UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

JERI PEARSON, ELIZABETH KLEM, BEN HOMAN, and ROB FOWLER	*	
Plaintiffs,	*	
VERSUS	*	CIVIL ACTION 3:23-cv-387
SHRINERS HOSPITALS FOR CHILDREN SHRINERS HOSPITALS FOR CHILDREN -- TEXAS, BEVERLY BOKOVITZ, FRANCES FARLEY, JERRY GANTT, JOHN McCABE, PHILLIP GRADY, AND CECILE ERWIN YOUNG	*	
Defendants	*	

* * * * * * * * * * * * *

PLAINTIFFS' OPPOSITION TO SHRINERS DEFENDANTS' MOTION TO DISMISS
(ORAL ARGUMENT REQUESTED)

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of April, 2024, I presented the foregoing pleading to the Clerk of Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ David J. Schexnaydre
DAVID J. SCHEXNAYDRE

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Shriners did not dispute Plaintiffs' claims that they had the right to refuse an investigational drug, an EUA product, or a PREP Act countermeasure. Shriners also did not dispute it was preempted from requiring use of those products under the Provider Agreement, its FWA, or because the drugs were classified as investigational. Shriners only claims freedom from liability.

A. 12(b)(2) Personal Jurisdiction. The Individual Defendants, outside of Texas, adopted a Policy for Shriners entities to carry out in Texas, which resulted in damages in Texas. As a result, it is within this Court's power to exercise personal jurisdiction over them. Additionally, the Vaccine Policy was issued to "All Shriners Hospitals for Children Employees and Contract Staff" by the Individual Defendants. Shriners, through the actions and decisions of the Individual Defendants, "transacts" business within Texas and has "contacts, ties, or relations" within the State. *International Shoe Co. v. Washington*, 326 U.S. 310 (1945). Thus, Shriners' claim that this lacks jurisdiction over the Individual Defendants should be denied. See *Mallory v Norfolk*, 143 S.Ct. 2028 (2023)

B. Time Barred. Shriners misconstrues *Chardon v. Fernandez.*[1] The injury in *Chardon* occurred when the Department of Education (DOE) notified a non-tenured administrator that he was not granted tenure. He received a notice that his employment would terminate one year later, allowing time to find other employment. There was nothing he could do to change the DOE's decision, so the court held that the termination notice, not the actual termination date, started the clock. In the instant action, Plaintiffs are not

[1] Doc 23, pp. 4-7

time-barred based on the wording of the Policy[2]: "**IF HCP does not comply** with the written notification of non-compliance with COVID-19 vaccination or N95 or equivalent respirator/masking requirement or COVID-19 weekly testing, the HCP supervisor/ manager or department leader will be notified. Failure to comply with this policy **may be** grounds for removal from the healthcare facility or termination." (Emphasis added) "If" and "may be" are conditional. The notice was not a termination notice; it was company policy notice. Plaintiffs could have changed their minds at the very last moment, accepted the shot, and continued working, which distinguishes *Chardon*.

C. Informed Consent (Doc 23, p. 13). Throughout Shriners' motion, it mischaracterizes Plaintiffs' arguments. Plaintiffs' Second Amended Complaint (SAC) is clear and speaks for itself, so Shriners' mis-recitation of Plaintiffs' allegations is of no help. For instance, Plaintiffs do not allege that "once the Shriners Parties enacted the COVID-19 Policy, their duty to provide the EUA 'informed consent' information to Plaintiffs was immediately triggered, giving Plaintiffs the right to reject the vaccination and remain employed." Shriners' duty to obtain informed consent emanates from the Provider Agreement, not the enactment of its Policy. Whether Shriners enacts a Policy or not, it still had a duty to inform Plaintiffs of their right to accept or refuse the EUA drugs and to accept Plaintiffs' chosen option without imputing a penalty to either option whenever they involved Plaintiffs with the State's CDC Program or any investigational drug. Moreover, Plaintiffs' right to reject the EUA/PREP Act drugs existed well before Shriners' Policy was

[2] Doc 20-4, Shriners Policy, p.5, Section F(3).

enacted. So how does Shriners enacting a Policy that its employees receive an EUA/PREP Act drug suddenly nullify that right?

Shriners' implication that it is not required to perform the ministerial function of accepting Plaintiffs' chosen option under the EUA statute because the Policy "did not require any of Shriners Parties to actually administer the vaccine to Plaintiffs" (Doc 23, p. 13) is nonsensical and baseless. First, as mentioned, the drugs were not classified by the FDA as "licensed vaccines." The FDA was explicit that they were "investigational vaccine[s] not licensed for any indication" (emphasis added) (Doc 20, ¶ 37)[3]. Second, Shriners, as the "Organization" under the Provider Agreement and the "vaccination provider"[4] under the EUA, had the legal duty to ensure that the conditions required by the HHS Secretary under the EUA, and the State of Texas, under the State's CDC Program, were met whenever a potential recipient was deciding whether to accept or refuse. The ministerial function required by the HHS Secretary under the EUA was to accept Plaintiffs' chosen option without applying pressure or a penalty. Shriners applied both. Therefore, whether Shriners or a third party administered the shot is immaterial because the ministerial function of accepting the chosen option is not dependent on who administered the shot; it only matters that Shriners had to accept the chosen option, period.

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[3] See Exhibit A, December 11, 2020, EUA Letter. Plaintiffs ask the court to take judicial notice of Exhibit A. Judicial notice is proper where the evidence "is not subject to reasonable dispute." Fed. R. Evid. 201(b). A court on a motion to dismiss may consider "records and reports of administrative bodies," *Mack v. S. Bay Beer Dist., Inc*., 798 F.2d 1279, 1282 (9th Cir. 1986), the content of state and federal regulations, *S. Bay United Pentecostal Church v. Newsom*, 985 F.3d 1128, 1132 (9th Cir. 2021), and public records and government documents available from reliable sources on the Internet, *U.S. ex rel. Modglin v. DJO Glob. Inc*., 114 F. Supp. 3d 993, 1008 (C.D. Cal. 2015).

[4] "Vaccination provider refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder…and who is enrolled in the CDC COVID-19 Vaccination Program." Doc 20-3, August 23, 2021, EUA Letter, Footnote 13 (See also Doc 20, ¶ 77)

Shriners' citation of the Sixth Circuit Court's erroneous ruling in *Norris v. Stanley* does not help its case (Doc 23, p.8). The Sixth Circuit erred by not abiding by the wording of the EUA statute. First, the statute contains no language requiring a healthcare worker to inform an individual of anything. Second, the EUA statute places a duty upon the HHS Secretary to establish conditions ensuring individuals are made aware of their right to accept or refuse the product. The HHS Secretary established those "conditions of authorization" under each EUA, see Doc 20-3, Letter "O." Those duties applied to the State and its agencies to "ensure" the "administration" of the "Program" were "consistent with the terms of" the letter. Moreover, the State had a duty to "identify vacciantion sites," make them aware of the letter, "instruct" them in the lawful administration of the Program, see Doc 20-3, Letter "P" and were preempted from amending the "conditions of authorization" which Defendant's Policy effectuated.

Additionally, the Secretary placed a duty upon the "vaccination provider" (i.e., Shriners) who "**will adminster** the vaccine in accordance with the authorization **and will** participate and comply **with the terms** and training required of the **CDC's COVID-19 Vaccination Program** (emphasis added) see Doc 20-3, see Letter "R" in addition to its other duties.

Therefore, the duty was placed upon the State first, then Organizations the state recruited and that signed the Provider Agreement. Nowhere does the HHS Secretary directly require any healthcare worker to inform any individual of their right to accept or refuse; that duty was placed upon the State, and its recruited parties, like Shriners, to ensure that every potential recipient's choice was honored and not pressured or penalized. *Norris*

is erroneous because the Defendant (Michigan State University) is a state agency under a duty to accept the students' statutory option without interference.

Moreover, for the sake of clarity, *Norris* never considered the facts as presented herein. *Norris* also failed to determine who had the right to accept or refuse the federal COVID-19 investigational drugs and by what authority a third party could interfere with that right. Plaintiffs allege that the individual considering the use of an EUA product is the sole owner of the right to accept or refuse, and a third party cannot interfere with that right. Shriners does not dispute these claims in their motion to dismiss.

Shriners' claim (Doc 23, p. 14) that it cannot be held liable for damages caused by its mandatory Policy "because they are not 'directly administering the vaccine' to employees" fails because "a person 'subjects' another to the deprivation of a constitutional right, within the meaning of section 1983, if he does an affirmative act, participates in another's affirmative acts, or omits to perform an act which he is legally required to do that causes the deprivation of which complaint is made." (Doc 20, ¶¶ 84,85)

Shriners cites to another erroneous ruling in *Children's Health Def., Inc. v. Rutgers.*[5] (Doc 23, p. 14) The Third Circuit held that "there is no unqualified right to decide whether to 'accept or refuse' an EUA product without consequence." First, the EUA statute is clear that the HHS Secretary is the only person empowered to authorize the unlicensed use of medical products, but not even the HHS Secretary can mandate the use of those products (21 U.S.C. §360bbb-3(l)). Second, *Norris* judicially implied a meaning to the word

[5] *Children's Health Def., Inc. v. Rutgers, the State Univ. of New Jersey*, 93 F.4th 66, 76 (3d Cir. 2024)

"consequence" without explaining how it arrived at its conclusion within the statute. In actuality, the FDA instructed the healthcare industry to only inform of the potential "health consequences"[6] of refusing. Third, in accordance with the Due Process Clause, no person outside of Congress can establish prohibited acts under 21 U.S.C. § 331 and then assign penalties under 21 U.S.C. § 333 and determine how those penalties will be applied.

The Third Circuit judicially implied that a third party can create its own version of the FDCA. These cases show a failure of the appellate courts to uphold the Constitutional protections under the Fourth, Fifth, Eighth, and Fourteenth Amendments. Now, per the Third Circuit, Rutgers can establish prohibited acts under the FDCA, establish penalties, and enforce them outside of the due process clause, right to privacy, excessive fines clause, and outside the equal protection of laws since the penalties can vary by the day and person establishing the penalties. Moreover, the *Rutgers* ruling did not take into consideration drug labeling laws and how those laws applied to the emergency use of products. The ruling literally voids entire swaths of the U.S. Code by allowing third parties to circumvent duties Congress placed upon the federal government, states, and any person acting in collaboration with them while preempting States from interfering in the federal goals under the statute. Moreover, the *Rutgers* ruling ignores well-established case law regarding the

[6] See Doc 12-5, FDA Guidance, Emergency Use Authorization of Medical Products, July 2007, p.18: "**Consequences** of not taking/using [PRODUCT], including possible health effects and quarantine, and of stopping the use of [PRODUCT] against the recommendation of the health care provider" (emphasis in original)

Supremacy Clause governing federal statutes.[7] The ruling was effectively a legislative act made outside the court's constitutional authority.

Shriners does not explain how it had the authority to amend the FDCA under its vaccination Policy nor did the Third Circuit Court of Appeals.

D. 45 C.F.R. 46. Shriners is incorrect when asserting that "unless the CDC COVID-19 Vaccination Program is 'research' as defined by 45 C.F.R. Part 46, then the 'informed consent' provisions of 45 C.F.R. Part 46 vanish from the scene" (Doc 23, p. 10). The ministerial duty of accepting an individual's chosen option is required under the EUA statute, the Provider Agreement, 45 C.F.R. Part 46, and under Shriners' IRB and FWA, and Plaintiffs' fundamental right to bodily integrity[8] to refuse[9] the administration of an IND without incurring a penalty or losing a benefit to which they are otherwise entitled.

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[7] *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.'") (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)). *See, Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *Geier v. Am. Honda Motor Co*., 529 U.S. 861, 881–82 (2000); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *Kurns v. R.R. Friction Prods. Corp*., 565 U.S. 625 (2012); *Bragdon v. Abbott*, 524 U.S. 624, 645 (1998).

[8] "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 Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891); "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment" (*Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990)); Requiring a person to lawfully submit to bodily intrusion "would defeat the sanctity of the individual and would impose a rule which would know no limits, and one could not imagine where the line would be drawn." *McFall v. Shimp*, 10 Pa. D. & C. 3d 90 (July 26, 1978)

[9] "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" which was the underpinning of the court's ruling that "[u]nless and until FDA properly classifies AVA [an anthrax vaccine] as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. §1107. Accordingly, the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver." *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004)

Shriners claiming it is "only" (Doc 23, p. 11) required to inform Plaintiffs of the right to refuse while implying that Shriners is not legally obligated to allow Plaintiffs to exercise that right without penalty is ludicrous. A right is only a right if it can be exercised without penalty, and if under penalty, then in accordance with due process. The court rulings in Doc 23, FN 54 hold that a person must only be *informed* of their right to accept or refuse, but once informed, they can somehow be penalized for refusing without due process, demonstrating the failure of the courts to uphold and protect the United States Constitution, not Defendants' right to violate it.

The manufacturers of the EUA drugs are required to submit their research findings to CBER (acting as the IRB under the regulatory requirement) "periodic safety reports at monthly intervals…" resulting from the research activities (Doc 20-3, p.9, Section G). Although Shriners articulated a fictitious legal theory as to why 45 C.F.R. 46 does not apply, the court should decline making factual findings that "the CDC COVID-19 Vaccination Program is 'deemed not to be research'" when Pfizer, Moderna, Johnson & Johnson, FDA, CDC, HHS, and the federal Office for Human Research Protections (OHRP) can submit a declaration or testify under oath during trial to these facts.

E. Investigational New Drug (IND). Shriners argued in Washington and Pennsylvania federal courts[10] that the Pfizer-BioNTech COVID-19 Vaccine drug was not investigational only after the FDA approved COMIRNATY® because it shared formulation. But Plaintiffs herein alleged in their SAC that the FDA issued EUAs

[10] *Roberts v. Inslee*, USDC, EDWA, 2:23-cv-295, Doc 32; *Boyd v. Shriners*, USDC, WDPA, 1:23-cv-342, Doc 19.

throughout 2021 and 2022, where the FDA placed a duty upon Shriners (because it agreed to abide by any EUA) mandating that "[a]ll descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that: This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA…for individuals 12 years of age and older."[11] It is curious that Shriners has now changed its argument, even refusing to cite to the *Roberts* court's erroneous ruling that the drug was "effectively approved" and "not under EUA." In the instant action, Shriners attempts a new approach since the *Curtis* case is on appeal to the Ninth Circuit, which must rule in favor of the FDA's authority to assign a drug its classification and that a federal judge is Constitutionally prohibited from judicially creating the new drug classification of "effectively approved."

Shriners is wholly incorrect when it states that "Plaintiffs make their case that the COVID-19 vaccine was an "investigational drug" by relying heavily upon the regulatory definitions found in 21 C.F.R. Part 312" (Doc 23, p. 12). Plaintiffs did not "imply" the drug was investigational. Plaintiffs stated it directly and referenced the FDA's December 11, 2020, EUA letter issued to each manufacturer assigning each drug its "investigational new drug" classification, including (1) Pfizer-BioNTech COVID-19 Vaccine under IND application 19736, (2) Moderna COVID-19 Vaccine under IND application 19745, (3) and Janssen COVID-19 Vaccine under IND application 22657 (Doc 20, footnote 20, ¶¶ 37-38).

[11] Doc 20-3, Letter "Y"

Shriners maintains that the drugs are not investigational new drugs, yet the FDA issued IND numbers to each of them in December 2020, and reiterated on August 23, 2021, that Pfizer "must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals…" (Doc 20-3, p.9, Section G) and many times thereafter. Shriners' analysis of 45 C.F.R. 46 and the drug's classification conflicts with judicially noticeable documents from the FDA and should be rejected.

"Pfizer-BioNTech COVID-19 Vaccine" (upper case "V") is the formal legal name for Pfizer's COVID-19 investigational drug technology under IND application 19736. Additionally, an EUA-authorized drug must be clothed with a legal classification for purposes of regulation (21 U.S.C. § 355(a), 21 U.S.C. §360bbb-3,) and, though it disputes the FDA's classification, Shriners does not provide support for any other classification. Shriners' conduct has been to ignore, at all times material, the FDA's assigned IND classification for the Pfizer-BioNTech COVID-19 Vaccine drug[12] in each issued EUA[13] on and after Comirnaty was approved by the FDA without legal support.

Under the terms of the CDC Program the State was required to inform Shriners of each EUA notice as published in the Federal Register, and that Shriners agreed (by the Provider Agreement) to obtain and comply with "any EUA" and knew that the Pfizer-BioNTech COVID-19 Vaccine drug was assigned the investigational new drug

[12] Doc 20-3, Letter "G" "Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736" and Footnote 8 "The products are legally distinct with certain differences that do not impact safety or effectiveness."

[13] (August 23, 2021), (September 22, 2021), (October 20, 2021), (November 19, 2021), (December 9, 2021), (December 16, 2021), (January 3, 2022), (March 29, 2022), (May 17, 2022), (June 17, 2022), (July 8, 2022), (August 31, 2022), (October 12, 2022), (December 8, 2022), (March 14, 2023), (April 18, 2023), and on (April 28, 2023)

classification. Shriners' mischaracterization of the FDA's IND classification, if believed, would misdirect the court into an erroneous ruling.

Moreover, Shriners misconstrues 21 U.S.C. § 360bbb-3(k). That section means a drug manufacturer cannot use EUA data as a "clinical investigation" for purposes of obtaining a Biologics License Application for marketing approval and for issues relating to animals, devices, and other activities. Simply because an IND is used under an EUA outside a clinical investigation does not mean it cannot simultaneously undergo a clinical investigation. Shriners' analysis is simply wrong.

Shriners citing to *Bridges v. Houston Methodist* does not help their case because Plaintiffs herein do not claim they were part of a clinical trial under 21 C.F.R. § 50. A clinical trial is conducted to obtain a BLA through the FDA. (21 C.F.R. 50.1) An EUA for drugs must come through the HHS Secretary and operate under an IRB under 45 C.F.R. 46 because those are "research" activities, not clinical trials. (21 U.S.C. 360bbb-3)

F. State Action. The Texas Health and Human Services Commission voluntarily entered into an agreement with the CDC to administer the federal government's COVID-19 investigational drugs through its existing immunization program and it agreed to recruit private parties (i.e., Shriners) to help achieve the goal of administering investigational drugs to voluntary participants, assuring the federal government that the State would "monitor" and "ensure" those participants complied with their duties under the program. Additionally, the State owed Fourteenth Amendment obligations to any person considering the use of the EUA/PREP Act drugs, and it could not delegate to Shriners the function of administering the State's CDC Program without also delegating those constitutional

obligations. Shriners volunteered to act on behalf of Texas to administer the drugs under the State's strict rules.

The State had duties under its FWA because it involved humans with federally funded INDs. It also had duties to perform under the CDC Program as outlined in the CDC Playbook (Doc. 20-1). Additionally, it had duties as the "emergency response stakeholder" under each EUA (Doc. 20-3, EUA Letter to Pfizer), and had duties under the Provider Agreement,[14] specifically line 12(a) (Doc 20-2, Provider Agreement). Therefore, it is irrefutable that the CDC Program was an official State program under the State's prerogative that Shriners could participate only with State authorization and Shriners' willful participation (21 U.S.C. §360bbb-3(l)). Moreover, it cannot be refuted that the State owed Plaintiffs Fourteenth Amendment protections when Plaintiffs were mandated use of federally funded investigational products.

The State was not authorized to administer the CDC Program outside of the federal requirements, and Shriners was not authorized to administer the Program's drugs outside of official State policy. Therefore, the State exclusively relied upon Shriners to help achieve the State's goal of administering the federal drugs and would be financially rewarded by the federal government based on the number of recruited parties administering them and the number of shots administered by those State Actors.

The State incorporated the Provider Agreement into official State Policy when requiring recruited parties to sign and comply with its terms as a condition of authorization

[14] The State had to ensure Shriners correctly filled out the Provider Agreement, complied with its terms, and keep a copy of the contract for three years in accordance with the terms outlined in the CDC Playbook (Doc 20-1).

to act on the State's behalf. The State informed Shriners via the Provider Agreement of its duties (Doc 20. ¶ 28), and those duties required Shriners to also comply with duties required under "any EUA" as the "vaccination provider." Therefore, Shriners was under the complete control, authority, and directive of the State regarding the administration of the federal COVID-19 EUA/PREP Act drugs. Moreover, Shriners was aware of its duties before agreeing to perform on the State's behalf (Doc 12-8).

Shriners was acting under color of law when involving Plaintiffs in the CDC Program via its Policy and must perform the ministerial function of accepting Plaintiffs' chosen option under the constraints of the Fourteenth Amendment.

1. The Public Function Test is met by Shriners exercising powers (1) exclusively held by the federal government and Texas[15], (2) that are part of the State's prerogative[16] (the State did not have to volunteer to participate, and Shriners operated exclusively under the State's authority), and (3) that the State itself is legally obligated to because the State voluntarily agreed to perform for the federal government.[17]

The U.S. Supreme Court held in *Jackson v. Metropolitan Edison Co*., 419 U.S. 345 (1974), "We have, of course, found state action present in the exercise by a private entity of powers traditionally exclusively reserved to the State." The function of introducing federally funded investigational drugs into commerce under 21 U.S.C. §360bbb-3 and establishing a federal program such as the CDC Program is exclusively reserved for

[15] *Jackson v. Metropolitan Edison Co*., 419 U.S. 345, 352 (1974)

[16] *Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 160 (1978). See also *Jackson v. Metropolitan Edison Co*., 419 U.S. at 353

[17] *Jackson v. Metropolitan Edison Co*., 419 U.S. at 353

governments and provided only as a public function. No private party could do so on its own, showing that it is a power exclusively reserved to the state.

2. Close Nexus Test is met because the HHSC Commissioner, Cecile Erwin Young, had the "power to override" (*Roberts v. Louisiana Downs, Inc*., 742 F.2d 221 (5th Cir. 1984)) her recruited parties' policies that imposed penalties upon licensed healthcare workers refusing the injection of the federal property under threat of penalty, The State involved itself directly in the challenged conduct by (a) allowing its recruited parties to ignore their ministerial function of accepting the individual's chosen option and applying *ultra vires* penalties to the right to refuse without even so much as a public notice of correction from the Commissioner, (b) denying unemployment benefits to healthcare workers refusing the drugs, and (c) requiring individuals to repay unemployment benefits to the State for refusing the federal COVID-19 INDs causing the public and recruited parties to "believe" the terminations were lawful state-authorized activities. There can be no stronger example of the State "encouraging"[18] the challenged conduct than the State itself engaging in unlawful conduct to support the enforcement of its recruited parties' *ultra vires* Policies.

The Fifth Circuit held that "private conduct is fairly attributable only when the state has had some affirmative role, albeit one of encouragement short of compulsion" *Frazier v. Bd. of Trustees of Northwest Miss*, 765 F.2d 1278, 1286 (5th Cir. 1985); see, *Missouri v. Biden*, 83 F.4th 350 (5th Cir. 2023) (social media decision).

[18] *Missouri v. Biden*, 83 F.4th 350 (5th Cir. 2023) (social media decision)

3. The Symbiotic/Joint Action Test/Participation Test[19] is met because Texas was required to obtain Plaintiffs' legally effective informed consent, and they relied upon Shriners to fulfill that function. Texas owed Fourteenth Amendment obligations to Plaintiffs which were delegated to Shriners.[20] Texas and Shriners are required to conduct ongoing research activities on behalf of the federal government. Texas could not achieve its goal without the help of its recruited parties and it was under immense legal obligations to conduct its affairs under the strict scrutiny of Congress and the Executive branch, which it relied on its recruited parties to comply with. The State, its recruited parties, and Shriners engaged in joint conduct[21] resulting in $27 billion in COVID-19 federal money flowing into the state. (Doc 20, ¶ 62)

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[19] *Brunette v. Humane Society of Ventura County*, 294 F.3d 1205 (9th Cir. 2002): "*Burton* (*Burton v. Wilmington Pkg. Auth*, 365 U.S. 715, 81 S. Ct. 856 (1961)) teaches that substantial coordination and integration between the private entity and the government are the essence of a symbiotic relationship. Often significant financial integration indicates a symbiotic relationship. *See Rendell-Baker v Kohn*, 457 U.S. 830, 842-43 (1982); *Vincent v. Trend W. Tech. Corp*., 828 F.2d 563, 569 (9th Cir. 1987). For example, if a private entity, like the restaurant in *Burton*, confers significant financial benefits indispensable to the government's "financial success," then a symbiotic relationship may exist. *Vincent*, 828 F.2d at 569. A symbiotic relationship may also arise by virtue of the government's exercise of plenary control over the private party's actions. *See Dobyns v. E-Systems, Inc*., 667 F.2d 1219, 1226-27 (5th Cir. 1982) (finding symbiotic relationship where the government-controlled a private peacekeeping force engaged in a government-directed field mission in the Sinai Peninsula).

[20] In *Giron v. Corrections Corp. of America*, 14 F. Supp. 2d 1245 (D.N.M. 1998), the court stated, "If a state government must satisfy certain constitutional obligations when carrying out its functions, it cannot avoid those obligations and deprive individuals of their constitutionally protected rights by delegating governmental functions to the private sector. *See Terry v. Adams*, 345 U.S. 461, 73 S. Ct. 809, 97 L. Ed. 1152 (1953). The delegation of the function must carry with it a delegation of constitutional responsibilities."

[21] As the court held in *Modaber v. Culpeper Memorial Hospital, Inc*., 674 F.2d 1023 (4th Cir. 1982): "we must inquire 'whether there is a sufficiently close nexus between the State and the challenged action of the regulated entity that the action of the latter may fairly be treated as that of the State itself." *Jackson v. Metropolitan Edison Co*., 419 U.S. 345, 351, 95 S.Ct. 449, 453, 42 L.Ed.2d 477 (1974); *accord, Flagg Brothers, Inc. v. Brooks*, 436 U.S. 149, 157, 98 S.Ct. 1729, 1733, 56 L.Ed.2d 185 (1978). In holding that a privately-owned utility's termination of service is not "state action", the Court in *Jackson* makes it clear that state involvement without state responsibility cannot establish this nexus. See 419 U.S. 358, 95 S.Ct. 457. A state becomes responsible for a private party's act if the private party acts (1) in an exclusively state capacity, (2) for the state's direct benefit, or (3) at the state's specific behest. It acts in an exclusively state capacity when it "exercises powers traditionally exclusively reserved to the state[,]" 419 U.S. 352, 95 S.Ct. 454; for the state's direct benefit when it shares the rewards and responsibilities of a private venture with the

The State's COVID-19 emergency medical countermeasure program is so intimately regulated,[22] licensed, and funded that "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). The *Burton* court held: "But no State may effectively abdicate its responsibilities by either ignoring them or by merely failing to discharge them whatever the motive may be. It is of no consolation to an individual denied the equal protection of the laws that it was done in good faith. Certainly the conclusions drawn in similar cases by the various Courts of Appeals do not depend upon such a distinction. By its inaction, the Authority, and through it the State, has not only made itself a party to the refusal of service, but has elected to place its power, property and prestige behind the admitted discrimination. The State has so far insinuated itself into a position of interdependence with Eagle that it must be recognized as a joint participant in the challenged activity, which, on that account, cannot be considered to have been so "purely private" as to fall without the scope of the Fourteenth Amendment." (*Id*., at 725).

4. The Customs Test The Supreme Court noted in *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

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state, see id., 357-58, 95 S.Ct. 456-57, *Burton v. Wilmington Parking Authority*, 365 U.S. 715, 723-24, 81 S.Ct. 856, 860-61, 6 L.Ed.2d 45 (1961); and at the state's specific behest when it does a particular act which the state has directed or encouraged."

[22] "to act 'under color of' state law for § 1983 purposes does not require that the defendant be an officer of the State. It is enough that he is a willful participant in joint action with the State or its agents. Private persons, jointly engaged with state officials in the challenged action, are acting "under color" of law for purposes of § 1983 action." *Dennis v. Sparks*, 449 U.S. 24 (1980)

respondent because of a state-enforced custom…" (emphasis added). By what authority did Shriners penalize Plaintiffs for refusing the federal COVID-19 drugs if not by a State-enforced custom?

Texas was under a legal obligation to "monitor" and "ensure"[23] that its recruited parties performed the ministerial function of accepting an individual's chosen option. Still, it chose to "see no evil, hear no evil" when its recruited parties established employment conditions upon healthcare workers to receive the administration of the federally owned COVID-19 drugs leading to a State-enforced custom of refusing healthcare workers employment should they refuse to surrender their constitutional protections.

Shriners acted on that pervasive[24] State-encouraged and enforced custom when it pressured and penalized employees who exercised their right to refuse an EUA/PREP Act investigational drug in the open without fear of retribution from Ms. Cecile Erwin Young or the State. Therefore, the State and Shriners conspired under a State custom to deprive Plaintiffs of their Constitutional and statutory rights and privileges.[25] "If a private actor is functioning as the government, that private actor becomes the state for purposes of state action." [26] When Shriners penalized Plaintiffs for not injecting EUA/PREP Act

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[23] See CDC Playbook (Doc 20-1) and FDA EUA (Doc 12-5).

[24] "Based upon the language of the statute legislative history [sic], and judicial decisions, the words 'under color of a . . . custom or usage, of [a] State, 'in § 1983, mean that the 'custom or usage 'must have the force of law by virtue of the persistent practices of state officials. Pp. 398 U. S. 162-169."

[25] Misuse 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. *United States v. Classic*, 313 U.S. 299 (1941), *citing Ex Parte Virginia*, 100 U. S. 339, 100 U. S. 346 (1879); *Home Telephone & Telegraph Co. v. Los Angeles*, 227 U. S. 278, 227 U. S. 287 (1913), *et seq*.; *Hague v. CIO*, 307 U. S. 496, 307 U. S. 507, 307 U. S. 519 (1939).

[26] *Terry v. Adams*, 345 U.S. 461, 469-70, 73 S. Ct. 809, 97 L. Ed. 1152 (1953); *See Jackson v. Metropolitan Edison Co.*, 419 U.S. at 353, 95 S. Ct. 449.

investigational drugs into their bodies, it was clothed with the power of a State-enforced custom because Shriners knew it would not be punished by the State and, in fact, would be rewarded by the State denying unemployment benefits to any employees refusing as a sign to all healthcare workers to inject or face penalty.

Although *Adickes* involved the state custom of racial discrimination, the precise custom is not the relevant point but rather the persistence of the custom, no matter its name. Moreover, *Adickes* referenced one Congressional supporter of § 1983, who stated:

> "[T]he chief complaint is not that the laws of the State are unequal, but that, even where the laws are just and equal on their face, yet, by a systematic maladministration of them, or a neglect or refusal to enforce their provisions, a portion of the people are denied equal protection under them…This interpretation of custom recognizes that settled practices of state officials may, by imposing sanctions or withholding benefits, transform private predilections into compulsory rules of behavior no less than legislative pronouncements."

In the instant action, the State-enforced custom denied equal protection of laws to, and deprived rights of, those who exercised their right to refuse an EUA/PREP Act drug.

Shriners, acting under State custom, usurped the federal government's authority by effectively amending the EUA statute, imposing sanctions, and withholding benefits as if by legislative pronouncement. Moreover, the CDC Program did not belong to Shriners, but Shriners was allowed to fulfill the exclusively public function of storing and administering federally owned COVID-19 EUA/PREP Act drugs on behalf of the State.

Shriners acted under color of law relative to the COVID-19 EUA/PREP Act drugs after it signed the Provider Agreement agreeing to abide by all applicable laws related to the administration of the drugs, and Shriners was made aware at that time that it could not

pressure or penalize potential recipients of EUA/PREP Act drugs. Yet, Shriners turned around and issued an employee vaccination Policy knowing that only EUA/PREP Act drugs were available in the marketplace for Plaintiffs to comply with the Policy. So, Shriners enacted a Policy it knew violated the rights of those who refused to be injected, but did so anyway, with impunity, and with the imprimatur of the State of Texas.

The Shriners Defendants, each a member of the Board of Directors who voted for and/or approved Shriners' enrollment in the CDC Vaccination Program and each of whom voted for and/or approved Shriners' employee vaccination Policy despite knowing that only EUA/PREP Act drugs were available to employees for compliance with the Policy, were individually responsible under the Provider Agreement for ensuring the duties of the "Organization" were adhered to. Having knowledge the CDC Program requirements, Shriners, including the individual Shriners Defendants, established a Policy "as if" it would rely on licensed drugs, but instead relied exclusively on investigational drugs, and required managers to execute that Policy, causing Shriners to "participate in another's affirmative acts" and because they "omit[ed] to perform" the act of informing Plaintiffs of their right to refuse and the ministerial function of accepting that chosen option without pressure or penalty.[27] Shriners and each of the Shriners Defendants are "persons" subject to § 1983 enforcement when acting on behalf of the State providing the public function of the State's emergency CDC Program, conducting joint activities with the State, and engaging in the unlawful activity protected by the State-enforced custom.

[27] *Johnson v. Duffy*, 588 F.2d 740, 743 (9th Cir. 1978) citing *Sims v. Adams*, 537 F.2d 829 (5th Cir. 1976)

G. Equal Protection, Due Process, Privacy. *Missouri v. Biden,* 142 S.Ct 647 (2022)[28] is not applicable because it only found that the President has authority under limited circumstances to issue a vaccination requirement in general and did not consider the use of investigational, EUA, or PREP Act products.

Shriners stating that "Shriners Parties had a rational basis to make vaccination a condition of employment" (Doc 23, p.29) is inapplicable. The U.S. Congress, the executive branch, COVID-19 manufacturers, the State of Texas, and Shriners agreed to manufacture, label, distribute, offer, and administer the drugs only under voluntary conditions knowing that a pandemic had ensued. There was never a "rational" basis to violate their constitutional, statutory, and contractual duties under these circumstances? Not only did Shriners NOT have a rational basis to enact such a Policy, it had NO RIGHT to do so.

Shriners' statement that "Plaintiffs' Due Process claims fail because they have alleged no protected interest" is factually incorrect. (Doc 23, p.30) What Plaintiffs alleged is set forth in Paragraph 95 of the SAC. The economic damages sustained by Plaintiffs is not alleged to be Plaintiffs' protected interests, but rather damages resulting from the deprivation of the fundamental right to refuse an investigational drug, which is akin to right to bodily integrity and right to privacy. Plaintiffs have, however, alleged a multitude of property interests.[29] First, the right to accept or refuse the EUA product is a property

[28] There are two *Missouri v Biden* cases. The one discussed above was the "social media" case. This one is the "CMS Mandate" case.

[29] See Doc 20, ¶¶ 96, 116, 118, Count Three, Four, Five, and Seven all include property interests held by Plaintiffs.

interest[30] held by Plaintiffs because the EUA statute exempts the drug from 21 U.S.C. § 355(a) during a declared emergency for Plaintiffs' benefit.[31] Second, the right to be informed of the "risks," "benefits," and "alternatives," without cost or fear of penalty for refusing is also a property interest held by Plaintiffs under the EUA statute, and both of those property interests were promised and expected benefits under the federally funded CDC Program. Additionally, Shriners' assertion that Plaintiffs' due process rights were not violated because Shriners did not "physically compel [Plaintiffs] to receive a vaccine" is misleading. Plaintiffs claimed they were placed under "threat of penalty"[32] and subjected to[33],[34] the use of the investigational drugs, causing a deprivation of rights.

Shriners, acting under color law, deprived Plaintiffs of their property interest under the EUA statute, PREP Act (i.e., right to due process if injured), 45 C.F.R. § 46.116, benefits under the FWA, the right to give informed consent under 10 U.S.C. § 980, and the third party beneficiary rights under the Provider Agreement (i.e., right to refuse, right to

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[30] To 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.""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." *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972)

[31] "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." Therefore, a drug is made available to Plaintiffs who have not met their obligations under this statute only during a declared emergency and for the Plaintiffs' benefit. This statute is why the HHS Secretary must inform the healthcare workers they are authorized to administer the unlicensed drug.

[32] Doc 20, ¶¶ 90,92,133

[33] Doc 23, ¶ 92

[34] Shriners seems to be confused about the legal meaning of "subjected." Black's Law Dictionary (2nd Ed) defines Subject To as "conditional or dependent on something" or "being under domination as of an authority or government."

obtain free medical counseling outside of pressure to participate, right to be told of the health consequences if they refuse, etc.)

It is undeniable that the PREP Act requires a person to voluntarily surrender their right to seek judicial relief (i.e., due process) if injured by a "covered countermeasure" or "person." Therefore, Shriners deprived Plaintiffs of their historical and deeply rooted substantive due process rights to refuse an investigational drug, and the right to their property interest statutory rights and in due process itself. The Supreme Court has long held that a person cannot be required to "barter away his life or his freedom, or his substantial rights" as a condition to enjoy a privilege of the State. *Home Ins. Co. of New York v. Morse*, 87 U.S. 455, 451 (1874).

Shriners implies it can lawfully incorporate investigational products authorized only for emergency use or covered countermeasures under the PREP Act into its vaccination Policy by stating, "termination of employment does not constitute 'interference' with a constitutional right where . . . the employee was at-will.'" (Doc 23, p. 25) That statement is incorrect. Plaintiffs' termination of employment is the penalty imposed upon them for exercising their right to refuse the federally owned COVID-19 investigational drugs, which Shriners does not dispute, and which is the State-enforced custom. But the at-will employment doctrine conflicts with the EUA statute and thus is expressly preempted by the PREP Act, see Doc 20, ¶ 48). Using the at-will employment doctrine to interfere with the FDCA and Plaintiffs' fundamental right to refuse those products is different from and conflicts with the PREP Act and the EUA statute. Moreover, the PREP Act's language

extending to the EUA statute means the State allowed Shriners to use its at-will employment laws even though they conflicted with the requirements under the FDCA.

Shriners creatively states, "The privacy right Plaintiffs claim (the right to consider whether to accept the COVID-19 vaccine) does not implicate the confidentiality branch of the Fourteenth Amendment." (Doc 23, p. 25, 26) Notice the use of the small "v" of "COVID-19 vaccine," denoting generic COVID-19 technology and not a specific drug label. Drugs are regulated only according to their labeling, and therefore, we do not know which laws Shriners speaks to since it did not reference a specific drug label.

H. Qualified Immunity. Shriners, acting under color of law, is not entitled to qualified immunity. The Supreme Court held in *Wyatt v. Cole*, 504 U.S. 158 (1992): "Even if there were sufficient common law support to conclude that [private defendants] should be entitled to a good-faith defense [to suits for unjustified harm arising out of the misuse of governmental processes], that would still not entitle them to what they obtained in the courts below: the qualified *immunity* from suit accorded government officials under *Harlow* v. *Fitzgerald,* 457 U. S. 800 (1982)." (Emphasis in original). Moreover, qualified immunity protects "all but…those who knowingly violate the law.[35]" Shriners' argument (Doc 23, p.26) that "[n]one of the Shriners Parties 'violate[d] clearly established statutory or constitutional rights of which a reasonable person would have known'" implies that Shriners is not a "person" that would have "reasonably known" that subjecting Plaintiffs to an investigational drug under threat of penalty violated Shriners' duties and obligations

[35] *Mullenix v. Luna*, 577 U.S. 7, 136 S. Ct. 305, 193 L. Ed. 2d 255 (2015)

under the aforementioned laws, regulations, and contracts. This is too attenuated of an argument even for Shriners, an entity with an FWA, an IRB, that regularly administers FDA-licensed as well as unlicensed drugs under EUA, that regularly uses drugs off-label, and is well aware of the requirement of informed consent any time an individual's skin is pierced in any medical procedure. Therefore, the only logical conclusion is that Shriners knowingly violated the law because it felt protected and encouraged by a State-enforced custom to deprive Plaintiffs of their constitutional and federal statutory rights.

I. EUA and § 1983. Shriners failed to discuss the very recent Supreme Court case of *Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 183 (2023) because Plaintiffs specifically aver (Doc 20, FN 50) that rights-creating language as discussed in *Talevski* exists in both the EUA statute (the option to accept to refuse) and the PREP Act (the right to be informed of the voluntary nature of the program and the right to refuse under the EUA statute), deprivation of which forms the basis of an enforceable § 1983 action. Moreover, the 7-2 decision in *Talevski* involved the Spending Clause and contracts issued by the federal government under that Clause, having rights creating language for individuals in the spending statute, as in the case at bar.

The *Talevski* Court held,

> *Gonzaga* sets forth our established method for ascertaining unambiguous conferral. Courts must employ traditional tools of statutory construction to assess whether Congress has "unambiguously conferred" "individual rights upon a class of beneficiaries" to which the plaintiff belongs. [citations omitted] Notably, it must be determined that "Congress intended to create a federal right" *for* the identified class, not merely that the plaintiffs fall "within the general zone of interest that the statute is intended to protect" *Gonzaga*, 536 U.S., at 283. This paradigm respects

> Congress's primacy in this arena and thus vindicates the separation of powers. *Id*., at 286. Conversely, we have rejected § 1983 enforceability where the statutory provision "contain[ed] no rights-creating language"; had "an aggregate, not individual, focus"; and serve[d] primarily to direct the [Federal Government's] distribution of public funds." *Id*., at 290
>
> We have held that the *Gonzaga* test is satisfied where the provision in question is "phrased in terms of the persons benefited" and contains "rights-creating," individual-centric language with an "unmistakable focus on the benefited class."

The Court held 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 "This framing is indicative of an individual "rights-creating" focus. Gonzaga, 536 U. S., at 284." The *Talevski* Court made clear what Shriners' confuses on the issue of private right of action and § 1983 – that a private right of action and a § 1983 action are mutually exclusive. If you have one, you can't have the other. The Court held: "the statute lacks any indicia of congressional intent to preclude §1983 enforcement, such as an express private judicial right of action…," meaning that if the statute includes a private right of action, then Plaintiffs most likely could NOT bring a § 1983 action.

While the federal statutes involved in the instant action and *Talevski* are different, the legal analysis is identical. Plaintiffs at bar claim that Congress created a right for them under 21 U.S.C. 360bbb-3(e)(1)(A)(ii)(III), in pertinent part:

> The Secretary…shall establish…conditions…to ensure that individuals to whom the product is administered are informed…of the option to accept or refuse administration of the product…

This language "unambiguously confers" the right to be informed of the option to accept or refuse administration of the product. Also, it speaks in terms of "individual rights

upon a class of beneficiaries" to which the plaintiff belongs. The provision actually uses the word "individuals" when describing to whom the right is conferred. The class of beneficiaries are those contemplating "administration of the product." By describing the right the way it did, Congress intended to create a federal right for the identified class.[36]

Shriners citing *Scott v. Pfizer* is curious because the Fifth Circuit does not make the statement pertaining to a § 1983 claim that Shriners implies.

Shriners citing *Foli v. Water Dist., of S. California* is not applicable because the court erred in its understanding of *Middlesex County Sewerage Authority v. National Sea Clammers Ass'n*. which held, "When the remedial devices provided in a particular Act are sufficiently comprehensive, they may suffice to demonstrate congressional intent to preclude the remedy of suits under § 1983." Courts look to congressional intent to remedy a plaintiff's constitutional injuries to determine if the statute forecloses a cause of action under § 1983. Foreclosing a private right of action relating to a "Fraud on FDA" claim is not the same as foreclosing a § 1983 cause of action to enforce the specific right created for Plaintiffs' benefit to accept or refuse investigational drugs.

21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) is unique in all of the FDCA because that statutory provision was a right specifically created for Plaintiffs and it does not rely upon the FDA to determine if, when, and how that right was violated. The FDA did not incur

[36] "Three principal factors determine whether a statutory provision creates a privately enforceable right: (1) whether the plaintiff is an intended beneficiary of the statute; (2) whether the plaintiff's asserted interests are not so vague and amorphous as to be beyond the competence of the judiciary to enforce; and (3) whether the statute imposes a binding obligation on the State." *Blessing v. Freestone*, 520 U.S. 329 (1997)

injury, but the Plaintiffs did. Moreover, Congress provided no other means of enforcement other than § 1983.

J. PREP Act. Shriners confuses a private right of action with a § 1983 cause of action for deprivation of Constitutional rights. While Shriners is correct that there is an express private right of action for death or serious physical injury, Plaintiffs are not bringing those claims, but that does mean that the Plaintiffs forfeit the rights conferred upon them by the language of the PREP Act. Specifically, the PREP Act includes the following rights-creating language:

> The Secretary shall ensure…that potential participants are educated with respect to…the voluntary nature of the program…[37]

Moreover, the PREP Act states that Defendants are preempted from interfering in any "requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq*.]" which includes the rights creating language under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). As *Talevski* pronounced, a conferred right is the basis for a § 1983 action, and the above rights-creating language serves as the basis of Plaintiffs' enforceable § 1983 action. Though Plaintiffs had the right to be educated about the voluntary nature of a PREP Act program and the right to refuse under the EUA statute, Shriners deprived Plaintiffs of those rights and instead "educated" the Plaintiffs that one of the COVID-19 PREP Act drugs was part of a "mandatory" program.

[37] 42 U.S.C. § 247d-6e(c)

K. 10 U.S.C. § 980. This applies because it was the Department of Defense that procured 100m doses of the Pfizer-BioNTech COVID-19 Vaccine drug and who made it available to the public. (Doc 20, p.28). The statute does not only apply to the "United States Armed Forces." Specifically, it applies to "funds appropriated to the Department of Defense" (10 U.S.C. § 980(a)) irrespective of who is involved in activities and products initiated by the DoD or any other person using DoD funding. The Legally Effective Informed Consent doctrine applies to DoD funding when that funding involves humans with investigational medical products and procedures. Shriners chose to mandate that Plaintiffs be injected with DoD funded investigational drugs nullifying legally effective informed consent leading to a § 1983 cause of action.

L. 45 C.F.R. 46. The Supreme Court stated that "'We do not lightly conclude that Congress intended to preclude reliance on § 1983 as a remedy.'"[38] Courts have held that a regulation cannot "conjure up a private cause of action that has not been authorized by Congress. Agencies may play the sorcerer's apprentice but not the sorcerer himself (*Alexander v. Sandoval*, 532 U.S. 275 (2001)). However, if a regulation is the source of a private right supporting the federal statute then it can be a source of a § 1983 cause of action (W*right v. Roanoke Redevelopment Auth.*, 479 U.S. 418 (1987)). In 1974, Congress established the "National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research"[39] to define the nature and legal definition of informed consent. In 1979 the "Belmont Report" was published with the Commission's findings. Congress

[38] *Golden St. Trans. v. Los Angeles*, 493 U.S. 103 (1989)

[39] https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf See, Title II Part A

also required the HHS Secretary to promulgate regulations enforcing the Commission's findings on its behalf.[40] The Secretary established 45 C.F.R. 46 (known as the Common Rule) specifically to protect Americans from medical research abuses by the Executive branch. The regulations are the rarest of all in that they behave as federal statutes themselves with only a direct request by Congress for their enactment. Every penny of the federal budget must filter through the Common Rule. The entire federal budget, its agencies, the military, and any person acting on behalf of the federal government is bound to the regulations by the express requirement of Congress. 45 C.F.R. § 46.116 lays out the Defendants duties when involving Plaintiffs with federally funded investigational products and those duties are unambiguous and their corresponding rights for Plaintiffs are equally unambiguous. Plaintiffs have a § 1983 cause of action under 45 C.F.R. § 46.116.

M. FWA and EUAs. Shriners is incorrect when stating that the FWA, Provider Agreement, or EUA letters are not creatures of Congress. (Doc 23, p. 29). The EUA letter is directly related to 21 U.S.C. §360bbb-3 and cannot be executed outside of the federal statute. The Provider Agreement operates under the authority of Congress as outlined under 12(a) and could not have the force of law without the Executive branch ensuring those federal statutes were complied with by all persons involved. Shriners voluntarily agreed to comply with 45 C.F.R. Part 46 and the Belmont Report as a condition to participate in federally funded investigational products and program. By direct extension of that agreement they owed duties to Plaintiffs for which the entire FWA program exists and as

[40] *Id*., Sec. 205 "Duties of the Secretary"

such it creates a § 1983 cause of action. Shriners signed the Provider Agreement requiring it to comply with "any EUA" providing duties and rights for persons authorized to participate in EUA products. First, a ministerial duty was placed upon Shriners to accept Plaintiffs' chosen option as required under each EUA. Second, the right to either accept or refuse was a condition established by Congress and executed through the issuance of the EUA. Therefore, the cause of action under § 1983 relates to the deprivation of that statutory right, loss of property interest in the right, unequal treatment regarding that right, and loss of due process when exercising the right.

N. Provider Agreement. The Provider Agreement required Shriners to perform the ministerial function of informing Plaintiffs of the risks, benefits, and alternatives to the EUA drugs without pressure to be injected. Whether Plaintiffs accepted or refused, being informed was specifically owed to Plaintiffs and outlined under 12(a) of the contract. Moreover, 12(a) required Shriners to "comply with all applicable requirements as set forth by the [FDA]", which includes to perform the ministerial function of accepting Plaintiffs' chosen option. Shriners' assertion that the Provider Agreement only applied if Plaintiffs received the drug is absurd, because it would require Plaintiffs to be injected with the drug in order to have the right to refuse the drug. An absurd result.

O. State Law Claims. The state law claims are valid because Shriners is preempted from using the at-will employment doctrine to terminate the employment relationship so as to penalize Plaintiffs for refusing an EUA/PREP Act investigational drug.

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of April, 2024, I presented the foregoing pleading to the Clerk of Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ David J. Schexnaydre
DAVID J. SCHEXNAYDRE

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