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	*	

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

SECOND AMENDED COMPLAINT
(JURY TRIAL REQUESTED)

NOW INTO COURT, through undersigned counsel, come Plaintiffs Jeri Pearson, Elizabeth Klem, Ben Homan, and Rob Fowler ("Plaintiffs"), who file this Second Amended Complaint against Shriners Hospitals for Children, Inc., Shriners Hospital for Children – Texas, Beverly Bokovitz, Frances Farley, MD, Jerry Gantt, John McCabe, Phillip Grady, and Cecile Erwin Young ("Defendants")[1], with allegations and causes of action as follows:

I. INTRODUCTION

1. This is a 42 U.S.C. § 1983 cause of action that arises out of (a) the failure of Cecile Erwin Young to perform ministerial duties under the State of Texas's COVID-19 vaccination

[1] Shriners Hospitals for Children, Inc., Shriners Hospital for Children – Texas, and its PolicyMakers, Beverly Bokovitz, Frances Farley, MD, Jerry Gantt, John McCabe, and Phillip Grady, are referred to as "Shriners."

program, (b) the creation of an unconstitutional State-enforced custom by Ms. Young whereby parties recruited to administer the federally owned COVID-19 EUA/PREP Act drugs on the State's behalf could deprive the rights of potential recipients without fear of consequence, (c) the following of that custom by Shriners, and (d) the policies adopted, executed, and enforced by Shriners, all of which resulted in the Plaintiffs suffering financial, emotional, and legal injuries when they were penalized for exercising their right to refuse federally funded investigational drugs.

##. The federal government's executive branch (the Department of Defense) purchased all COVID-19 drugs authorized for emergency use and introduced them into commerce through the federally funded CDC COVID-19 Vaccination Program ("CDC Program").

2. The only drugs offered through the CDC Program were FDA-labeled as investigational drugs, federally funded, under required research activities, authorized only for emergency use, under PREP Act immunity, and not FDA-licensed for commercial marketing.

3. Because the drugs were FDA-labeled investigational and federally funded, the CDC Program was legally bound to comply with 45 C.F.R. Part 46, the Belmont Report, Article VII of the ICCPR Treaty, 21 U.S.C. §360bbb-3 (the EUA statute), the PREP Act, and the Federal Wide Assurance ("FWA") program requiring only voluntary participation by Plaintiffs.

4. The federal government recruited states to participate because each state had a Federal Wide Assurance ("FWA") agreement adhering to the same laws required of the federal government when offering individuals federally funded investigational drugs.

5. The State of Texas agreed to perform for the federal government under the CDC Program, including conducting research activities, recruiting private parties to administer the

federally owned drugs, and obtaining the legally effective informed consent of individuals to whom the investigational drugs were offered.

6. The drugs were labeled "investigational" by the FDA, thus the State owed Fourteenth Amendment obligations (equal protection and due process) to potential participants in the CDC Program, and the State could not delegate to Shriners the function of administering the federal property without also delegating the State's constitutional obligations.

7. The State recruited Shriners and required the Chief Nursing Officer and Chief Medical Officer to sign the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement"), assuring the state and federal governments that Shriners would not place individuals under sanctions for refusing, or under pressure to accept, an injection of federally owned COVID-19 EUA/PREP Act drugs.

8. Shriners breached their contractual agreement, statutory obligations, and constitutional duties because they followed the unconstitutional State custom created by Cecile Erwin Young whereby parties recruited to administer the federally owned COVID-19 EUA/PREP Act drugs on the State's behalf could deprive Plaintiffs' rights without fear of consequence.

9. Ms. Young and Shriners willfully deprived Plaintiffs of their federal statutory and constitutional rights by penalizing Plaintiffs for refusing federally owned COVID-19 EUA/PREP Act drugs, despite having contractually agreed that they would not penalize anyone for refusing the federally owned COVID-19 EUA/PREP Act drugs.

10. As a direct and proximate result of the acts and omissions described herein, Plaintiffs suffered compensatory and special damages in an amount to be determined by a jury.

II. JURISDICTION AND VENUE

11. This Court has original jurisdiction under 28 U.S.C. §§ 1331 and 1343.

12. This Court has original jurisdiction under 42 U.S.C. §§ 1983 and 1988.

13. This Court has the authority to award costs and reasonable attorney's fees under 42 U.S.C. § 1988.

14. The civil rights portions of this action raise federal questions under the Spending Clause and the Fourteenth Amendment to the U.S. Constitution.

15. This court has supplemental jurisdiction over Plaintiffs' state law claims.

16. This Court has personal jurisdiction over Defendants as they are domiciled within this Court's jurisdictional boundaries.

17. This Court has subject matter jurisdiction over the parties because all acts complained of herein were committed by Defendants in the State of Texas and caused damage and/or deprivation to the Plaintiffs listed herein.

18. Venue is proper in this court because all events underlying the claims in this Complaint occurred in the State of Texas, which is situated within this Court's jurisdiction, and all Defendants reside in the State of Texas.

III. PLAINTIFFS

19. The following individuals are plaintiffs herein:

19.1. Plaintiff Jeri Pearson is an adult individual who, at all times pertinent, resided in the State of Texas and was previously an employee of Shriners in Texas.

19.2. Plaintiff Elizabeth Klem is an adult individual who, at all times pertinent, resided in the State of Texas and was previously an employee of Shriners in Texas.

19.3. Plaintiff Ben Homan is an adult individual who, at all times pertinent, resided in the State of Texas and was previously an employee of Shriners in Texas.

19.4. Plaintiff Rob Fowler is an adult individual who, at all times pertinent, resided in the State of Texas and was previously an employee of Shriners in Texas.

IV. DEFENDANTS

20. The following are named as defendants herein:

20.1. Defendant, Shriners Hospitals for Children, Inc., is a charitable 501C (3) non-profit corporation incorporated in the State of Colorado and headquartered in Tampa, Florida, who, when interacting with individuals, including Plaintiffs, regarding the federally owned COVID-19 EUA/PREP Act drugs under the terms of the CDC Provider Agreement, was acting under color of law.

20.2. Defendant, Shriners Hospital for Children – Texas, at all times pertinent, was a subsidiary of Shriners Hospitals for Children, was the employer of Plaintiffs, and was authorized to do and doing business in Galveston, TX, who, when interacting with individuals, including Plaintiffs, regarding the federally owned COVID-19 EUA/PREP Act drugs under the terms of the CDC Provider Agreement, was acting under color of law.

20.3. Defendant, Beverly Bokovitz, was at all times pertinent, the Chief Nursing Officer and PolicyMaker of Shriners and was aware and responsible for duties owed to Plaintiffs under the organization's FWA, IRB, CDC COVID-19 Vaccination Program Provider Agreement on behalf of Shriners. Ms. Bokovitz is named as a defendant in her official and individual capacities.

20.4. Defendant, Frances Farley, MD, was at all times pertinent, the Chief Medical Officer and PolicyMaker of Shriners and was aware and responsible for duties owed to Plaintiffs under the organization's FWA, IRB, CDC COVID-19 Vaccination Program Provider Agreement on behalf of Shriners. Dr. Farley is named as a defendant in her official and individual capacities.

20.5. Defendant, Jerry Gantt, was at all times pertinent, the Chairman of the Board of Trustees and PolicyMaker of Shriners, is an individual of the full age of majority and a resident of Houston, Texas, and was a signatory to Shriners' COVID-19 policy. Mr. Gantt is named as a defendant in his official and individual capacities.

20.6. Defendant, John P. McCabe, was at all times pertinent, the Executive Vice President and Chief Operating Officer and PolicyMaker of Shriners, is an individual of the full age of majority and a resident of Florida, and was a signatory to Shriners' COVID-19 policy. Mr. McCabe is named as a defendant in his official and individual capacities.

20.7. Defendant, Phillip Grady, was at all times pertinent, the Vice President of Hospital Operations and PolicyMaker of Shriners, is an individual of the full age of majority and a resident of Florida, and was a signatory to Shriners' COVID-19 policy. Mr. Grady is named as a defendant in his official and individual capacities.

20.8. Defendant, Cecile Erwin Young, is the Executive Commissioner and policymaker of Texas Health and Human Services, the state agency that administers the CDC COVID-19 Vaccination Program, but is sued here solely in her individual capacity.

V. FACTUAL ALLEGATIONS

21. In October 2020, the federal government established the CDC Program and recruited the State to contract with healthcare providers such as Shriners to perform the ministerial duty of administering the federally owned COVID-19 EUA/PREP Act drugs.

a. The CDC Playbook

22 The CDC published its "COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations"[2] ("Playbook") to help the State "operationalize a vaccination

[2] See Exhibit A, CDC Playbook

response to COVID-19 within their jurisdictions" and to help the State with its "COVID-19 vaccination program planning and implementation."

23. The Playbook informed the State that:

(1) Vaccination provider refers to any facility, organization, or healthcare provider licensed to possess/administer vaccine or provide vaccination services. A COVID-19 vaccination provider is any vaccination provider who has been enrolled in the COVID-19 Vaccination Program,[3]

(2) Jurisdiction/jurisdictional, as used in the Playbook document, refers to the federal immunization funding awardees described in the Executive Summary and their state public health emergency preparedness counterparts who are tasked with developing COVID-19 vaccination plans for submission to CDC,[4]

(3) To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program[5] and the vaccination provider must agree to the Provider Agreement whereby they promise to Comply with FDA's requirements, including EUA-related requirements **described in FDA's Letter of Authorization**, as applicable. Providers **must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws** (emphasis added),[6]

(4) Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement,[7]

(5) Jurisdictions must facilitate and monitor IIS [Immunization Information System] reporting by enrolled vaccination providers,[8]

(6) State-level personnel must closely 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,[9]

[3] See Exhibit A, CDC Playbook, Footnote 1
[4] See Exhibit A, CDC Playbook, Footnote 2
[5] See Exhibit A, CDC Playbook, p. 21
[6] The State incorporated the Provider Agreement as its policy when requiring each public or private party to sign and agree to the terms of the CDC Program as a condition of engaging in the joint conduct of administering the federally owned COVID-19 drugs on the State's behalf.
[7] See Exhibit A, CDC Playbook, p. 21
[8] See Exhibit A, CDC Playbook, p. 35
[9] See Exhibit A, CDC Playbook, p. 8

(7) Help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure),[10]

(8) Jurisdictions will be provided an opportunity to opt out of having pharmacies in their area receive direct allocations,[11]

(9) Ensure provider agreement, profile form, and redistribution agreement (if applicable) are thoroughly and accurately completed by each enrolled provider, retained on file for a minimum of 3 years, and made available to CDC upon request.[12]

24. The Playbook demonstrates the extensive and intimate involvement of the State in the CDC Program and how the State was responsible for implementing, monitoring, and enforcing the Program, including as to the recruited parties acting on the State's behalf, such as Shriners.

25. The CDC informed the States: "At this time, **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. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law." (See Exhibit B.)

26. "[A]dministration…outside the parameters of the Program" includes pressuring an individual to be injected with the drugs outside of their free will and voluntary consent.

[10] See Exhibit A, CDC Playbook, p. 42
[11] See Exhibit A, CDC Playbook, p. 26
[12] See Exhibit A, CDC Playbook, p. 22

b. CDC COVID-19 Vaccination Program Provider Agreement

27. The federal government created the CDC COVID-19 Vaccination Program Provider Agreement[13] ("Provider Agreement") for the State to incorporate as State policy and to require each recruited party to sign as a condition of participation.

28. The Provider Agreement placed duties upon the State and its recruited State Actors, such as Shriners, including, but not limited to:

> (1) Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP),
>
> (2) Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization,
>
> (3) Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees,
>
> (4) Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative,[14]
>
> (5) Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS), [15]
>
> (6) Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in **any EUA** that covers COVID-19 Vaccine (Emphasis added),
>
> (7) Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.[16]

[13] See Exhibit B, Provider Agreement
[14] The Fact Sheet serves the purpose of obtaining an individual's legally effective informed consent.
[15] This "reporting" constitutes "research" under 45 C.F.R. Part 46 and the Belmont Report.
[16] The Provider Agreement is not only an agreement between the "Organization" and the federal government, but also an agreement between the Organization and the State since the State incorporated the Provider Agreement requirements into State policy.

c. Protection of Human Subjects

29. When the State volunteered its IIS to administer the federal government's CDC Program, the Program became an exclusive function of the State.

30. Congress restricts the federal government[17] and persons (i.e., State and Shriners) acting on behalf of the federal government from placing individuals under "sanctions," "coercion," "undue influence," or "unjustifiable pressures"[18] when offering them federally funded investigational drugs[19] (e.g., Pfizer-BioNTech COVID-19 Vaccine[20])[21] because such outside pressures nullify legally effective informed consent.

[17] 45 CFR § 46.101(c) and 45 CFR § 46.101(i) require any federally funded research activity to be subject to the Belmont Report. It and 45 C.F.R. § 46.116 provide the only known definition of what Congress intends as "legally effective informed consent."

[18] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.– Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979. See Part C "voluntariness"

[19] The terms "investigational new drug" and "investigational drug" are deemed synonymous by 21 CFR 312.3. Investigational new drug "means a new drug or biological drug that is used in a clinical investigation." (21 CFR 312.3 "Investigational new drug") Clinical investigation "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." (21 CFR 312.3 "Clinical investigation"). Also, investigational new drug means, "A substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people…" NCI Dictionary of Cancer Terms. National Cancer Institute. Published 2023. Accessed June 25, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/investigational-new-drug

[20] The FDA improperly allowed Pfizer to include the word "Vaccine" within its investigational formal name to give the appearance that the drug was classified as a vaccine. The capital "V" denotes the formal name for Pfizer's unlicensed investigational drug "Pfizer-BioNTech COVID-19 Vaccine." "Pfizer-BioNTech COVID-19 vaccine" (lowercase v) denotes Pfizer's COVID-19 vaccine technology and is not attributed to any specific drug label. COMIRNATY® is the only Pfizer COVID-19 drug licensed by the FDA for general commercial marketing and was not available at all times pertinent to this Amended Complaint. Pfizer-BioNTech COVID-19 Vaccine is under investigational new drug application 19736.

[21] Congress enacted The National Research Act ("NRA") in 1974 to prevent medical research abuses by the executive branch, military, and persons acting on behalf of the federal government. The NRA required the Secretary to promulgate 45 C.F.R. Part 46 to protect persons involved in investigational new drugs under research conditions. "Research" under the legal framework is not a clinical trial but an activity "designed to develop or contribute to generalizable knowledge" about the product, theory, process, etc. As an example, college students studying medical charts is "research" or the EUA statute requiring the "manufacturer," "emergency response stakeholder," and "vaccination provider" to "monitor" and "report" adverse events of the drugs 'involvement with a human is research because the requirement is "designed to develop or contribute to generalizable knowledge." The Belmont Report, required by the NRA, established the principles of informed consent and is required adherence under 45 C.F.R. Part 46 (§§ 101(c),(i)).

31. Legally effective informed consent means, at a minimum, that an individual must be free from all outside pressures to be injected with federally owned EUA/PREP Act investigational drugs.

32. When the federal government makes investigational drugs available to individuals, it must first establish a legally approved environment that requires individuals to be free from outside pressures to be injected with the drug. A sanction, penalty, or withholding of a benefit for refusing nullifies legally effective informed consent.[22]

d. Federal Wide Assurance

33. To ensure the federal government complies with 45 C.F.R. Part 46 and the Belmont Report whenever it makes investigational drugs available to individuals, it created the Federal Wide Assurance ("FWA") program.[23]

34. The CDC Program, the EUA statute, and each EUA letter required the State and its State Actors, such as Shriners, to obtain the private identifiable information of individuals, monitor their reactions to the drugs, analyze the data, and add that data to the generalizable knowledge regarding the federally funded drug.

35. Therefore, when the State volunteered to administer the federally owned COVID-19 EUA/PREP Act drugs, Ms. Young was responsible for ensuring that the State performed its duties by creating a legally approved environment, ensuring individuals were not under threat of penalty when considering use of the federally owned drugs. Such an environment ensures the individuals' legally effective informed consent is obtained.

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[22] 45 CFR 46.116(a)(1)

[23] The federal government established the FWA to ensure it complied with its lawful obligations to protect humans who are offered investigational drugs. The FWA requires persons participating in federally funded investigational research activities to assure the federal government that it will comply in whole with 45 C.F.R. Part 46 and specifically the Belmont Report. The federal government issuing a FWA number to an organization means the organization provided a written assurance to HHS that it would comply with the regulatory framework when involved in federally funded research activities such as the CDC COVID-19 Vaccination Program.

e. Emergency Use Authorization

36. A person cannot introduce a drug into commerce until the FDA approves it for general commercial marketing and assigns the drug a National Drug Code (NDC) (21 U.S.C. §355(a)). However, Congress created "expanded access to unapproved therapies and diagnostics" for reasons of compassion, education, and emergencies under 21 U.S.C. §360bbb *et. seq*., providing access to investigational products under conditions created by Congress and the Health and Human Services Secretary ("Secretary").

37. The Secretary issued expanded access protocols for COVID-19 drugs by issuing an emergency use authorization ("EUA") for the (1) Pfizer-BioNTech COVID-19 Vaccine on December 11, 2020, stating that "Pfizer-BioNTech COVID-19 Vaccine" "is an investigational vaccine not licensed for any indication,"[24] (2) "Moderna COVID-19 Vaccine" on December 18, 2020 stating that "Moderna COVID-19 Vaccine" "is an investigational vaccine not licensed for any indication,"[25] and (3) "Janssen COVID-19 Vaccine" on February 27, 2021, Inc., stating that "Janssen COVID-19 Vaccine" "is an investigational vaccine not licensed for any indication."[26]

38. Moreover, all drugs provided under each EUA were FDA-labeled as investigational drugs.

39. An EUA cannot be issued if there are FDA-licensed products to meet the intended emergency use.

40. "Unlicensed use" means the use of a medical product for a purpose not licensed by the FDA (e.g., legal indication, usage, and contraindications) according to the product's labeling.

[24] 86 Fed.Reg. 5200, Jan. 19, 2021
[25] 86 Fed.Reg. 5200, Jan. 19, 2021
[26] 86 Fed.Reg. 28608, May 27, 2021

"Legal indication" means the FDA-licensed purpose of the drug pursuant to 21 U.S.C. § 355(a) and labeled according to 21 CFR 201.57(c).

41. An investigational drug does not have a legal indication to treat, cure, or prevent any known disease or virus and can never come under a mandate because the product does not have a legal indication to fulfill the mandate's purpose.[27]

42. Although Congress empowers the Secretary to grant expanded access protocols to unlicensed drugs (e.g., Pfizer-BioNTech COVID-19 Vaccine) or devices (e.g., masks, testing articles), it denies the Secretary "any authority to require any person[28] to carry out any activity that becomes lawful pursuant to an authorization under this section" [29] and his authority is nondelegable.

43. In other words, the Secretary can issue an EUA for the Pfizer-BioNTech COVID-19 Vaccine investigational drug, but he does not have the authority to require Pfizer to manufacture it, a doctor to administer it, or a person to be injected with it.

44. The authority to accept an EUA drug is exclusively held by the individual,[30] with which no person may interfere. Such authority ensures the individual's legally effective informed consent is always obtained.

f. PREP Act

45. The COVID-19 drugs offered under the CDC Program were, and still are, listed as countermeasures under the PREP Act.[31]

[27] See, for example, Exhibit C, FDA's EUA Letter to Pfizer.
[28] "[I]ndividual, partnership, corporation, and association" 21 U.S.C. § 321(e)
[29] 21 U.S.C. §360bbb-3(l)
[30] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)
[31] 85 FR 15198 and has been amended eleven times, of which the latest was on May 12, 2023 (88 FR 30769).

46. The PREP Act conferred upon Plaintiffs the statutory right to be "educated with respect to…the voluntary nature of the program." 42 U.S.C. § 247d-6e(c).

47. The State and its State Actors, such as Shriners, are preempted from interfering in the "voluntary nature"[32] of the PREP Act program by requiring nonconsensual participation in a covered countermeasure or related activity.

48. Specifically, the EUA statute contains the following express preemption provision:

> During the effective period of a declaration under subsection (b)…no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that— (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the…administration…of the covered countermeasure, or to any matter included in a 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**." ("FDCA")[33] (emphasis added).

49. The EUA statute, at 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III), expressly creates for Plaintiffs the option to accept or refuse, a right with which Defendants cannot interfere by penalizing Plaintiffs for their chosen option because such a penalty is "different from, or in conflict with, any requirement" under the PREP Act and 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).

50. Because the PREP Act is primarily an immunity statute, it means that individuals must prospectively and voluntarily surrender their Fourteenth Amendment right to due process (i.e., the right to sue) from any resulting injury.

51. The State and its State Actors, such as Shriners, could not change the "voluntary nature of the program" by requiring Plaintiffs to involuntarily surrender their due process rights as a condition of using their State-issued medical licenses, or of continued employment, or of any other benefit.

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[32] 42 U.S.C. § 247d-6e(c)
[33] 21 U.S.C. § 301 *et. seq*.

52. Moreover, Shiners was preempted from using the State's at-will employment law to retaliate against Plaintiffs who refused to be injected with a PREP Act countermeasure because the use of that law for that purpose conflicted with the statute's federal goals.[34]

g. Defendant Cecile Erwin Young

53. Cecile Erwin Young ("Ms. Young") was appointed Executive Commissioner of the Texas Health and Human Services Commission (HHSC) by Governor Greg Abbott on Aug. 14, 2020, and her office has general supervision and control over all matters relating to the health of the citizens of the State of Texas,[35] and has the authority to examine, investigate, enter, and inspect any public place or building as the department determines necessary for the enforcement of any health law of the state.[36]

54. Ms. Young was responsible for ensuring that the State's duties under the CDC Program, Provider Agreement, the State's FWA (FWA00028877), any EUA, and any PREP Act declaration were fulfilled.

55. Ms. Young's duties included ensuring that recruited parties, such as Shriners, administered the federally funded investigational drugs in accordance with federal law, the U.S. Constitution, and Plaintiffs' rights.

56. As the Emergency Response Stakeholder[37] ("ERS") under each EUA, Ms. Young had duties to ensure State Actors were in compliance with any EUA (see, Provider Agreement 12(a)).

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[34] *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))

[35] Texas Health and Safety Code § 12.0001, *et seq*.

[36] Texas Health and Safety Code § 12.0011

[37] Emergency Response Stakeholder "refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal,

57. Ms. Young's duties required her to: (1) "identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine **and ensure its** distribution and **administration**, **consistent** with the terms of this letter and CDC's COVID-19 Vaccination Program" and (2) "ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, **instruct them about the means** through which they are **to obtain and administer the vaccine under the EUA**, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website)" (emphasis added).[38]

58. This duty requires the State to "instruct" parties they recruit on the lawful administration of the EUA product. At the bare minimum, this must include ensuring that individuals are made aware of their right to accept or refuse and that the recruited party performs the ministerial function of accepting the chosen option without imposing penalties.

59. Starting in 2021, and continuing through the filing of this Second Amended Complaint, Ms. Young's recruited parties, such as Shriners, placed State-licensed healthcare workers, contractors, and volunteers under "sanctions," "coercion," "undue influence," and "unjustifiable pressures" to accept the federally funded investigational drugs in violation of the rights created for those individuals by the EUA statute (i.e. right to refuse), the PREP Act (i.e., right to be educated about the voluntary nature of the program), and the CDC Program.

territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation." Exhibit C, EUA Letter, Footnote 12

[38] Exhibit C, EUA Letter, Letters "O," "P," "Q," "X," "Y"

60. Ms. Young knew of the State's duty under the CDC Program to "monitor" Shriners' administration of the federally owned COVID-19 EUA/PREP Act drugs.

61. Despite the public outcry and voluminous lawsuits filed over healthcare workers' right to refuse the EUA/PREP Act investigational drugs, Ms. Young willfully remained silent about her duties and watched Shriners deprive Plaintiffs of their constitutional and federal statutory rights.

62. Ms. Young had a duty to intervene and correct Shriners' illegal conduct and was empowered by the State legislature to end the illegal activity, but Ms. Young prioritized the State earning an estimated $27 billion from the administration of the product over performing the ministerial function of honoring the plaintiffs' right to refuse.

63. The result of Ms. Young's willful violation of her duties led to a State-enforced custom whereby State Actors like Shriners could ignore Plaintiffs' statutory and constitutional rights without fear of consequence from the State. Ms. Young took a "see no evil, hear no evil" approach to the illegal conduct of her recruited parties that penalized, segregated, humiliated, and ultimately retaliated against Plaintiffs by terminating their employment.

64. The State-enforced custom is so well-established that the Texas Workforce Commission required individuals to return unemployment benefits to the State upon the Commission's finding that the individual engaged in "misconduct" when refusing to be injected with federally owned COVID-19 EUA/PREP Act investigational drugs.

65. Ms. Young neither instructed nor ensured that the State and its State Actors complied with their duties to (1) obtain Plaintiffs' legally effective informed consent under applicable FWAs, (2) protect Plaintiffs' Equal Protection rights, (3) protect Plaintiffs' Due Process rights, (4) perform the ministerial duty of accepting Plaintiffs' chosen option under 21 U.S.C.

§360bbb-3(e)(1)(A)(ii)(III) when considering the use of federally owned COVID-19 EUA/PREP Act investigational drugs.

66. The State owed statutory and constitutional obligations to Plaintiffs and could not delegate to Shriners the function of administering the federal EUA/PREP Act drugs without also delegating those statutory and constitutional obligations.

67. Therefore, Ms. Young's willful and wanton disregard for the duties of her office led to a State-enforced custom that Shriners acted in accordance with when penalizing Plaintiffs for exercising their right to refuse the federally owned COVID-19 EUA/PREP Act drugs, which is the direct and proximate cause of Plaintiff' financial, emotional, and legal injuries.

68. Plaintiffs sustained financial, emotional, and legal damages directly related to Ms. Young's State-enforced custom that deprived Plaintiffs of their Constitutional and federal statutory rights to be free from "sanctions," "coercion," "undue influence," and "unjustifiable pressures" when offered federally owned COVID-19 EUA/PREP Act investigational drugs.

69. Ms. Young's willful disregard for the duties of her office created a State-enforced custom that was "different from, or in conflict with, any requirement" under the PREP Act, EUA statute, EUA letters, Provider Agreement, and the Fourteenth Amendment (Equal Protection and Due Process).

70. Ms. Young's deliberate indifference to her duties is atrocious and outrageous, and never before in the history of the State of Texas has one individual been directly involved in the complete deprivation of constitutional rights of an entire labor force. Plaintiffs lost the use of their State-issued personal property (licenses to work as healthcare providers), employment, health insurance, retirement savings, emotional well-being, financial well-being, dignity, feelings

of equality, and equality before the law for no other reason than exercising a right secured for them by Congress, which Ms. Young willfully agreed to protect but intentionally failed to do.

71. Ms. Young achieved by reckless and wanton disregard for the duties of her office that which she could not achieve by the judicial or legislative branches of the State government —penalizing individuals for refusing federally owned EUA/PREP Act investigational drugs.

h. Shriners

72. Shriners Hospitals for Children is a network of not-for-profit medical facilities incorporated in Colorado, and it is licensed by the State of Texas to conduct business as a hospital.

73. At all times pertinent, Plaintiffs were employed by Shriners Hospitals for Children, located at 815 Market Street, Galveston, Texas, and were subject to the authority of Shriners PolicyMakers.

74. At all times pertinent, Shriners acted under color of law when (1) interacting with individuals considering whether to be injected with one of the COVID-19 investigational drugs, (2) administering the federally owned COVID-19 EUA/PREP Act investigational drugs, (2) acting in accordance with Ms. Young's State-enforced custom, (3) conducting COVID-19 research activities for the State, (4) performing the ministerial duty of accepting an individual's chosen option, and (5) obtaining an individual's legally effective informed consent.

75. Shriners operates under FWA00025698 whenever they treat humans with federally funded investigational drugs, owing duties to ensure that Plaintiffs are not under outside pressures to be injected with such drugs.

76. Shriners is an "Organization" under the Provider Agreement and is subject to its terms and conditions, meaning Shriners agreed to ensure that no individuals (e.g., employees,

volunteers, contractors, patients) were offered the federally funded drugs without being given the right to refuse without penalty.

77. Shriners is a "vaccination provider"[39] under each and every COVID-19 EUA.

78. Shriners is legally sophisticated in laws applicable to the investigational drug classification and oversees a multi-million-dollar research program utilizing investigational drugs, which requires strict adherence to 45 C.F.R. Part 46, the Belmont Report, and the EUA statute.[40] Moreover, Shriners has routinely administered investigational drugs authorized under 21 U.S.C. §360bbb *et. seq*., for decades. Shriners knew that Plaintiffs had the explicit right to refuse the investigational drugs without penalty but chose to deprive that right anyway.

79. Shriners agreed with the State to administer the federally owned COVID-19 EUA/PREP Act drugs and agreed to section 12(a) of the Provider Agreement to perform the ministerial function of accepting Plaintiffs' chosen option to accept or refuse without penalty.

80. Shriners agreed to "administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program,"[41] among other requirements under each EUA.

81. On September 14, 2021, William S. Bailey, Imperial Potentate of Shriners International, Jerry G. Gantt, Chairman of the Board of Trustees of Shriners Hospitals for Children, and John P. McCabe, Executive Vice President of Shriners Hospitals for Children, as Shriners PolicyMakers, issued and signed an unlawful directive to "all Shriners Hospitals for Children

[39] "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." Exhibit C, EUA Letter, Footnote 13

[40] https://www.shrinerschildrens.org/en/research-and-expertise/research-at-shriners-childrens

[41] See Exhibit C, EUA Letter, Letter "R"

Employees and Contract Staff" regarding a new company policy titled, "COVID-19 Vaccine Policy"[42] ("Policy").

82. The memo stated in part:

> (1) "Last week the Joint Boards approved a policy requiring nearly everyone in our organization to get fully vaccinated against COVID-19,"
>
> (2) "Everyone at every Shriners Hospitals for Children location in the United States and Canada, including Headquarters, must comply with the policy. All employees, contract employees, vendors, and volunteers who have a need to enter a building owned and/or operated by Shriners Hospitals for Children are required to be fully vaccinated against the COVID-19 virus,
>
> (3) "Everyone will need their first shot of the vaccination series by October 11, and must be fully vaccinated or have an appropriate exemption approved by December 6,"
>
> (4) "It is a requirement of employment with Shriners Hospitals for Children that all eligible persons be fully vaccinated. Those few who receive exemptions will be required to follow strict protocols that are anticipated to include masking with a special N95 mask and weekly COVID testing,"
>
> (5) "The requirements for medical or religious exemptions are specific. Talk to your local Human Resources team about your personal situation. To apply for an exemption, you must submit supporting documentation as well as a completed request form. All exemption requests will be vetted by a team including corporate leadership."

83. At all times material, the only drugs available to Plaintiffs for compliance with the Policy were the federally owned COVID-19 drugs classified as "investigational" and subject to the Provider Agreement, CDC COVID-19 Program, the EUA statute, the PREP Act, the State's FWA, Shriners' FWA, and each EUA providing Plaintiffs with the right to refuse without penalty.

84. "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

[42] See Exhibit D, Shriners Policy

complaint is made." *Johnson v. Duffy*, 588 F.2d 740, 743 (9th Cir. 1978) citing *Sims v. Adams* (5th Cir. 1976).

85. Shriners enacted and executed the Policy and required its management to enforce it, but the Policy and its enforcement, relying exclusively on the federally owned COVID-19 EUA/PREP Act investigational drugs, were *ultra vires*, unlawful, and the direct cause of Plaintiffs' injuries.

86. For decades, Shriners instructed, educated, and required its healthcare professionals to obtain patients' legally effective informed consent when administering investigational drugs, so Plaintiffs knew their right to refuse investigational drugs without penalty.

87. Still, Shriners treated the federally owned COVID-19 EUA/PREP Act investigational drugs "as if" they were licensed,[43] thus acting under pretense to compel Plaintiffs' involuntary use of the product.

88. At all times material, Shiners never informed Plaintiffs of their right to refuse an EUA or PREP Act drug without penalty.

89. When Plaintiffs refused to surrender their Equal Protection, Due Process, and federal statutory right to refuse federally owned COVID-19 EUA/PREP Act investigational drugs, Shriners, in violation of the PREP Act's preemption language and Congress's complete preemption of the field of EUA products, used the State's at-will employment law to retaliate against Plaintiffs for exercising their statutory right to refuse by gaslighting Plaintiffs' concerns and complaints and ultimately terminating their careers.

[43] To promote a drug "as if" it is something other than its labeling is misbranding. "Misbranding" is a prohibited act under 21 U.S.C. § 331(a). In 2009, the FDA charged Pfizer with a felony for promoting four drugs outside of their legal indication and fined them over $1.19 billion. The Department of Justice noted, "Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called 'off-label' uses – i.e., any use not specified in an application and approved by FDA."- Justice Department Announces Largest Health Care Fraud Settlement in Its History. Justice.gov. Published September 2, 2009

90. Shriners intentionally placed Plaintiffs under duress (i.e., threat of losing employment and employment benefits, threat of not being able to use their healthcare licenses, humiliation, etc.) to compel them to accept federally funded investigational drugs.

91. Moreover, Shriners, under pretense, promoted an unlicensed investigational drug (Pfizer-BioNTech COVID-19 Vaccine) as if it was licensed (COMIRNATY®) for the purpose of gaslighting Plaintiffs' claim that they could lawfully refuse the drugs.

92. Plaintiffs did not suffer injury for refusing to comply with a company vaccine policy or mandate. Plaintiffs suffered injury for exercising their right to refuse the federally owned COVID-19 EUA/PREP Act drugs, which right Shriners agreed to protect by their signature and FWA, but turned around, deprived that right, and subjected Plaintiffs to those very drugs under threat of penalty, and when Plaintiffs refused to surrender their Constitutional and federal rights, Shriners engaged in the unthinkable – intentionally inflicting emotional damage upon Plaintiffs as an example to other individuals and injuring Plaintiffs as described herein.

93. Pfizer-BioNTech COVID-19 Vaccine is "legally distinct" [44] from COMIRNATY®, and that distinction requires the potential recipient of the Pfizer-BioNTech COVID-19 Vaccine drug to consent to (1) forfeit civil litigation rights (due process) resulting from injuries;[45] (2) allow their private identifiable information to be collected and used for a variety of purposes by unknown persons;[46] (3) allow their use of the EUA drug to be cataloged by various persons for unknown purposes, (4) allow any of their adverse event data to be utilized by researchers for unknown purposes and for eternity,[47] and (5) assume greater risks to their safety,

[44] See Exhibit C, EUA Letter, Footnote 8
[45] PREP Act forfeits all civil actions for damages in most situations.
[46] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to obtain private identifiable information.
[47] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to monitor, report and study a variety of adverse reactions to EUA products.

health, and legal rights.[48]

94. Therefore, the enforcement of the Policy, relying upon the exclusive use of federally owned COVID-19 EUA/PREP Act investigational drugs, violated Plaintiffs' equal protection rights because it treated Plaintiffs' chosen option differently than individuals choosing the option to accept and it did not "requir[e]…everyone in [the] organization" to be treated equally.

95. The Policy deprived Plaintiffs of their fundamental right to refuse an investigational drug without penalty.

96. The Policy provided Plaintiffs no procedural due process before depriving them of their employment, employment-related benefits, and use of their State-issued healthcare licenses in which Plaintiffs had a property interest.

97. Shriners was preempted from enacting the Policy (a) expressly, (b) by the field preemption doctrine as it applies to investigational drugs, (c) by the terms of the Provider Agreement, and (d) by their FWA. Therefore, Shriners' Policy was *ultra vires*, demonstrating that Shriners misrepresented its authority to Plaintiffs and fraudulently amended the "Conditions of Authorization" established by the HHS Secretary for each EUA.

98. Moreover, Shriners lacked the authority to amend the EUA and Provider Agreement to require Plaintiffs to seek a medical or religious exemption as a condition to refuse.

99. Therefore, Shriners, requiring that which Congress prohibits (nonconsensual injection of federally owned COVID-19 EUA/PREP Act investigational drugs and/or requiring medical or religious exemption requests from individuals who already have the right to refuse without penalty) is the direct and proximate cause of Plaintiffs' financial, emotional, and legal

[48] 21 U.S.C. §360bbb-3 requires potential recipients to be made aware of the risks, alternatives, and the fact that the product is only authorized by the Secretary under emergency conditions. These elements provide potential recipients with the required information to make a quality and legally effective decision to consent. Therefore, consent means the individual agrees to assume more than minimal risk as defined in 21 CFR 50.3(k).

injuries.

100. Shriners engaged in lawless activity that shocks the conscience as outrageous, intolerable, and extreme, and placed Plaintiffs under severe emotional distress, fearing for their lives if they were injected with these drugs,[49] and for their livelihoods if they were not. The moral turpitude of Shriners caused Plaintiffs to suffer compensatory and special damages in an amount to be determined by a jury.

VII. LEGAL CLAIMS

101. The facts described above constitute a deprivation of rights guaranteed to Plaintiffs by the United States Constitution, federal statutes, and treaties. These deprivations are actionable under 42 U.S.C. § 1983[50] because Defendants acted under color of state law when they deprived Plaintiffs of their right to refuse an EUA product and failed to educate the Plaintiffs about the voluntary nature of a PREP Act program, thereby violating the Provider Agreement and the federal statutes cited therein.

102. The Supremacy Clause and the express preemption language in the PREP Act restrict public and private employers from using state laws, including any at-will employment doctrine, that conflict with any provision of the EUA statute and/or the PREP Act.

COUNT ONE § 1983 – Deprivation of the Option to Refuse

103. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

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[49] VAERS reported 1,562,008 entries from December 2020 through May 26, 2023, including 35,272 deaths (1.6 per hour) and 263,462 (12.11 per hour) serious injuries for the new and unvetted mRNA drugs. These numbers demonstrate historical entries for any drug reported to VAERS since it was first established.

[50] *Maine v. Thiboutot*, 448 U.S. 1 (1980), the court held that "Even were the language ambiguous, however, any doubt as to its meaning has been resolved by our several cases suggesting, explicitly or implicitly, that the §1983 remedy broadly encompasses violations of federal statutory as well as constitutional law." See also, *Health and Hospital Corporation of Marion Cty. V. Talevski.* The *Talevski* case demonstrates that federal statutes and regulations with rights conferring language are enforceable under 42 U.S.C. §1983

104. The EUA statute and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

105. Shriners' refusal to perform the ministerial act of accepting Plaintiffs' chosen option under the EUA statute, which acceptance is required under the Provider Agreement, the FWA, and the Fourteenth Amendment is the direct cause of Plaintiffs' financial, emotional, and legal injuries.

106. Ms. Young willfully failed to perform her duties to ensure that her recruited parties performed the ministerial act of accepting healthcare workers' option under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III), FWA, 45 C.F.R. § 46.116, and the Belmont Report, leading to a State-enforced custom of penalizing potential recipients of the federally owned COVID-19 EUA/PREP Act investigational drugs who exercised their option to refuse, a custom with which Shriners acted in accordance.

107. The Defendants' actions described above, individually and/or collectively, acting under color of state law, and in deprivation of the Constitutional rights and rights secured by the above federal statutes, regulations, and contracts, unlawfully deprived Plaintiffs of the right to refuse an EUA products without penalty or outside of their legally effective informed consent as described in the above facts, thereby causing them damages described in Paragraphs 180 through 184, *infra.*

COUNT TWO § 1983 – Deprivation of Equal Protection Rights

108. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

109. The Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution clearly and unambiguously creates rights enforceable pursuant to 42 U.S.C. § 1983, and it guarantees equal protection of the laws.

110. At all times pertinent, Shriners, acting under color of law, treated healthcare workers exercising their right to accept differently than those exercising the right to refuse.

111. Shriners' discriminatory treatment violated the federally funded CDC Program, Provider Agreement, federal law, and the U.S. Constitution by depriving Plaintiffs of their Equal Protection rights under the Fourteenth Amendment.

112. Ms. Young willfully failed to perform her duties to ensure that her recruited parties, such as Shriners, treated the option to accept equal to the option to refuse. This failure led to a State-enforced custom of penalizing potential recipients of the federally owned COVID-19 EUA/PREP Act investigational drugs if they exercised their option to refuse, a policy that Shriners enforced against Plaintiffs.

113. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, have deprived the Plaintiffs of their equal protection rights as described in the above facts, thereby causing them damages described in Paragraphs 180 through 184, *infra*.

COUNT THREE § 1983 – Deprivation of Procedural Due Process Rights

114. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

115. The Due Process Clause of the Fourteenth Amendment to the U.S. Constitution guarantees the right to due process of law before infringing a citizen's interest in life, liberty, or property.

116. The right to be free from losing one's finances, education, career, health, dreams, goals, and aspirations in life is a legitimate property interest by Plaintiffs, and such was their expectation when the State agreed to perform for the federal government.

117. The CDC Program, affirmatively adopted by the State, obligated the State to provide the following promised benefits to Plaintiffs: (1) offer the opportunity to participate free of costs, (2) inform individuals of their right to accept or refuse, (3) provide a Fact Sheet (which acts as part of the informed consent doctrine), and (4) perform the ministerial act of accepting the individual's chosen option.

118. The right to accept or refuse free from penalty, undue influence, or outside pressures is a property interest the State promised the federal government it would provide to Plaintiffs.

119. Plaintiffs were deprived of the right to refuse without penalty and without the opportunity to be heard.

120. "The fundamental requisite of due process of law is the opportunity to be heard." *Louisville & Nashville R. Co. v. Schmidt*, 177 U. S. 230, 177 U. S. 236; Plaintiffs have the Constitutional right "to present [their] case and have its merits fairly judged." *Logan v. Zimmerman Brush Co*., 455 U.S. 422 (1982).

121. At all times pertinent, Defendants refused to acknowledge Plaintiffs' Constitutional and statutory rights and did not provide Plaintiffs with a date, time, place, or procedure to present their case and have their merits fairly judged by an impartial body before depriving them of their liberty and property, and, regardless of any claimed procedure by Defendants, at no time did Defendants acknowledge Plaintiffs' right to refuse the federally funded investigational drugs without penalty.

122. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, have deprived the Plaintiffs of their procedural due process rights as described in the above facts, thereby causing them damages described in Paragraphs 180 through 184, *infra*.

COUNT FOUR § 1983 – Substantive Due Process Rights - Investigational Drugs

123. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

124. The Due Process Clause of the Fourteenth Amendment to the U.S. Constitution guarantees the right to due process of law before infringing a citizen's interest in life, liberty, or property.

125. The EUA statute (21 U.S.C. §360bbb-3) clearly and unambiguously creates rights enforceable pursuant to 42 U.S.C. § 1983.

126. The Supreme Court established a two-pronged approach[51] to analyze a substantive-due-process claim. First, the Due Process Clause protects fundamental rights and liberties deeply rooted in this nation's history and tradition. *Moore* v. *East Cleveland,* 431 U. S. 494, (1977). Second, the Court requires a "careful description" of the asserted fundamental liberty interest. *Reno* v. *Flores,* 507 U. S. 292 (1993)

127. Plaintiffs have a fundamental right to refuse an investigational drug without penalty.

128. Plaintiffs have a fundamental right to refuse an investigational drug without penalty because involuntary injection of investigational drugs violates a person's right to bodily autonomy,

[51] *Washington v. Glucksberg*, 521 U.S. 702 (1997)

a person's right to refuse unwanted medical treatment, and because the drug does not have a legal indication for safety, efficacy, or treatment of any known disease.

129. Regarding being deeply rooted, starting in 1938 (the FDC Act), the federal government prohibited drugs from being introduced into commerce before the FDA approved them for general marketing according to their labeling (21 U.S.C. § 355(a)). In 1974, Congress passed the National Research Act requiring an institutional review board to monitor research activities involving humans and unapproved therapeutics and devices. In 1978, the Belmont Report was published and formed the basis of the Common Rule (45 C.F.R. Part 46). In 1992, the U.S. Senate ratified Article VII of the ICCPR Treaty. In 2001, the federal government required all persons conducting business with its agencies, departments, or the military to have an FWA on file before they use federal funding when involving humans with investigational medical products. The State of Texas has more than 1,300 active FWAs out of 30,000 nationwide.

130. Congress places strict requirements upon persons relating to investigational drugs under 21 U.S.C. 321, 331, 351, 352, 355 360bbb, and 371; 42 U.S.C. 262; 10 U.S.C. § 1107; 45 C.F.R. Part 46; 21 C.F.R. §§ 50,56; 10 U.S.C. § 980; Article VII ICCPR Treaty; 21 C.F.R. § 312; and the Belmont Report.

131. The primary requirement of these statutes, agreements, and treaties is that a person offering a federally funded investigational product must ensure that the potential recipient is never under outside pressure to participate, such as "sanctions," "coercion," "undue influence," and "unjustifiable pressures."

132. The right to refuse an investigational drug is a fundamental right that is pervasive, historical, and deeply rooted in the $600b pharmaceutical research industry and this nation.

133. No constitution, statute, regulation, or treaty provides any person any authority to require another person to be injected with an investigational drug under threat of penalty.

134. Shriners, acting under color of law, committed a substantive due process violation when they deprived the Plaintiffs of their fundamental right to refuse the injection of an investigational drug without penalty.

135. Ms. Young willfully failed to ensure that her recruited parties, like Shriners, did not mandate compulsory use of the federally funded investigational drugs, leading to a State-enforced custom of penalizing potential recipients of federally owned COVID-19 EUA/PREP Act investigational drugs if they exercised their option to refuse, a policy that Shriners acted upon.

136. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, constituted a substantive due process violation when they deprived the Plaintiffs of their fundamental right to refuse an investigational drug as described in the above facts, thereby causing Plaintiffs to sustain the damages described in Paragraphs 180 through 184, *infra*.

COUNT FIVE § 1983 – Substantive Due Process Rights under the PREP ACT

137. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

138. The Due Process Clause of the Fourteenth Amendment to the U.S. Constitution guarantees the right to due process of law before infringing a citizen's interest in life, liberty, or property.

139. The PREP Act (42 U.S.C. §§247d-6d,6e) and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

140. Individuals have the explicit and fundamental right to due process, and Defendants could not require Plaintiffs to participate in a PREP Act activity or use a PREP Act countermeasure because such participation or use requires Plaintiffs to surrender their right to seek judicial relief (due process) from sustained injuries resulting from the use of an immunized countermeasure or participation in an immunized "program" activity.

141. There has not been a time in American history when an entire nation was subject to the loss of due process in direct violation of federal law, as witnessed during these last three years.

142. The actions of Ms. Young and Shriners described above constituted a substantive due process violation when Defendants required Plaintiffs' nonconsensual use of PREP Act covered countermeasures or lose the use of their State-issued healthcare licenses, which is a property interest. The PREP Act expressly preempted such actions.

143. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, have deprived the Plaintiffs of their substantive due process rights under the PREP Act as described in the above facts, thereby causing them damages described in Paragraphs 180 through 184, *infra*.

COUNT SIX § 1983 - Unconstitutional Conditions Doctrine

144. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

145. The unconstitutional conditions doctrine reflects the Supreme Court's repeated pronouncement that the government may not deny a public benefit to a person on a basis that infringes his constitutionally protected interests.[52]

[52] *Perry v. Sindermann*, 408 U.S. 593, 597 (1972)

146. While the doctrine does not have a formal test, the basic principle is that the government normally may not require a person, as a condition of receiving a public benefit, to relinquish a constitutional right.[53]

147. Ms. Young established a State-enforced custom that violated the unconstitutional conditions doctrine because she required Plaintiffs, as a condition of being able to continue using their State-issued healthcare licenses, to relinquish their fundamental constitutional right to refuse being injected with an investigational drug, and to relinquish their right to equal protection and procedural due process, as explained herein.

148. The State-enforced custom penalized potential recipients of the federally owned COVID-19 EUA/PREP Act investigational drugs if they exercised their option to refuse by making the use of their State-issued medical licenses impossible without being injected with an investigational drug.

149. Additionally, the CDC Program provided the general public with the benefits of (a) becoming educated about the COVID-19 drugs, (b) having the option to accept or refuse without coercion, sanctions, undue pressure, or undue influence, and (c) having the drugs provided at no charge.

150. Once the Program was implemented and Plaintiffs had the ability to avail themselves of its benefits, including the option to accept or refuse without coercion, sanctions, undue pressure, or undue influence, no person acting under the color of law could require them to relinquish a constitutional right in order to obtain the public benefits bestowed by the CDC Program.

[53] *Id.*, at 597.

151. When Shriners, acting under color of law as an Organization in the CDC Program, and Ms. Young, a State official, advised Plaintiffs that in order to receive the public benefits bestowed upon them by the CDC Program, they must relinquish their fundamental right to refuse an investigational drug, of equal protection under the law, and of procedural due process, they created an unconstitutional condition.

152. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, established an unconstitutional condition described in the above facts, thereby causing them damages described in Paragraphs 180 through 184, *infra*.

COUNT SEVEN § 1983 – Deprivation of Privacy Rights

153. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 103, as if fully set forth herein.

154. The Fourteenth Amendment provides individuals with protection against unwanted and unwarranted invasion of privacy by persons acting under the color of State law.

155. Ms. Young did not ensure that her recruited State Actors, like Shriners, honored the privacy rights of healthcare workers who were considering whether to be injected with federally owned COVID-19 EUA/PREP Act drugs, leading to a State-enforced custom of the State Actors mandating that healthcare workers inform the State Actors if and when the healthcare workers participated in the federal COVID-19 program.

156. Shiners' Policy relied exclusively on federally funded EUA/PREP Act investigational drugs for compliance, which did not have a legal indication to treat, cure, or prevent any known disease.

157. Use of an investigational drug or participating in a federal program is a personal and private matter on which Shriners could not condition employment.

158. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, violated Plaintiffs' Fourteenth Amendment privacy rights described in the above facts, thereby causing them damages described in Paragraphs 180 through 184, *infra*.

COUNT SEVEN Breach of Contract, Third Party Beneficiary

159. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

160. Plaintiffs have enforceable third-party beneficiary rights under the CDC Provider Agreement.

161. The third-party beneficiary right intended for Plaintiffs by the Provider Agreement under the EUA statute is right to be informed of the option to accept or refuse an EUA product without penalty.

162. The third-party beneficiary right intended for Plaintiffs by the Provider Agreement under the PREP Act is the right to be educated about the voluntary nature of the program.

163. These statutory rights are expressed in terms of individual potential recipients of EUA/PREP Act products and are specifically intended to benefit the Plaintiffs herein.

164. Shriners breached both of these third-party beneficiary rights when Shriners penalized Plaintiffs for refusing an EUA investigational drug and for failing to educate Plaintiffs that participation in a PREP Act program was voluntary.

165. Ms. Young breached both of these third-party beneficiary rights when she established a State-enforced custom that allowed Shriners to violate Plaintiffs' third-party beneficiary rights under the Provider Agreement.

166. The Defendants' actions described above, individually and/or collectively, and in breach of the CDC COVID-19 Vaccination Program Provider Agreement, deprived the Plaintiffs of the third-party beneficiary rights conferred upon them by the EUA statute and PREP Act, and by the terms and conditions of the CDC COVID Vaccination Program Provider Agreement as described in the above facts, thereby causing them damages described in Paragraphs 180 through 184, *infra*.

COUNT EIGHT Wrongful Termination

167. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 103, as if fully set forth herein.

168. The Supremacy Clause and the express preemption language in the PREP Act preempt State laws and legal requirements that conflict with the EUA statute and/or the PREP Act. As such, Shriners cannot use Texas's at-will employment doctrine to penalize Plaintiffs for exercising their right to refuse an EUA/PREP Act investigational drug.

169. The Plaintiffs did not consent to the deprivation of labor, wages, or employment.

170. Shriners' is preempted from using Texas's at-will employment doctrine to terminate Plaintiffs' employment because such action conflicts with the EUA statute and the PREP Act as described in the above facts, thereby causing Plaintiffs damages described in Paragraphs 180 through 184, *infra*.

COUNT NINE Intentional Infliction of Emotional Damage

171. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

172. Despite the United States Congress prohibiting Defendants from penalizing potential recipients of EUA/PREP Act drugs who exercised their right to refuse, Defendants engaged in a scorched earth policy and inflicted, with malicious intent, severe emotional distress to the fullest extent of their positions of authority and power to the detriment of Plaintiffs' emotional well-being.

173. To prove intentional infliction of emotional distress, Plaintiffs must demonstrate that Shriners (1) acted intentionally or recklessly; (2) engaged in extreme and outrageous conduct; (3) caused Plaintiffs emotional distress; and (4) caused emotional distress that was severe. *Hoffmann--La Roche Inc. v. Zeltwanger*, 144 S.W.3d 438, 447 (Tex. 2004).

174. Defendants knew that they could not engage in their reckless conduct nor pressure Plaintiffs to use federally funded COVID-19 EUA/PREP Act drugs by using the tactics of depriving Plaintiffs of their chosen profession and use of their State-issued medical licenses.

175. The facts and the Defendants' conduct committed with gross negligence, reckless, or intent, as described above in the Complaint, give rise to a claim of intentional infliction of emotional distress under the common law of the State of Texas against the Defendants for the damages described in Paragraphs 180 through 184, *infra*.

COUNT TEN Implied Private Right of Action 21 U.S.C. §360bbb-3

176. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 102, as if fully set forth herein.

177. Should the court not agree that Shriners was acting under color of law, Plaintiffs claim that the EUA statute contains an implied private right of action pursuant to *Cannon v. University of Chicago*, 441 U.S. 677 (1979), *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498 (1990), and *Cort v. Ash*, 422 U.S. 66 (1975).

178. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty have deprived the Plaintiffs of their explicit right to refuse the administration of an emergency use authorized drug and/or medical product without penalty as described in the above facts, thereby causing them damages described in Paragraphs 180 through 184, *infra*.

VIII. DAMAGES RECOVERABLE AND DEMANDED

179. The following paragraphs are hereby incorporated by reference into Counts One through Ten, as if set forth here *in extenso*.

180. As a direct and proximate result of the Defendants' unreasonable and unlawful actions, Plaintiffs have suffered past damages and will suffer future damages, both compensatory and general, including, but not limited to, front and back pay; loss of benefits; loss of accumulated sick pay; loss of retirement accounts; lost earnings on retirement funds; vacation time, compensatory time, and paid time off; negative tax consequences (in the event of a lump sum award), including related accountant fees; attorney's fees; emotional distress; mental, psychological and physical harm; loss of income; loss of enjoyment of life; for which defendants are liable in compensatory, punitive, exemplary, legal, equitable, and all other damages that this Court deems necessary and proper.

181. When the Defendants' behavior reaches a sufficient threshold, punitive damages are recoverable in § 1983 cases. *Smith v. Wade*, 461 U.S. 30 (1983).

182. Because Defendants' actions were intentional, willful, reckless, or with callous indifference to the Plaintiffs' federally protected rights, or motivated by evil motive or intent, Plaintiffs are entitled to, and hereby demand, an award of punitive damages against each Defendant in an amount sufficient to deter them, individually and collectively, from repeating their unconstitutional actions. *Smith v. Wade*, 461 U.S. 30 (1983)

183. Plaintiffs seek recovery of attorney's fees under the Civil Rights Attorney's Fees Awards Act of 1976 and 42 U.S.C. § 1988, and under any other provision of law or basis.

184. Plaintiffs seek recovery of all court costs and out-of-pocket litigation expenses, including but not limited to expert fees, and legal interest on any amount of damages awarded.

IX. JURY TRIAL DEMAND

185. Plaintiffs are entitled to, and hereby demand, a trial by jury on all issues of fact.

WHEREFORE, Plaintiffs pray that Defendants be served with a copy of this Second Amended Complaint and be duly cited to appear and answer same, and after due proceedings are had, there be judgment herein against the Defendants awarding Plaintiffs all damages claimed herein, plus legal interest, taxable costs, expert fees, and attorney's fees, and all other relief determined to be just and equitable by this Court.

CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of March, 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

SCHEXNAYDRE LAW FIRM

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