegated that governmental function to Shriners.(45 C.F.R. Part 46) The State and Shriners were expressly prohibited from establishing legal requirements conflicting with Plaintiffs' option to refuse and were under a ministerial duty to execute the CDC Program, the EUAs, and PREP Act declarations without arbitrarily amending those conditions, but they did so anyway when misrepresenting their authority to Plaintiffs, and penalized them for exercising their right to refuse investigational drugs.

The Supremacy Clause dictates that if the Secretary cannot mandate nonconsensual use of EUA drugs, then neither can states, their recruited agents, or persons volunteering to execute the Secretary's conditions of authorization. *See*

Arizona v. United States, 567 U.S. 387, 399 (2012) ("[Congress's] intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Id*., quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947). (JA-069)

The State of Pennsylvania recruited Shriners (JA-210) to assume the role of "vaccination provider" under each EUA to help administer the drugs to the public on the State's behalf, and Shriners willfully agreed (JA-213) to comply with the Provider Agreement, including Sections 12(a) and (b), requiring Shriners to comply with "any EUA" and all applicable laws relating to the administration of investigational drugs. However, after agreeing to offer the investigational drugs only under voluntary conditions, Shriners deprived Plaintiffs of their constitutional and federal statutory right to refuse to be injected with one of the investigational drugs by penalizing those who refused, thereby directly violating Shriners' federal and State agreements and Plaintiffs' Fourteenth Amendment rights under the CDC Program. (JA-145).

At bottom: As delegated by the USG through the State under the CDC Program, Shriners was required to obtain Plaintiffs' legally effective informed consent but nullified such consent when presenting Plaintiffs with an opportunity to

use EUA/PREP Act investigational drugs under threats of penalty. Shriners is sophisticated in the laws discussed herein and knows that it is expressly prohibited from mandating that any person use investigational drugs under threats of penalty, irrespective of its relationship with the individual. (JA-096, ¶383).

Moreover, operating under FWA Contract No. 00025698, Shriners promised the USG never to place an individual under threat of penalty to use an investigational drug, which Shriners violated when pressuring individuals to use EUA/PREP Act investigational drugs and when penalizing Plaintiffs for refusing. (JA-058) Additionally, Shriners assured the State that Shriners would ensure that Plaintiffs could exercise the option to refuse under the CDC Program but then deprived Plaintiffs of that right.

Plaintiffs sued Shriners for monetary and other damages for the deprivation of Fourteenth Amendment rights owed to them by the State under the federal program. (JA-16) Shriners filed a Rule 12(b)(6) motion to dismiss. (JA-156) Instead of accepting Plaintiffs' allegations as true, the district court found "Defendants' arguments and the other courts' decisions persuasive." (JA-2) The district court erroneously accepted as true *Defendants' "arguments,"* rather than *Plaintiffs' factual allegations*. Shriners' Rule 12(b)(6) motion is not the procedurally proper time to find Defendants' "arguments…persuasive." It is the time to accept Plaintiffs' allegations as true and examine plausibility based on those facts. This Court holds

that under *Twombly* and *Iqbal*, a district court must "accept [] as true" Plaintiffs' allegations "even if it strikes a savvy judge that actual proof of those facts alleged is improbable and that a recovery is very remote and unlikely" and that "the proper place to resolve factual disputes is not on a motion to dismiss, but on a motion for summary judgment." *Doe v. Princeton University*, 30 F.4th 335 (3rd Cir., March 31, 2022).

This Court has previously established that a district court "may take judicial notice of another court's opinion—not for the truth of the facts recited therein, but for the existence of the opinion" as noted in *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Grp. Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999) and reaffirmed in *Kamal v. J. Crew Grp., Inc.*, 918 F.3d 102, 118–19 (3d Cir. 2019), as referenced in *Doe*, *supra*. The district court went beyond merely taking judicial notice of other opinions. It reviewed rulings from courts outside the Third Circuit and outside of Plaintiffs' alleged facts and applied those rulings—which were specific to the facts alleged in those separate cases—to the specific facts alleged in the instant action without explanation. Such procedural maneuvering is problematic because it prejudices Plaintiffs' ability to respond to the court's reasoning properly.

Plaintiffs stated above that this case is about which Federal Branch decides what legal indication is assigned to a drug and the conditions under which investigational drugs are introduced into commerce. The district court cited to cases

where judges replaced Executive and Legislative Branch actions with judicial preference. In the instant action, the district court perpetuates those constitutional violations as described below, constituting reversible error.

Rulings Presented for Review

On December 30, 2024, the district court issued its Memorandum and Order dismissing Plaintiffs' Counts I, II, III, IV, V, VI, VII, and XI with prejudice and Counts VIII, IX, and X without prejudice and instructing the Clerk to close the matter. (JA-5) The district court cited six other district court rulings as jurisprudence without explanation for dismissing the Plaintiffs' Complaint under Rule 12(b)(6). The district court held that "[a]s a threshold matter, Plaintiffs' Section 1983 claims set forth in Counts I-VII of the Complain [sic] fail as a matter of law because Defendants are not state actors within the meaning of that statute." (JA-2) However, by the district court only citing to other court cases without explaining what it found persuasive relating to Plaintiffs' allegations in the instant action, it is difficult to inform this court what specific issues need review.

SUMMARY OF THE ARGUMENT

Plaintiffs have plausibly alleged claims for deprivation of: (1) the right to refuse unwanted investigational drugs, (2) the right to refuse EUA drugs, (3) the right to refuse PREP Act countermeasures, (4) the right to be treated equally before the law, and (5) the right to privacy. Plaintiffs identified an injury related to each claim, and

each claim can be redressed by the relief Plaintiffs requested. The district court dismissed the case on a Rule 12(b)(6) motion but only after it failed to accept as true facts that Defendants did not even dispute, thus disputing the facts on Defendants' behalf, demonstrating reversible error.

ARGUMENT

Standard of Review is *De Novo*

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)

I. THE DISTRICT COURT ERRED BY FAILING TO ACCEPT PLAINTIFFS' ALLEGATIONS AS TRUE

The district court stated,

> "**As *Defendants* repeatedly point out**, even assuming for purposes of this Motion that Shriners Children's, as a healthcare provider, administered Covid-19 vaccines to the public pursuant to a government program, that action had nothing to do with Shriners Children's, as a private employer, requiring employees to get a vaccine, wherever they chose to do so. Moreover, and in any event, Plaintiffs ignore the ample caselaw rejecting similar

> arguments and holding that facilitation of a government-funded vaccine program is not a public function that somehow converts a private entity into a state actor." (emphasis added)(JA-004)

Ironically, it was the district court ignoring the Plaintiffs' allegations, not Plaintiffs "ignoring…ample caselaw," that brings this action before this Court. First, Plaintiffs alleged that Shriners required Plaintiffs to be injected with investigational drugs, not vaccines. Vaccines are not implicated in this case. Second, while Shriners may have the authority to issue an employer vaccination requirement relying on the use of an FDA-licensed vaccine, it does not have the authority to amend the CDC Program, the EUA Statute, and the PREP Act and deprive only certain individuals of their constitutional and federal right to refuse EUA/PREP Act investigational drugs. (Plaintiffs reiterate that they are not alleging that Shriners' state action was the issuance of an "employer vaccination mandate," but rather the deprivation of Plaintiffs' rights under the CDC Program.)

Shriners voluntarily agreed to perform under CDC Program predicated upon Shriners agreeing to abide by the regulatory framework set forth in the Provider Agreement, EUA Statute, and PREP Act, notwithstanding separate obligations it owed to Plaintiffs under Shriners' FWA and IRB programs, thereby completely prohibiting Shriners from pressuring any individual, employee or not, to use EUA/PREP Act investigational drugs, an allegation completely ignored by the district court and which is the gravamen of Plaintiffs' case as noted in Count One

titled, "Subjected to Investigational Drug Use." (JA-095, FN # 110) Moreover, neither the USG nor the State could constitutionally enter into a contractual relationship with Shriners on the condition that Shriners could exempt "employees," "contractors," or "volunteers" from their entitlement right to refuse investigational medical treatments because the USG and Pennsylvania owe Plaintiffs constitutional obligations under the CDC Program and cannot use private parties to avoid constitutional obligations.

Plaintiffs explicitly drew a distinction between a *vaccination* mandate and an *investigational drug* mandate. (JA-25) The district court ignored that distinction without explanation. It also took Plaintiffs' allegations that the federal programs provide Plaintiffs with a programmatic right to refuse and recharacterized the entire case as being simply an "employer vaccination requirement" relying on drugs licensed by the FDA as vaccines, which is not supported by the allegations and constitutes reversible error.

II. THE DISTRICT COURT ERRED BY IGNORING THE LEGALLY EFFECTIVE INFORMED CONSENT STANDARD.

A. Legally effective informed consent is a property right subject to the Fourteenth Amendment Due Process Clause. (JA-093)

The Supreme Court clearly established the criteria for recognizing constitutionally protected property interests. In the landmark case of *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972), the Court held: "[T]o have

a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it."

The Court further clarified the source of such property interests:

"Property interests, of course, are not created by the Constitution. Rather, they are created, and their dimensions are defined, by existing rules or understandings that stem from an independent source such as state law -- rules or understandings that secure certain benefits and that support claims of entitlement to those benefits. Thus, the welfare recipients in *Goldberg v. Kelly*, 397 U.S. 254 (1970), had a claim of entitlement to welfare payments that was grounded in the statute defining eligibility for them." (*Id.*)

Plaintiffs' property interests arise from acts of the federal government's Executive and Legislative Branches that directly benefit Plaintiffs and impose upon Shriners specific obligations that Shriners voluntarily agreed to abide by on the State's behalf. The comprehensive framework created by the CDC Provider Agreement, the EUA Statute, any EUAs issued by the Secretary, the PREP Act, 10 U.S.C. §980; 45 C.F.R. §§ 46.116, 122; and the Belmont Report; collectively established "rules or understandings," secured the specific benefit for Plaintiffs to give their legally effective informed consent. As the Supreme Court stated in

Cruzan, *supra*, "The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment."

The right under the CDC Program and EUAs to be informed of the investigational drugs' risks, benefits, and alternatives and of the right to accept or refuse provides Plaintiffs with a legitimate claim of entitlement to expect accurate information before deciding whether the drugs fit within Plaintiffs' autonomous health goals and the freedom to choose one option over the other without penalty or pressure. (JA-108)

The duties imposed by 45 C.F.R. §46.116—particularly the requirement to ensure that individuals do not incur penalties or lose benefits for refusing investigational drugs—create an expected benefit for individuals considering the use of the investigational drugs. (JA-047) This legal framework establishes that:

1. The right to be informed of the risks, benefits, and alternatives of the drugs;
2. The right to be informed of the individual's right to refuse those drugs under the CDC Program and applicable EUAs; and,
3. The right to make a decision free from coercion or penalty.

The duty placed upon Defendants to obtain legally effective informed consent demonstrates that Congress expressly conferred upon Plaintiffs the property right to give or withhold that consent. This legal framework does not merely establish procedural guidelines—it creates substantive rights vested in the individual, as

discussed in *Roth, supra.* When Congress requires legally effective informed consent, it provides potential recipients from whom consent must be obtained the entitlement to refuse without penalty or pressure. This entitlement creates constitutionally protected property interests subject to the Due Process Clause that are enforceable under 42 U.S.C. § 1983 when violated by persons acting under color of law, such as Defendants.

The Supreme Court stated in *Dennis v. Higgins*, 498 U.S. 439 (1991), "we have given full effect to its broad language, recognizing that §1983 'provide[s] a remedy, to be broadly construed, against all forms of official violation of federally protected rights' and 'we refused to limit the phrase to 'personal' rights, as opposed to 'property' rights.'" *Id*., *citing Lynch v. Household Finance Corp.,* 405 U.S. 538 (1972). *Dennis* also held: "The right to enjoy property without unlawful deprivation, no less than the right to speak or the right to travel, is, in truth, a 'personal' right, whether the 'property' in question be a welfare check, a home, or a savings account." *Id.*

The district court ignored Plaintiffs' allegations relating to the legally effective informed consent duties and cited to no cases discussing the legal standard.

B. Legally Effective Informed Consent Relating To Investigational Drugs Is A Deeply Rooted Fundamental Right.

Legally effective informed consent is a legal standard applicable to investigational drugs, not licensed vaccines. (JA-033) Therefore, the drug classification holds paramount importance to Plaintiffs' allegations.

The federal government's desire to prevent nonconsensual use of investigational drugs is longstanding. In 1938, Congress enacted the FDCA, explicitly prohibiting the introduction of a drug into commerce until it is approved for general commercial marketing by the FDA (21 U.S.C. §355(a)). (JA-227)

As previously discussed, Congress enacted the 1974 National Research Act that established the foundation for the Common Rule, which became required compliance for persons authorized under the FWA program, establishing the legally effective informed consent standard.

The legally effective informed consent doctrine, established 44 years ago by the USG, has evolved into a fundamental liberty interest that meets the stringent constitutional test set forth in *Washington v. Glucksberg*, 521 U.S. 702 (1997). This doctrine is both "deeply rooted" in our nation's traditions and "implicit in the concept of ordered liberty," reaching a status so fundamental that "neither liberty nor justice would exist if [it was] sacrificed." (*Id.*) This evolution reflects the doctrine's essential role in protecting individual autonomy in federally funded

medical and research contexts such as the CDC COVID-19 Program, research Shriners agreed to conduct on the USG's behalf.

All States and Territories have agreed to comply with 45 C.F.R. Part 46 and the Belmont Report's ethical guidelines through the FWA program. (JA-035). The totality of the federal and military budgets must comply with the legally effective informed consent requirement. (45 C.F.R. § 46.122; 10 U.S.C. § 980) Moreover, although the Common Rule is required of the entirety of the federal government (45 C.F.R. § 46.101(a)), the principle is directly incorporated within the regulatory framework of most of the USG's agencies: 22 C.F.R. Part 225 (Agency for International Development); 7 C.F.R. Part 1c (Dept. of Agriculture); 28 C.F.R. Part 46 (Dept. of Prisons); EO 12333, EO 13284, EO 13555, EO 13470 (Central Intelligence Agency); 15 C.F.R. Part 27 (Dept. of Commerce); 16 C.F.R. Part 1028 (Dept. of Product Safety Commission); 32 C.F.R. Part 219 (Dept. of Defense); 34 C.F.R. Part 97 (Dept. of Education); 10 C.F.R. Part 745 (Dept. of Energy); 40 C.F.R. Part 26 (Environmental Protection Agency); 28 C.F.R. Part 46 (Federal Bureau of Investigation); 45 C.F.R. Part 46 (Health and Human Services); 6 C.F.R. Part 46 (Dept. of Homeland Security); 24 C.F.R. Part 60 (Dept. of Housing and Urban Development); 28 C.F.R. Part 46 (Office of Justice Programs); 29 C.F.R. Part 21 (Dept. of Labor); 14 C.F.R. Part 1230 (National Aeronautics and Space Administration); 45 C.F.R. Part 690 (National Science Foundation); EO 12333, EO

13284, EO 13555, EO 13470 (Office of Director of National Intelligence); 20 C.F.R. Part 431 (Social Security Information); 49 C.F.R. Part 11 (Dept. of Transportation); 38 C.F.R. Part 16 (Dept. of Veteran Affairs); 42 C.F.R. Part 50 (Public Services Act-sterilization of persons in federally assisted family planning projects); EO 13129 (requirement to obtain informed consent of any military or civilian); 48 C.F.R. Parts 297, 235, 252 (Defense Federal Acquisition Regulation Supplement—DFARS Case 2007-D008); DoDI 3216.02 (DoD: Research Integrity and Misconduct); DoDI 6200.02 (DoD: IND regulation for military and civilian use); DoDD 5400.11-R (DoD Privacy Program); AR 70-25 (U.S. Army: Research Protocols); ALARACT 031/2008, DTG 141557Z Feb 08 (Army Human Subjects Protection Requirements); HQ MRDC IRB Policies and Procedures (U.S. Army Medical Research and Development Command which is responsible for investigational and EUA drug administration DoD-wide). (JA-227)

Moreover, the legally effective informed consent standard governs the Executive Branch's agreements under the International Conference on Harmonization E-6 Guidelines, the Council for International Organizations of Medical Sciences Guidelines, the Canadian Tri-Council Policy Statement, and the Indian Council of Medical Research Ethical Guidelines.

Finally, the Senate ratified the International Covenant on Civil and Political Rights Treaty (ICCPR) in 1992. Article VII states, "no one shall be subjected

without his free consent to medical or scientific experimentation." *Id.* The legal definition of "experimentation" aligns with the FDA's definition under 21 C.F.R. § 312.3 "Clinical investigation," which states, "an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." "In FDA parlance, experimental drugs that have not yet been approved for public use are deemed investigational drug[s].' See 21 C.F.R. § 312.3(b)." *Abigail Alliance v. Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007). (JA-192)

Therefore, it is clear that the legally effective informed consent doctrine is deeply rooted within this nation's traditions, and it governs all uses of investigational drugs without exception. Because the FDA does not license the investigational new drug classification with a legal indication for its safety and efficacy for any known disease, they are considered investigational medical treatment aligning with the Supreme Court's precedent relating to unwanted medical treatment:

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. *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250 (1891).

More recently, in *Cruzan, supra*, *citing In re Conroy*, 98 N.J. 321, 348, 486 A.2d 1209, 1223 (N.J. Jan. 17, 1985), the Court held:

"[O]n balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons generally are permitted to refuse medical treatment, even at the risk of death. Most of the cases that have held otherwise, unless they involved the interest in protecting innocent third parties, have concerned the patient's competency to make a rational and considered choice."

In *Washington v. Glucksberg*, *supra*, the Court clarified:

"The right assumed in *Cruzan*, however, was not simply deduced from abstract concepts of personal autonomy. Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation's history and constitutional traditions."

"The protections of substantive due process have, for the most part, been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity." *Albright v. Oliver*, 510 U.S. 266, 272 (1994).

These legal standards led Judge Sullivan of the D.C. Circuit to vacate the Executive Branch's requirement of military members and civilians to inject investigational drugs into their bodies, stating, "The Court is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate." *Doe v. Rumsfeld*,

341 F. Supp. 2d 1 (D.D.C. 2004) He ruled, "Accordingly, the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver." (emphasis added). (JA-039-040) Notably, Congress only authorizes the President to issue a waiver of informed consent for military members relating to investigational drugs. (10 U.S.C. § 980) No legal conditions exist under which a government can waive Plaintiffs' legally effective informed consent rights.

Irrespective of the CDC Program and FWA program, EUAs, or any other source of law, Plaintiffs hold the fundamental right to refuse unwanted investigational drugs, which the Fourteenth Amendment protects. Therefore, whether a property right under the CDC Program, FWA, 10 U.S.C. § 980, or a fundamental right under the Fourteenth Amendment, neither the USG, Pennsylvania, nor Shriners could issue "vaccination" requirements exclusively relying upon investigational drugs for compliance, thereby depriving Plaintiffs of their fundamental right to give their legally effective informed consent.

Shriners' deprivation of Plaintiffs' informed consent rights transgressed statutory and regulatory boundaries and constitutional limitations on governmental power that protect bodily autonomy and medical decision-making rights without unwanted governmental intrusion. *Griswold v. Connecticut*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965).

The district court erred by not enforcing the legally effective informed consent standard based on Plaintiffs' alleged facts for purposes of Rule 12(b)(6), which constitutes reversible error. Moreover, none of the district court's cited cases addressed the legal standard.

III. THE DISTRICT COURT ERRED BY HOLDING SHRINERS IS NOT A STATE ACTOR UNDER THE CDC PROGRAM.

The district court stated, "As Defendants aptly explain in their briefing, a 'private nonprofit hospital, along with its officers and employees, do not qualify as state actors when they make corporate decisions, including by setting internal policies intended to protect their staff and patients and their families.'" (JA-4)

This statement ignores Plaintiffs' allegation that when a private hospital enters into a contractual relationship with the State to administer federally-funded investigational drugs to the public under legally effective informed consent standards, it is a State Actor because the State promised to obtain such consent on the USG's behalf and the State Actor agreed to carry out that governmental function. If the State owes a governmental function to Plaintiffs, so do its recruited agents. Moreover, Shriners does not have the authority to voluntarily agree to participate in and enjoy the benefits of the federal CDC Program but then later claim it was not under a requirement to perform the functions it contracted to perform. (JA-078-090)

Plaintiffs' alleged facts are that (1) the USG purchased all COVID-19 drugs, (2) the USGF established the CDC Program to administer the drugs through states,

(3) the "Pennsylvania Department of Health voluntarily entered into an agreement with the CDC to administer the federal government's COVID-19 investigational new drugs," (4) the State informed Shriners that "Enrolled vaccine providers are expected to be familiar with and consider all laws and regulations relating to nondiscrimination in the provision of health care services," (5) Shriners agreed to execute the Secretary's authorization conditions and conduct research activities on behalf of the state, (6) the "State was under a legal obligation to obtain Plaintiffs' legally effective informed consent in accordance with the equal protection of laws and due process as guaranteed to them under the Fourteenth Amendment," (7) the "State delegated that function to Defendants." (JA-16)

The district court's statement that "the weight of authority addressing this issue that a private entity's creation and implementation of a Covid-19 vaccine policy for its employees fails to meet this exacting standard" (JA-3) misses the mark because no court has addressed whether a private entity agreeing on the State's behalf to obtain an individual's legally effective informed consent under a nationally declared emergency and under the CDC Program can establish legal requirements conflicting with the obligations under the emergency program to ensure that no person is under pressure to use the drugs or penalized for refusing.

The Supreme Court holds, "Private persons, jointly engaged with state officials in the prohibited action, are acting under color of law for purposes of the

statute. To act 'under color' of law does not require that the accused be an officer of the State. It is enough that he is a willful participant in joint activity with the State or its agents." *United States v. Price*, 383 U.S. 794 (1966). The prohibited action is not placing individuals under threat of penalty to use the drugs and then punishing them when they refuse.

In *Jackson v. Metropolitan Edison Co*., 419 U.S. 345 (1974), the Supreme Court held that "the inquiry must be whether there is a sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself." Shriners was, at all times, under the complete control and authority of the State relating to the CDC Program, with discretionary authority limited to offering individuals an opportunity to use the drugs and then performing the ministerial duty of accepting the individual's chosen option without penalty or pressure.

The Supreme Court further stated in *Jackson, supra*:

"A particularized inquiry into the circumstances of each case is necessary in order to determine whether a given factual situation falls within 'the variety of individual-state relationships which the [Fourteenth] Amendment was designed to embrace.' *Ibid.* As our subsequent discussion in *Burton* made clear, the dispositive question in any state action case is not whether any single fact or relationship

presents a sufficient degree of state involvement, but rather whether the aggregate of all relevant factors compels a finding of state responsibility.'"

Pennsylvania was completely responsible for the CDC Program within its jurisdiction and promised to monitor Shriners for compliance to ensure that it only offered the drugs under voluntary conditions.

The Supreme Court concluded in *United States v. Classic,* 313 U.S. 299, 313 U.S. 326 (1941), that "[m]isuse of power, possessed by virtue of state law and made possible only because the wrongdoer is clothed with the authority of state law, is action taken 'under color of state law.'" Similarly, Plaintiffs alleged, "Federal law prohibits the unlicensed use of drugs, biologics, and devices outside the prescribed conditions as established by a valid act of Congress." (JA-086) Plaintiffs' also alleged, "The State owed constitutional obligations to Plaintiffs and had full authority to train and educate medical facilities and healthcare workers it licensed of those obligations. Moreover, it had the same authority to enforce the laws, regulations, and contractual agreements it was under when involving citizens with the federal COVID-19 drug property." (JA-087) However, as Plaintiffs alleged, "Governor Tom Wolf today announced that commonwealth employees in state health care facilities and high-risk congregate care facilities will be required to be fully vaccinated against COVID-19 by September 7, 2021. Individuals who are not vaccinated will be required to undergo weekly COVID-19 testing. Additionally,

beginning September 7, all new external hires in these facilities must be vaccinated before commencing employment." (JA-088)

Governor Wolf issued the vaccination policy in violation of the State's duties under the CDC Program, and the policy "stripped Plaintiffs of their legal right to choose the EUA statute's option to refuse without consequence and subjected them to involuntary participation in a PREP Act countermeasure without a hearing." (JA-089) "Thomas Wolf established a State Custom having the force of law replacing federal law, and contractual agreements, and in defiance of the Fourteenth Amendment's equal protection and due process guarantees," *Id.* which "Shriners Policymakers acted on this State-encouraged and enforced custom when engaging in their unlawful conduct, which led to the deprivation of Plaintiffs' statutory and Constitutional rights" because Shriners was "clothed with the authority of state law" which state law was a custom. (*Id.)*

"If a private actor is functioning as the government, that private actor becomes the state for purposes of state action." *Terry v. Adams*, 345 U.S. 461, 469-70, 73 S. Ct. 809, 97 L. Ed. 1152 (1953); *See Adickes v. S. H. Kress & Co*., 398 U.S. 144 (1970) that the "Petitioner will have established a claim under §1983 for violation of her equal protection rights if she proves that she was refused service by respondent because of a state-enforced custom…"

Plaintiffs were deprived the right to consider participation in the CDC Program without punishment not by a private employer but by an Organization whose CEO and CMO agreed to comply with the Program's terms and conditions and any EUA specifically on behalf of the State requiring the Organization to ensure that individuals were informed of their right to refuse and to accept their freely given consent without penalty or pressure. However, due to the state-enforced custom of allowing the deprivation of constitutional and federal rights under the CDC Program, Shriners was allowed to pressure and punish Plaintiffs when they exercised their right to refuse unwanted investigational drugs, by depriving Plaintiffs of the use their State-issued healthcare license in a place of employment. This deprivation strikes at the heart of informed consent principles established in *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129-30 (1914) (establishing that "every human being of adult years and sound mind has a right to determine what shall be done with his own body") and reinforced in *Cruzan, supra,* (recognizing a constitutionally protected liberty interest in refusing unwanted medical treatment). Here, Plaintiffs assert the fundamental right to refuse unwanted, unlicensed investigational drugs, not licensed vaccines.

Although state action by a private party is always fact-dependent, to survive a Rule 12(b)(6) motion, Plaintiffs only have to allege that the USG owned the drugs, that the drugs were not licensed for any indication by the FDA, that the drugs could

only be obtained through the CDC Program, and that the USG and its delegated agents were obligated to obtain Plaintiffs' legally effective informed consent in accordance with the Fifth and Fourteenth Amendments, but failed to do so. The chain of delegation carried constitutional obligations that prohibited Shriners from depriving individuals of rights Shriners willfully agreed to protect on the State's behalf. In *Lugar v. Edmondson Oil Co., supra,* the Court made clear that, if a defendant's conduct satisfies the state action requirement of the Fourteenth Amendment, "that conduct [is] also action under color of state law and will support a suit under § 1983." The USG and states that agreed to participate in the CDC Program possessed the governmental function of distributing and administering EUA/PREP Act investigational drugs under that Program. It is a governmental function because no private party, Shriners included, had the ability to obtain EUA/PREP Act investigational drugs directly from the manufacturers and distribute them to anyone. Rather, the USG, the State, and Shriners owed Plaintiffs a duty not to pressure them to use the drugs nor punish them should they refuse, duties that were breached by Shriners while acting under color of law. The State was required to protect on behalf of the USG Plaintiffs' right to refuse unwanted investigational drugs, and it cannot avoid its constitutional obligations by delegating to Shriners the governmental function of administering EUA/PREP Act investigational drugs

without delegating its constitutional obligation to obtain Plaintiffs' legally effective informed consent.

The Supreme Court stated, "The State has so far insinuated itself into a position of interdependence…that it must be recognized as a joint participant in the challenged activity." *Burton v. Wilmington Pkg. Auth*, 365 U.S. 715, 81 S. Ct. 856 (1961). Additionally, "[W]hen private individuals or groups are endowed by the State with powers or functions governmental in nature, they become agencies or instrumentalities of the State and subject to its constitutional limitations" *Evans v. Newton,* 382 U.S. 296, 299, 86 S.Ct. 486, 15 L.Ed.2d 373 (1966)

Moreover, the PREP Act's express preemption clause preempted Governor Wolf from issuing his mandatory policy relying exclusively upon the use of EUA/PREP Act drugs. His policy was issued only under *ultra vires* authority, which the district court did not address. Instead, the district court ignored the Plaintiffs' detailed allegations relating to how Shriners was engaged in state action when it deprived Plaintiffs of their constitutional rights under the CDC Program, constituting reversible error.

IV. THE DISTRICT COURT ERRED BY DISMISSING PLAINTIFFS' COUNTS UNDER RULE 12(b)(6)

The scope of 42 U.S.C. § 1983 is deliberately broad: it creates a cause of action to enforce rights conferred by the federal constitution, all federal laws, and even Spending Clause legislation. The only prerequisite is that the underlying law

must unambiguously confer a substantive, individual "right." *Talevski* held that the Federal Nursing Home Reform Act's language that the "right to be free from . . . any physical or chemical restraints" and "the right to advanced notice of discharge provisions of the FNHRA statute meet[s] this test," stating that "[t]his framing is indicative of an individual 'rights-creating' focus. *Gonzaga*, 536 U. S., at 284." The plain language of §1983 thus provides a "source of express congressional authorization of private suits." *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 509 n.9 (1990) (*quoting Middlesex Cty. Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453U.S. 1, 19 (1981)); *see also Livadas v. Bradshaw*, 512 U.S. 107, 132 (1994) (stating that "Section 1983 provides a federal cause of action for the deprivation, under color of law, of a citizen's 'rights, privileges, or immunities secured by the Constitution and laws' of the United States.") The express cause of action provided in § 1983 provides "a method for vindicating federal rights elsewhere conferred" in the Constitution and federal statutes. *Baker v. McCollan*, 443 U.S. 137, 144 n.3 (1979). Whether the right is derived from rights-creating language as designated in statute, such as the option to accept or refuse under the EUA Statute, or as incorporated into the PREP Act under its express preemption clause as discussed in *Talevski, supra*, or a programmatic federal benefit which is a property right as discussed in *Roth, supra*, Plaintiffs' allegations fit squarely with Supreme Court case precedent.

A. Count One "Subjected to Investigational Drug Use" (JA-100)

Plaintiffs hold property rights under the CDC Program, the EUA Statute, 10 U.S.C. § 980 (the investigational drugs were procured using DoD funding), the Common Rule, the Belmont Report, and the FWA Program because the duty to obtain Plaintiffs' legally effective informed consent means Congress delegated to Plaintiffs the property right to give such consent, deprivation of which is subject to § 1983 remedy pursuant to *Talevski* and *Dennis*. For purposes of Rule 12(b)(6), these allegations establish plausibility based on the terms of the various federal programs providing Plaintiffs with federal benefits owed to Plaintiffs by the State, which Shriners did not deny they owed.

B. Count Two "Deprivation of Equal Protection Rights" (JA-102)

The option to accept or refuse is an alternative option that cannot be treated unequally under the law. Plaintiffs might be Shriners' employees, but they are still subject to the State's authority relating to the CDC Program, and Shriners was required to not discriminate against individuals who chose the option to refuse, irrespective of Shriners' relationship with the individual. As the Supreme Court has held, "[W]e have explained that '[t]he purpose of the equal protection clause of the Fourteenth Amendment is to secure every person within the State's jurisdiction against intentional and arbitrary discrimination, whether occasioned by express terms of a statute or by its improper execution through duly constituted agents.'

Sioux City Bridge Co., supra, at 445 (quoting *Sunday Lake Iron Co.* v. *Township of Wakefield,* 247 U. S. 350, 352 (1918)).” *Village of Willowbrook v. Olech*, 528 U.S. 562 (2000). The State and its “duly constituted agent,” (i.e., Shriners) improperly implemented the CDC Program, depriving Plaintiffs of their equal protection guarantees subject to § 1983 remedy.

C. Count Three “Procedural Due Process” (JA-103)

Plaintiffs hold programmatic rights under the CDC Program to learn of the drugs’ risks, benefits, and alternatives without coming under pressure to participate or incur a fee, penalty, or lose a benefit when the option to refuse is exercised. “The hallmark of property is an individual entitlement grounded in state law, which cannot be removed except ‘for cause.’” *Logan, supra*. Neither the State nor its recruited agent (i.e., Shriners) provided Plaintiffs with a date, time, or place to have their “merits fairly judged” before being deprived of their Fourteenth Amendment guarantees. *Id*.

D. Count Four “Substantive Due Process” (JA-104)

The right to refuse unwanted investigational drugs is protected under the Fourteenth Amendment’s Due Process Clause. As *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250 (1891) held, “[n]o 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 of interference of

others unless by clear and unquestionable authority of law." *See Cruzan*, *Glucksberg*, and *Albright, supra*.

"The right to be free of state-sponsored invasion of a person's bodily integrity is protected by the [constitutional] guarantee of due process." *Guertin v. Michigan*, 912 F.3d 907, 921 (6th Cir. 2019) (quoting *In re Cincinnati Radiation Litig*., 874 F. Supp. 796, 810–11 (S.D. Ohio 1995)).

The State "in practical operation" used Shriners as a "procedural device" to "produce a result which the State could not command directly," which was to subject Plaintiffs to nonconsensual use of investigational drugs outside of their Fourteenth Amendment guarantees which deprivation is subject to § 1983 remedy. See *Speiser v. Randall*, 357 U.S. 513 (1958).

E. Count Five "Spending Clause" (JA-106)

Plaintiffs were offered an opportunity to use drugs that were procured with DoD funding (10 U.S.C. § 980), classified by the FDA as investigational, and subject to 45 C.F.R. § 46.122. The option under the federally funded CDC program to be informed of the right to accept or refuse an EUA drug is unambiguous language subject to § 1983 remedy pursuant to *Talevski* and *Dennis, supra*.

F. Count Six "Unconstitutional Conditions Doctrine" (JA-110)

"A man may not barter away his life or his freedom, or his substantial rights." *Home Ins. Co. of New York v. Morse*, 87 U.S. 455, 451 (1874). "For at least a quarter-

century, this Court has made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests." *Perry v. Sindermann*, 408 U.S. 593, 92 S.Ct. 2694, 33 L.Ed.2d 570 (1972)(emphasis added). The State and Shriners conditioned the use of their state-issued license to work in the healthcare industry upon Plaintiffs surrendering their Fourteenth Amendment right to refuse unwanted investigational drugs, their due process rights if injured by the drugs or CDC program under the PREP Act, and their private health information to unknown persons, reasons, and length of time. The State and Shriner established unconstitutional conditions when they conditioned the use of Plaintiffs' State-issued healthcare licenses on the relinquishment of the Constitutional right to bodily autonomy.

G. Count Seven "PREP Act" (JA-111)

The PREP Act expressly preempts the State and its recruited agents from establishing or continuing in effect with any legal requirement that conflicts with the "voluntary nature" of the Program or any requirement applicable to a countermeasure under the FDCA, which extends to the option to accept or refuse under the EUA. Therefore, the PREP Act's express preemption clause incorporates

the option to accept or refuse under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) as a required condition to comply with under the PREP Act, which is enforceable via *Talevski* and *Dennis*, *supra*.

The PREP Act is primarily an immunity statute. However, providing immunity to a person who injures another member of society burdens the Plaintiffs' right to bring a cause of action for product liability, medical malpractice, fraud, and battery; seek tort remedies for bodily harm caused by another member of society; and be made whole for damages to their finances and emotional well-being, which rights are subject to the Due Process Clause.

The Supreme Court holds that a common law cause of action is a property right, stating: "The hallmark of property is an individual entitlement grounded in state law, which cannot be removed except 'for cause." *Logan, supra*. "The first question, we believe, was affirmatively settled by the *Mullane* case itself, where the Court held that a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause." *Id. See, Tulsa Prof. Collection Svcs. v. Pope,* 485 U.S. 478 (1988)*; Phillips Petroleum Co. v. Shutts,* 472 U.S. 797 (1985). The PREP Act does not deprive a person of their property interest because it only requires voluntary participation. (42 U.S.C. §247d-6e(c)). Instead, Defendants, acting under color of law and requiring Plaintiffs to use a covered countermeasure under threat of penalty, is the conduct that requires Plaintiffs to surrender their due process rights

under the Act nonconsensually, which is an unconstitutional condition and a deprivation of due process. Neither the State nor Shriners can condition benefits on Plaintiffs surrendering their right to seek judicial relief if injured under the CDC Program.

H. Count Nine "Wrongful Termination" (JA-115)

Pennsylvania Superior Court holds that a "discharged employee can now seek relief through an action in tort for wrongful discharge. A discharge is 'wrongful' when it transgresses a clearly-articulable public policy or when the employer intends to harm the employee." *See Geary v. United States Steel Corp.,* 456 Pa. 171 (Pa. 1974), 319 A.2d 174; *Tourville v. Inter-Ocean Ins. Co.,* 353 Pa. Superior Ct. 53 (1986), 508 A.2d 1263*; Clay v. Advanced Computer Applications*, 370 Pa. Super. 497, 510-11 (Pa. Super. Ct. 1988)

The State agreed to perform the function of obtaining the Plaintiffs' legally effective informed consent, with which the Supremacy Clause preempts all state laws from conflicting, and the PREP Act expressly preempts the State from allowing private employers to use the state's at-will employment laws to deprive Plaintiffs of their rights under the federal program.

Although the public policy exception to the at-will employment doctrine is a state law, the allegations relating to the exception only involve federal questions, which the lower court should have addressed to ensure that the interests of the

federal government are protected during nationally declared emergencies. Shriners could not legally terminate Plaintiffs for exercising their right to refuse the investigational drugs that the State agreed to only offer them under voluntary conditions.

I. Count Ten "Intentional infliction of emotional damage"

Plaintiffs stand by their allegations.

V. THE DISTRICT COURT ERRED BY CITING RULINGS UNCONSTITUTIONALLY EXERCISING ARTICLE II POWERS OR HELD AN ERRONEOUS VIEW OF THE LAW.

A. *Roberts v. Shriners Hospitals for Children*, No. 2:23-cv-0295 (E.D. Wash. Feb. 8, 2024)

The *Roberts* court was informed that Shriners was under a ministerial duty by the Executive Branch to "conspicuously" state that Pfizer-BioNTech COVID-19 Vaccine had "not been approved or licensed by FDA." However, Judge Rice ruled that the drug was "effectively FDA approved," which has no legal meaning as there are no statutes establishing an "effectively FDA approved" drug. The *Roberts* ruling violated the Separation of Powers doctrine. The *Roberts* court holding that the Pfizer drug was "effectively FDA approved" has placed the drug under two legally distinct conditions. Under the Executive Branch, it is not approved or licensed for any legal indication and is required to operate under investigational application 19736 and comply with laws applicable to investigational drugs. However, according to the *Roberts* court, it is effectively FDA-approved and allowed to operate as if licensed

with a legal indication. This dual regulatory approach to the single legally distinct drug is an absurd result of the *Roberts* ruling.

The district court agreeing with the *Roberts* ruling also usurps the Executive Branch's exclusive constitutional powers because the court judicially assigned the Pfizer-BioNTech COVID-19 investigational drug with a legal indication as a vaccine, which would require the HHS Secretary to immediately end all EUAs and initiate protocols for disposing of the drugs as required by Congress since the drugs cannot be commercially marketed under their EUA labeling. (21 U.S.C. § 360bbb-3(b)(2)(B)) The *Roberts* case is on appeal to the Ninth Circuit Court of Appeals.

B. *Pearson v. Shriners Hosps. for Child*., No. 3:23-CV-387, 2024 WL 3022397 (S.D. Tex. June 7, 2024)

The *Pearson* court held that since Shriners did not administer the drugs to Plaintiffs, the right to refuse never came into being, thereby judicially creating a loophole in the EUA and PREP Act statutes that renders the legally effective informed consent doctrine nonfunctional whereby a signatory to the CDC Provider Agreement can eschew its duties toward a class of potential recipients (i.e., employees, contractors, vendors) by instructing them to go to another authorized Vaccination Provider under the CDC Program and then penalize the employees if they exercise their right to refuse an EUA/PREP Act investigational drug from that other Vaccination Provider. In the instant action, the district court agreed with *Pearson* and deprived the Legislative and Executive Branches of their constitutional

authority to prohibit USG-authorized agents from placing Americans under outside pressure to use investigational drugs and medical treatments. The Fifth Circuit Court of Appeals did recently affirm Pearson, but those plaintiffs are requesting reconsideration and *en banc* review, and, if ultimately necessary, Supreme Court review.

C. *Bridges v. Methodist Hosp*., No. 4:23-CV-1699, 2024 WL 4354816 (S.D. Tex. Sept. 30,2024)

The *Bridges* court cited to *Pearson* as the basis for dismissing the Bridges' Plaintiffs' allegations under Rule 12(b)(6), which also amended valid acts of the Legislative and Executive Branches without explanation. *Bridges* is on appeal to the Fifth Circuit Court of Appeals.

D. *Timken v. S. Denver Cardiology Assocs*., P.C., No. 23-CV-02859-GPG-SBP, 2024 WL 4407003, at *2 (D. Colo. Aug. 29, 2024)

The *Timken* court only cited the same rulings as the district court in the instant case, violating the Separation of Powers doctrine. *Timken* is on appeal to the Tenth Circuit Court of Appeals.

E. *Curtis v. PeaceHealth*, No. 3:23-CV-05741-RJB, 2024 WL 248719 (W.D. Wash. Jan. 23, 2024).

The *Curtis* court held that the drugs were not investigational despite being informed that the FDA described them as such in its EUA letter to Pfizer and Executive Branch placed Pfizer-BioNTech COVID-19 Vaccine under

investigational new drug application 19736. *Curtis* is on appeal before the Ninth Circuit Court of Appeals for reasons of judicial overreach.

F. *Sweeney v. Univ. of Colorado Hosp. Auth.*, No. 23-CV-02451-NYW-MDB, 2024 WL 3713835 (D. Colo. July 12, 2024)

The *Sweeney* court acknowledged that the drugs were investigational but violated the Separation of Powers doctrine and usurped Congressional authority by claiming Colorado and its political subdivisions can mandate EUA/PREP Act investigational drugs despite Congress expressly preempting that conduct under the EUA Statute, the PREP Act, the CDC Program, 10 U.S.C. § 980, the FWA program, the Common Rule, and the state's own laws relating to investigational drugs. The district court in the case at bar also violated the Separation of Powers holding that Governor Wolf and the State's recruited actors can mandate the use of EUA/PREP Act investigational drugs.

None of the cited cases addressed the duties owed by the State to Plaintiffs in the instant action relating to the CDC Program and its investigational drugs. Moreover, those courts did not address the PREP Act's express preemption clause, legally effective informed consent, Supremacy Clause, 10 U.S.C. § 980, the CDC Program, or the fact that all defendants were subject to the Federal Wide Assurance program promising never to pressure individuals to use investigational medical treatments. Therefore, it is uncertain how the district court in the case at bar found

those arguments persuasive enough to dismiss Plaintiffs' allegations under Rule 12(b)(6).

VI. THE DISTRICT COURT ERRED BY DISMISSING PLAINTIFFS' COMPLAINT WITH PREJUDICE.

This Court holds that "in the event a complaint fails to state a claim, unless amendment would be futile, the District Court must give a plaintiff the opportunity to amend her complaint." *Phillips v. County of Allegheny*, 515 F.3d 224 (3rd Cir., Feb. 5, 2008). The reason that the district court held that amendment would be futile is because it encroached upon the exclusive constitutional domains of the Legislative and Executive Branches to amend the drugs' classification from investigational to "effectively FDA approved," ignored the PREP Act's express preemption clause, duties under the CDC Program, constitutional obligations owed to Plaintiffs by the State, the fact that the USG owned the drugs, nullified the FWA program, and required the State and Shriners to ensure that when they presented Plaintiffs with the opportunity to use EUA/PREP Act investigational drugs under the CDC Program, they must inform Plaintiffs of their right to refuse without penalty or pressure.

VI. CONCLUSION

The Court should reverse and render a decision holding that (1) Shriners was prohibited from pressuring Plaintiffs to be injected with federally funded EUA/PREP Act investigational drugs and from penalizing them when they refused, (2) Shriners was operating under color of law when interacting with Plaintiffs regarding the

COVID-19 EUA/PREP Act drugs available under the CDC Program, (3) Defendants' actions deprived Plaintiffs of their constitutional and federal statutory rights, and (4) Plaintiffs plausibly stated causes of action.

STATEMENT REGARDING ORAL ARGUMENT

Appellants respectfully request oral argument.

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 11,879 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 April 7, 2025, 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: April 7, 2025s

Respectfully submitted

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