UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ASHLEY PETROWSKI AND TRACEY ABBEY	*	CIVIL ACTION:
Plaintiffs,	*	
VERSUS	*	
SHRINERS HOSPITALS FOR CHILDREN BEVERLY BOKOVITZ, FRANCES FARLEY JERRY GANTT, JOHN McCABE, AND PHILLIP GRADY	*	
Defendants	*	

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

COMPLAINT
(JURY TRIAL REQUESTED)

Now into court, through undersigned counsel, come Plaintiffs, Ashley Petrowski and Tracey Abbey, (hereinafter "Plaintiffs"), who file this Complaint against Defendants, Shriners Hospitals for Children, Inc., Beverly Bokovitz, Frances Farley, MD, Jerry Gantt, John McCabe, and Phillip Grady (hereinafter collectively referenced as "Shriners") presenting allegations and causes of action as follows:

I. Introduction

1. This action arises out of Shriners Hospitals for Children ("Shriners"), a state actor when performing under the State-run CDC COVID-19 Vaccination CDC Program ("CDC Program") and when acting pursuant to a State-enforced custom discussed *infra*, established and enforced a policy, requiring Plaintiffs to inject unlicensed investigational new drugs ("INDs") into their bodies under threat of penalty, thus mandating that Plaintiffs surrender their Fourteenth

Amendment rights guaranteed to them by the federal government and Massachusetts under the CDC Program.

2. The Fourteenth Amendment guarantees Plaintiffs the right to (1) enjoy the benefits of a federal program (a property right), (2) exercise statutory entitlements (a property right), (3) refuse public disclosure of their private health and identifiable information (right to privacy), (4) refuse to become human subjects under federally funded research activities (right to bodily autonomy and integrity), and (5) refuse unwanted investigational drugs and unwanted medical treatments (right to bodily autonomy and integrity), without incurring a penalty or losing a benefit to which they are otherwise entitled.

3. Plaintiffs are former employees of Shriners.

4. On September 14, 2021, Shriners issued an investigational new drug mandate ("IND Mandate") requiring all employees (in addition to volunteers, contractors, and vendors) to inject into their bodies federally funded investigational drugs offered exclusively under the CDC Program or to obtain an exemption from Shriners as a condition of continued employment with Shriners.

5. The only drugs offered under the CDC Program were wholly owned by the federal government, FDA-classified as investigational, authorized only for emergency use, immunized from liability under the PREP Act, and subject to the legally effective informed consent doctrine.

6. The mandatory use of the drugs offered under the CDC Program violates Plaintiffs' liberty interest to refuse unwanted investigational drugs and medical treatments.

7. The IND Mandate, and enforcement thereof, violated Plaintiffs' fundamental rights guaranteed to them by the Fourteenth Amendment, federal law, and the CDC Program.

8. The IND Mandate and enforcement thereof is the direct and proximate cause of Plaintiffs' injuries.

9. Plaintiffs bring this suit as a civil rights action under the United States Constitution, 42 U.S.C. §1983, and Massachusetts common law seeking monetary damages.

II. JURISDICTION AND VENUE

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

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

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

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

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

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

III. PLAINTIFFS

18. The following individuals are plaintiffs herein:

19. Plaintiff Ashley Petrowski is an adult individual who, at all times pertinent, resided in the State of Massachusetts and was previously an employee of Shriners in Massachusetts.

20. Plaintiff Tracey Abbey is an adult individual who, at all times pertinent, resided in the State of Massachusetts and was previously an employee of Shriners in Massachusetts.

IV. SHRINERS

21. The following are named as defendants herein:

22. 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, and was authorized to do and doing business in Massachusetts.

23. 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 Hospitals for Children. Ms. Bokovitz is named as a defendant in her official and individual capacities.

24. 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 Hospitals for Children. Dr. Farley is named as a defendant in her official and individual capacities.

25. Defendant, Jerry Gantt, was at all times pertinent, the Chairman of the Board of Trustees and PolicyMaker of Shriners Hospitals for Children, is an individual of the full age of

majority, and was a signatory to Shriners Hospitals for Children's COVID-19 policy. Mr. Gantt is named as a defendant in his official and individual capacities.

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

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

V. The Gravamen of the Case

28. Plaintiffs hold the fundamental right to refuse, without penalty or pressure, unwanted federally funded investigational drugs irrespective of the federal agency, department, or program offering the drugs.

29. All drugs offered through the CDC Program were investigational.

30. Plaintiffs hold property rights under the CDC Program and applicable laws discussed herein to accept or refuse the federally funded INDs, which Shriners prospectively agreed to protect on behalf of Massachusetts and the United States Government ("USG") under the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement") and the Federal Wide Assurance ("FWA") program, but Shriners unlawfully deprived Plaintiffs of the specific property right to refuse by applying *ultra vires* penalties to that chosen option, which conduct was outside the scope of Shriners' discretionary authority.

31. There is no legal condition under which Shriners can mandate that Plaintiffs use an IND, EUA product, or PREP Act countermeasure, nor can Shriners terminate an employee for refusing the drug pursuant to Shriners' voluntary agreement to obtain Plaintiffs' "legally effective informed consent" on behalf of Massachusetts and the USG, a purely governmental function under the CDC Program as well as Shriners' Institutional Review Board ("IRB"), and FWA agreements.

VI. Factual Allegations

A. BACKGROUND

32. This case appears to present several matters of first impression within the First Circuit regarding the intersection of federal programs and constitutional rights involving investigational drugs authorized under the EUA Statute and immunized from liability under the PREP Act.

33. No court in the First Circuit appears to have analyzed (1) the CDC Program; (2) the requirements for legally effective informed consent; (3) the fundamental rights implicated under the PREP Act; (4) the Federal Wide Assurance program; or (5) how these programs and principles interact with Plaintiffs' Fourteenth Amendment rights.

34. Given the apparent absence of rulings relating to these legal principles and how they apply to the Supreme Court's controlling precedent involving bodily autonomy, privacy, due process, and property rights, Plaintiffs will provide a comprehensive background on the congressional framework governing the use of investigational new drugs on human subjects so that the Court can fully evaluate Congress's legislative intent regarding human subject protections under the facts presented herein, particularly regarding informed consent requirements and fundamental rights protected by the Fourteenth Amendment.

35. In 2020, the federal government's executive branch established the CDC Program as an emergency public function to distribute and administer COVID-19 INDs to willing recipients.

36. The FDA assigns IND status when a drug manufacturer requests authorization pursuant to 21 C.F.R. §312 (Investigational New Drug Application) to administer an unlicensed drug to humans involving investigational activities. This is the first step to obtaining a Biologics License Application pursuant to 21 U.S.C. §355(a).

37. INDs do not have a legal indication for their safety and efficacy for treating, curing, or preventing any known disease.

38. INDs are considered investigational when used in the normal course of medical practice.

39. Similarly, drugs granted an Emergency Use Authorization ("EUA") are considered investigational because EUA drugs cannot already be licensed to treat, prevent, or cure the intended emergency use (21 U.S.C. §360bbb-3(c)(3).

40. A drug is regulated according to its classification and labeling, not its formulation.

41. The use of INDs funded or authorized by the United States federal government ("USG") must comply with 21 U.S.C. §360bbb *et seq*. (Expanded Access to Unapproved Therapies and Diagnostics), 45 C.F.R. Part 46 (Protection of Human Subjects), the Belmont Report, 10 U.S.C. §980 (Limitation on Use of Humans as Experimental Subjects), and Institutional Review Boards ("IRB"), when offered to humans whose private identifiable information will be

known, and data collected about their use of the product will be studied to add to the product's generalizable knowledge (45 C.F.R. Part 46), which are considered research conditions.[1]

42. The primary governmental function required of any person agreeing to act on behalf of the USG when administering an IND is to obtain an individual's legally effective informed consent as outlined under 45 C.F.R. §46.116 and the Belmont Report.

43. The legally effective informed consent principle requires the person offering an individual an IND to first establish a legally approved environment that ensures the individual is not under "coercion," "undue influence," "unjustifiable pressures," or a sanction to use the drug. There are no exceptions to this ministerial requirement.[2]

44. The unique principle of legally effective informed consent is that it places a ministerial duty upon persons acting under the USG's authority to ensure that a potential recipient is not under outside pressure to use the IND by informing the potential recipient of the right to refuse without penalty or pressure.

45. Legally effective informed consent is nullified whether the outside pressure is positive (i.e., unjustifiable monetary awards) or negative (i.e., loss of benefits).

46. The INDs mandated by Shriners are drugs under such research and legal conditions.[3]

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[1] "Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied." 45 CFR 46.122. The USG and persons acting on the USG's behalf as part of the CDC Program were required to adhere to the federal scheme at all times material.

[2] 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. Part C "Voluntariness"

[3] The CDC Program and each assigned EUA required the State and its recruited parties to conduct research activities on behalf of the USG, requiring adherence to 45 C.F.R. Part 46 and the Belmont Report.

47. The USG established the Federal Wide Assurance ("FWA") program in 2001 to ensure that persons acting on its behalf complied with the federal scheme[4] designed to protect humans from medical research abuses resulting from the 1974 National Research Act.[5]

48. Shriners' FWA with the USG is triggered upon Shriners accessing federal funding or acting under the USG's authority when offering humans INDs.

49. Massachusetts[6] has an active FWA and, as a result, is intimately familiar with the protocols under the regulatory scheme[7] requiring protection of human subjects involved in federally authorized research activities, such as the CDC Program and any Emergency Use Authorization ("EUA") issued under 21 U.S.C. §360bbb-3 ("EUA Statute").

50. Shriners has an active FWA[8] requiring it to comply with the same legal duties.

51. Pursuant to the 1974 National Research Act, the Belmont Report[9] established the legal nature of informed consent known as "legally effective informed consent" promulgated under 45 C.F.R. §46.116, making it a property right subject to the Fourteenth Amendment's Due Process Clause relating to bodily autonomy.

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[4] The FWA program requires the organization offering INDs to humans to provide the USG with a written assurance that they will comply with 45 C.F.R. Part 46 and the Belmont Report. The primary duty is to comply with 45 C.F.R. §46.116 "legally effective informed consent." The program is managed by the Office of Human Research Protections (OHRP) under the Health and Human Services (HHS) agency.

[5] H.R.7724 - National Research Act, 93rd Congress (1973-1974), See Title II

[6] FWA00000786

[7] *Department of Public Health CONDUCT of HUMAN SUBJECT RESEARCH*.; 2013. Accessed November 27, 2024. https://www.mass.gov/doc/conduct-of-human-subject-research-protocol/download

[8] FWA00025698

[9] 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

52. Congress clearly established a property interest for Plaintiffs, stating, "Before involving a human subject in research covered by this policy, an investigator **shall obtain** the legally effective informed consent of the subject or the subject's legally authorized representative." (45 CFR §46.116(a)(1)) (emphasis added).

53. The phrase "shall obtain" means Congress has conferred upon Plaintiffs a right to give their legally effective informed consent,[10] thereby making legally effective informed consent a property right involving bodily autonomy, which the Fourth Circuit[11] and Supreme Court holds is a fundamental liberty interest. Specifically, the Supreme Court holds:

> "No right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear and unquestionable authority of law." *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250 (1891);
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> "[O]n balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons generally are permitted to refuse medical treatment, even at the risk of death. Most of the cases that have held otherwise, unless they involved the interest in protecting innocent third parties, have concerned the patient's competency to make a rational and considered choice" *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 273 (1990), citing In re Conroy, 98 N.J. 321, 348, 486 A.2d 1209, 1223 (N.J. Jan. 17, 1985);

[10] "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." *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972). And "[p]roperty interests, of course, are not created by the Constitution. Rather, they are created, and their dimensions are defined, by existing rules or understandings that stem from an independent source such as state law -- rules or understandings that secure certain benefits and that support claims of entitlement to those benefits. Thus, the welfare recipients in *Goldberg v. Kelly*, 397 U.S. 254 (1970), had a claim of entitlement to welfare payments that was grounded in the statute defining eligibility for them." *Id*.

[11] "The right to be free of unwanted physical invasions has been recognized as an integral part of the individual's constitutional freedoms, whether termed a liberty interest protected by the Due Process Clause, or an aspect of the right to privacy contained in the notions of personal freedom which underwrote the Bill of Rights. The right to refuse medical treatment has been specifically recognized as a subject of constitutional protection." *U.S. v. Charters*, 829 F.2d 479 (4th Cir. 1987)

> "The right assumed in *Cruzan*, however, was not simply deduced from abstract concepts of personal autonomy. Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation's history and constitutional traditions." *Washington v. Glucksberg*, 521 U.S. 702 (1997);
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> "The protections of substantive due process have for the most part been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity." *Albright v. Oliver*, 510 U.S. 266, 272 (1994)

54. Drugs classified by the FDA as INDs do not have a legal indication to treat, prevent, or cure the disease that is the subject of the emergency and, therefore, fall under the Supreme Court's precedent involving unwanted medical treatment because the drugs are only used for investigational purposes.

55. Therefore, whenever a human is presented with an opportunity to use a federally funded IND, they have a liberty interest in providing or withholding legally effective informed consent.

56. Punishing individuals for refusing investigational drugs and unwanted medical treatments violates Plaintiffs' fundamental right to bodily autonomy and their property rights under the CDC Program and applicable laws, all of which guarantee that Plaintiffs will not incur a penalty or lose a benefit to which they are otherwise entitled.[12]

57. In 2020, the federal government's executive branch (the Department of Defense) purchased all COVID-19 INDs (see, *infra*) and established the CDC Program (using social security and Medicare funding) requiring recruited parties (i.e., states) to perform research activities on its behalf.

[12] "A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." 45 CFR §46.116(b)(8)

58. The USG informed Shriners that:

> "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 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." (Emphasis added)

59. The USG is under a ministerial duty to obtain an individual's legally effective informed consent when offering one of the COVID-19 INDs because those drugs and the CDC Program require Plaintiffs to become human subjects (45 CFR §46.102(e)(1)) in federally funded research activities (45 CFR §46.102(l)).[13]

60. The USG is under a ministerial duty to obtain Plaintiffs' legally effective informed consent when offering INDs because it purchased the COVID-19 INDs using DoD funding (10 USC §980).[14]

61. The USG is under a ministerial duty to inform Plaintiffs of their right to accept or refuse the drugs authorized only for emergency use under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).

62. The option to accept is a property right because it allows Plaintiffs to access unapproved drugs that are exempt from 21 U.S.C. §355(a) during a declared emergency. The option to refuse is a property right because it allows Plaintiffs to refuse the drugs without cost,

[13] The research activities are listed in the Provider Agreement and the "conditions of authorization" in each EUA. See Exhibit A, Provider Agreement; Exhibit B, December 11, 2020 EUA Letter; Exhibit C, August 23, 2021 EUA Letter.
[14] See Exhibit D, DoD Purchase of COVID-19 Drugs

despite a chemical, biological, radiological, nuclear, or pandemic event, specifically because the drugs are not approved for their intended emergency use.

63. The duty to inform Plaintiffs of their right to refuse means Plaintiffs have the right to refuse at all times without any additional legal conditions placed upon them by any third party. The right is a federally secured right with which no other person can interfere by requiring an individual to seek a religious or medical exemption to exercise that right.

64. To comply with its legal obligations relating to the INDs, the USG established the CDC Program in 2020, publishing guidelines under "COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations" ("Playbook") to help states it recruited to "operationalize a vaccination response to COVID-19 within [its] jurisdiction" and to help the State with its "COVID-19 vaccination program planning and implementation."[15]

65. The Playbook informed states that:

> (1) A COVID-19 vaccination provider is any vaccination provider who has been enrolled in the COVID-19 Vaccination Program,[16]
>
> (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,[17]
>
> (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 [18] 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**

[15] See Exhibit E, CDC Playbook
[16] See Exhibit E, CDC Playbook, Footnote 1
[17] See Exhibit E, CDC Playbook, Footnote 2
[18] See Exhibit E, CDC Playbook, p. 21

compliance with all applicable state and territorial vaccine laws (emphasis added),[19]

(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,[20]

(5) Jurisdictions must facilitate and monitor IIS [Immunization Information System] reporting by enrolled vaccination providers,[21]

(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,[22]

(7) **Help the public to understand key differences in FDA emergency use authorization and FDA approval** (i.e., licensure),[23] (emphasis added)

(8) Jurisdictions will be provided an opportunity to opt out of having pharmacies in their area receive direct allocations,[24]

(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.[25]

66. Therefore, any state volunteering to perform for the USG is responsible for ensuring it and its recruited state actors comply with any EUA, educate the public about the legal distinctions between a licensed drug and an EUA drug, and ensure all persons it recruits signs the Provider Agreement and maintain a copy of that agreement on file for a minimum of three years.

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[19] Massachusetts 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 administering the federally owned COVID-19 drugs on the State's behalf.
[20] See Exhibit E, CDC Playbook, p. 21
[21] See Exhibit E, CDC Playbook, p. 35
[22] See Exhibit E, CDC Playbook, p. 8 (emphasis added)
[23] See Exhibit E, CDC Playbook, p. 42
[24] See Exhibit E, CDC Playbook, p. 26
[25] See Exhibit E, CDC Playbook, p. 22

67. The Executive Branch only recruited U.S. States and Territories because those entities have active FWAs requiring them to comply with the same legal obligations as the USG.

68. Massachusetts agreed to perform for the USG under the CDC Program, and no entity within the State could administer the drugs without first being authorized by the State and agreeing to administer the drugs within the constitutional restraints of the Fourteenth Amendment.

69. At all times material, Massachusetts was required to perform the governmental function of accepting Plaintiffs' legally effective informed consent anytime it, or persons acting on its behalf, presented Plaintiffs with an opportunity to use the INDs.

70. Though novel, the CDC Program is an emergency public function reserved for the state by the USG. The state was obligated to perform the USG's functions, which are traditional and exclusive government functions requiring private parties that volunteered to serve as Organizations under the CDC Program to owe constitutional obligations to individuals who are offered the federally owned INDs.

71. Under the CDC Program, the Massachusetts Department of Health willfully assumed the role of the "Emergency Response Stakeholder"[26] under each EUA.

72. The State is legally required 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

[26] See Exhibit C, August 23, 2021 EUA Letter, FN12, "emergency response stakeholder"

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).[27]

73. Therefore, the State is under a ministerial duty to ensure the "conditions of authorization" of each EUA are lawfully implemented, including ensuring that all individuals are informed of their right to accept or refuse the EUA drug.

74. The CDC Program provided Massachusetts with the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement") to ensure the State complied with its legal duties when it recruited others to act on its behalf.[28]

75. Massachusetts incorporated the Provider Agreement into official State policy and required recruited parties to sign and comply with its terms. The Agreement also required potential recipients to have the right to refuse without penalty or pressure.

76. The Provider Agreement placed duties upon the State and its recruited parties (i.e., vaccination providers), 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

[27] See Exhibit C, August 23, 2021 EUA Letter, p. 10. "Conditions of Authorization," Letter "O"
[28] See Exhibit A, Provider Agreement

vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative,[29]

(5) Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS), [30]

(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.[31]

77. The duties of Massachusetts and its recruited parties include administering the CDC program lawfully, providing the "Vaccine Information Fact Sheet" (i.e., official drug label) to potential recipients, monitoring and reporting adverse events to VAERS, complying with the Provider Agreement in full, and informing all potential recipients that the drug "has not been approved or licensed by the FDA" when promoting the product to any person for any reason.[32]

78. The State agreed to conduct research activities on behalf of the USG, including to "report moderate and severe adverse events following the drug's administration to the Vaccine Adverse Event Reporting System (VAERS)," and "provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient,

[29] The Fact Sheet is part of the process of obtaining an individual's legally effective informed consent.
[30] This "reporting" constitutes "research" under 45 C.F.R. Part 46 and the Belmont Report.
[31] 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 official State policy.
[32] See Exhibit C, 8/23/2021 EUA Letter, Sections R - Y

or other legal representative" by ensuring its recruited "Organizations" that signed the Provider Agreement knew how to monitor and report those adverse reactions to VAERS.[33]

79. These two required conditions extend to all of Massachusetts' recruited parties because the USG cannot delegate the governmental function to Massachusetts and its recruited parties without delegating the USG's legal obligations.

80. The Conditions of Authorization of each EUA require each manufacturer, State health agency, and vaccination provider to obtain a person's private health information, monitor them for adverse events, research "a pre-specified list of adverse events of special interest, along with deaths and hospitalizations"[34] and report that data to the Center for Biologics and Evaluation Research (CBER, an FDA department) and to the Vaccine Adverse Event Reporting System ("VAERS") to "contribute to generalizable knowledge" (45 CFR 46.102(l)) of the product.

81. The CDC Program was a federally funded program involving research activities requiring the USG to comply with 45 CFR Part 46 requirements, the Belmont Report, 10 USC §980, the FWA agreement, and the federal constitution relating to privacy and unwanted investigational medical treatment.

82. Therefore, Massachusetts agreed to perform the ministerial function of accepting Plaintiffs' chosen option under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) and to obtain Plaintiffs' "legally effective informed consent" on behalf of the USG, which was also required of Massachusetts' recruited parties.

[33] See Exhibit A, Provider Agreement.
[34] See Exhibit C, 8/23/2021 EUA Letter, Section N

B. Shriners

83. Shriners Hospitals for Children is a network of not-for-profit medical facilities incorporated in Colorado.

84. Shriners is licensed by the State of Massachusetts to conduct business as a hospital.

85. At all times pertinent, Plaintiffs were employed by Shriners Hospitals for Children, located at 51 Blossom Street, Boston, Massachusetts, and were subject to the authority of Shriners.

86. At all times pertinent, Shriners acted under color of law as a state actor under the State-run CDC Program because Massachusetts cannot delegate its governmental functions without delegating its Fourteenth Amendment obligations.

87. Upon information and belief, Shriners signed the CDC COVID-19 Vaccination Provider Agreement, agreeing to perform governmental functions for the State.

88. Shriners' FWA00025698 is their written assurance to the USG that it will ensure that Plaintiffs' right to refuse federally funded INDs is protected anytime Shriners presents Plaintiffs with an opportunity to use the INDs, such as under Shriners' IND Mandate.

89. Shriners is an "Organization" under the Provider Agreement and is subject to its terms and conditions.

90. Shriners is a "vaccination provider" under each EUA, and as the Organization under the Provider Agreement, it is required to inform Plaintiffs of their right to accept or refuse the INDs without penalty or pressure.

91. Shriners had a duty under each EUA to "clearly and conspicuously [] state that: This product has not been approved or licensed by FDA, but has been authorized for emergency use by the FDA..."[35]

[35] Exhibit C, August 23, 2021 EUA Letter, Section "Y", p. 12.

92. Shriners was required to provide the CDC Program's benefits to all persons equally, free of charge, and to perform the governmental function of accepting the individual's chosen option irrespective of the relationship that Shriners had with the individual.

93. Under the Provider Agreement, the CEO and CMO, or their equivalents, were required to sign and comply with the agreement and to perform the duties required by Massachusetts under the CDC Program.[36] Moreover, Shriners had to list all persons responsible for the administration of the CDC Program on the Provider Agreement.

94. Under the Provider Agreement, Shriners agreed to comply with "any EUA."[37]

95. 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, issued and signed an unlawful directive to "all Shriners Hospitals for Children Employees and Contract Staff" regarding a new company policy titled, "COVID-19 Vaccine Policy"[38] ("IND Mandate").

96. The memo stated in part:

A. "Last week the Joint Boards approved a policy requiring nearly everyone in our organization to get fully vaccinated against COVID-19."

B. "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."

C. "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."

[36] Exhibit A, Provider Agreement, p. 1.
[37] Exhibit A, Provider Agreement, p. 3, Section 12(a)
[38] See Exhibit F, Shriners' Policy

D. "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."

E. "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."

97. The IND Mandate exclusively relied upon the federally owned COVID-19 INDs for compliance in violation of Shriners' ministerial duties under the CDC Program.

98. Shriners' mandate that Plaintiffs inject federally owned INDs under threat of penalty conflicted with the CDC Program, Shriners' FWA, the USG's duties, Massachusetts' duties, and the Provider Agreement and deprived Plaintiffs of their Fourteenth Amendment rights.

99. Shriners' mandate that Plaintiffs inject federally owned INDs under threat of penalty deprived Plaintiffs of rights under the EUA statute, the PREP Act, 45 CFR §46.116, and 10 U.S.C. §980, and the CDC Program.

100. Shriners' IND Mandate vitiated Plaintiffs' legally effective informed consent when Shriners required the use of federally funded INDs under threat of penalty despite promising the USG and Massachusetts that Shriners would never place individuals, such as Plaintiffs, under outside pressure to use the drugs, nor penalize Plaintiffs when they refused. The specific and sole reason Shriners terminated Plaintiffs was for refusing to inject the federally owned INDs into their bodies.

101. Shriners' IND Mandate exceeded Shriners' authority under the CDC Program because Shriners mandated the use of the drugs available under the Program but failed to inform Plaintiffs of the right to refuse without pressure or penalty and Shriners failed to inform Plaintiffs that the drugs were not approved or licensed by the FDA.

102. Shriners' IND Mandate exceeded Shriners' authority under the CDC Program when it required Plaintiffs to seek a medical or religious exemption as the only means of refusing the INDs because Plaintiffs already possessed the right to refuse without penalty or pressure.

103. Shriners exceeded its authority under the CDC Program when it required Plaintiffs to become human subjects in federally funded research activities.

104. Shriners' IND Mandate exceeded Shriners' authority under the CDC Program when Shriners required Plaintiffs to involuntarily surrender their private health information to unknown persons, for unknown reasons, and for an unknown length of time, as required under the Program.

105. Shriners' IND Mandate deprived Plaintiffs of their fundamental right to refuse EUA/PREP Act investigational drugs and unwanted medical treatments.

106. Shriners' IND Mandate exceeded Shriners' authority under the CDC Program when Shriners presented the EUA/PREP Act investigational drugs as if the FDA labeled them with a legal indication as a vaccine,[39] or for their safety and efficacy.

C. State Action.

107. Shriners was a state actor in two ways – when it interacted with anyone regarding the drugs available under the CDC Program and when it acted in accordance with Massachusetts' State-enforced custom of allowing penalties to be imposed on potential recipients of the EUA/PREP Act investigational drugs.

108. Massachusetts voluntarily assumed responsibility for ensuring the implementation of the CDC Program within its jurisdiction on behalf of the USG.

[39] "A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." 21 C.F.R. §312.7

109. Massachusetts was under a constitutional duty to obtain Plaintiffs' legally effective informed consent anytime Plaintiffs were presented with an opportunity to use one of the federally owned INDs.

110. Massachusetts was legally obligated to ensure that all individuals were informed of their option to accept or refuse the INDs and to prevent any other person or entity from interfering with that right.

111. The CDC Program requires a person to voluntarily (1) become a human subject in federally funded research activities, (2) surrender their due process rights to bring a common law cause of action resulting from injury, (3) assume greater risks to their health and legal rights, (4) agree to the injection of investigational unlicensed drugs, (5) allow their private health information and data collected about their interaction with the drugs to be shared with unknown persons for unknown reasons for an unknown length of time.

112. Massachusetts is constitutionally prohibited from mandating a person to (1) subject themselves to biomedical research activities, (2) surrender their Fourteenth Amendment rights to bring a cause of action should the drugs injure them, (3) assume greater risks to their health, and legal rights, (4) inject investigational drugs into their bodies, (5) allow unwarranted governmental intrusion into their private lives, as a condition of enjoying public benefits. (*Perry v. Sindermann*, 408 U.S. 593, 92 S.Ct. 2694, 33 L.Ed.2d 570 (1972).)

113. Massachusetts could not issue a mandate requiring a person to forfeit their constitutional right to exercise their property interest under the CDC Program to refuse the INDs.

114. While Massachusetts was not required to engage private entities to perform the federal government's function of administering federally owned EUA/PREP Act investigational drugs under the CDC Program, it chose to do so under its exclusive authority.

115. Because Massachusetts agreed to perform the function of obtaining Plaintiffs' informed consent on behalf of the USG under the CDC Program, it was required to delegate that governmental function and its Fourteenth Amendment obligations to its recruited state actors, such as Shriners. See *West v. Atkins*, 487 U.S. 42, 56 (1988) (state cannot avoid constitutional obligations by delegating functions to private actors).

116. Massachusetts' responsibilities under the CDC Program, including obligations related to federally owned EUA/PREP Act investigational drugs, flowed through Massachusetts to Shriners via the Provider Agreement and the federal laws cited herein.

117. Therefore, under Supreme Court precedent, because Massachusetts owed Fourteenth Amendment obligations to its citizens, it could not allow a private party to participate in the CDC Program unless Massachusetts required that private party to administer the program in accordance with the Fourteenth Amendment.

118. Shriners was a state actor because it agreed to, and did, engage in joint action with the State and USG and thus owed Fourteenth Amendment obligations to Plaintiffs under the CDC Program.

119. Shriners was a state actor because it was in a symbiotic relationship with Massachusetts, where it was under a legal obligation to ensure that persons it offered the drugs to in any form (i.e., IND Mandate) were informed of their right to accept or refuse the drugs, and was further under a legal obligation to accept the individual's chosen option, with which Shriners had no discretionary authority to interfere.

120. Moreover, Shriners was already under a legal duty via its FWA agreement when it promised the USG that it would never place an individual under outside pressure to use federally funded INDs.

121. Shriners engaged in joint conduct with Massachusetts to help the State perform for the USG under the CDC Program, from which Shriners had no discretionary authority to deviate.

122. Shriners was under Massachusetts' complete control and authority anytime Shriners engaged in any activity related to the CDC Program.

123. Therefore, Shriners, acting under the Provider Agreement, assumed not only operational responsibilities but also constitutional obligations that Massachusetts owed in administering the federal program.

124. The USG owed Plaintiffs the constitutional right to refuse the INDs without penalty or pressure, which obligation was delegated to Massachusetts, who in turn delegated that duty to Shriners. This chain of delegated responsibilities and obligations preserves all constitutional protections for all potential recipients of the drugs available under the CDC Program.

125. Shriners' discretionary authority under the CDC Program consisted of determining when, where, and to whom it would administer the INDs, but Shriners was always under a ministerial duty to obtain an individual's legally effective informed consent.

126. Despite the CDC Program and applicable laws providing potential recipients with the right to accept or refuse the drugs without penalty or pressure, Massachusetts, owing Fourteenth Amendment obligations to all individuals, established a State-enforced custom whereby its recruited state actors could ignore their duties under the CDC Program and punish Plaintiffs should they refuse the EUA/PREP Act investigational drugs.

127. The use of official State policy to deny public benefits to Plaintiffs for the sole reason that they exercised their liberty interest under the CDC Program demonstrates a pervasive State-enforced custom subject to 42 U.S.C. §1983 remedy. See, *Adickes v. S. H. Kress & Co*., 398 U.S. 144 (1970); *Peterson v. City of Greenville*, 373 U.S. 244 (1963); *Burton v. Wilmington*

Parking Authority, 365 U.S. 715 (1961); *Wickersham v. City of Columbia*, 481 F.3d 591 (8th Cir. 2007).

128. Massachusetts had a duty to ensure its licensed medical facilities did not promote a drug outside of its legal indication[40], which Massachusetts refused to enforce under the CDC Program, establishing a custom in Massachusetts that the drugs were not investigational but rather approved by the FDA, which is false.

129. Massachusetts had a duty to ensure that no person was placed under outside pressure to use drugs subject to 45 CFR Part 46, which the CDC Program was. However, Massachusetts turned a blind eye to its legal duties and allowed its recruited state actors, such as Shriners, to mandate drugs that were undergoing clinical trials, labeled as investigational, and introduced into commerce only under emergency expanded access protocols of its employees, volunteers, vendors, and contractors, or whatever class of citizens the state actor mandated.[41]

130. Shriners was a state actor when acting upon a pervasive State-enforced custom that deprived Plaintiffs of their Fourteenth Amendment rights, which is subject to §1983 remedy.

D. 42 U.S.C. §1983 Traceability – Causation of Injury or Damage

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

[40] Massachusetts General Law – Part 1, Title XV, Chapter 94, Section 187
[41] Plaintiffs are not alleging that they were included in the clinical investigation. Rather, Plaintiffs allege that they were offered the same drugs that were undergoing clinical trials and were not FDA-licensed according to their labeling.

132. Shriners deprived Plaintiffs of a constitutional right because Shriners either engaged in an affirmative act (i.e., established the unlawful IND Mandate), participated in another's affirmative act (i.e., enforced the IND Mandate), or omitted to perform an act (i.e., obtain Plaintiffs' legally effective informed consent) it was legally required to perform that caused Plaintiffs' injuries.

133. Shriners Defendants, individually and/or collectively, signed the Provider Agreement, authorized Shriners to perform for Massachusetts under the CDC Program, issued a policy violating Shriners' promise to Massachusetts, and/or failed to perform the duty of accepting Plaintiffs' refusal of the EUA/PREP Act investigational drugs without penalty or pressure.

134. Shriners' IND Mandate unconstitutionally conditioned Plaintiffs' property rights and liberty interests under the CDC Program and applicable laws upon seeking a religious or disability exemption and deprived Plaintiffs of their statutorily conferred right to refuse, which was an unconstitutional requirement because Shriners deprived Plaintiffs' of their fundamental rights to refuse unwanted medical treatment and unwanted investigational drugs.

135. Shriners' establishment and enforcement of the IND Mandate is the direct and proximate cause of Plaintiffs' injuries.

136. Shriners required only persons refusing to inject the federally funded INDs to seek exemptions, engage in unwanted investigational medical testing, and/or be threatened with varieties of punishments, and Shriners ultimately only terminated the careers of those (i.e., Plaintiffs) who refused to surrender their Fourteenth Amendment rights guaranteed under the CDC Program.

137. The laws and legal precedents cited herein were clearly established at the time the IND Mandate was issued, and thus Shriners knew or should have known that the foregoing actions violated Plaintiffs' constitutional and federal rights.

FIRST CAUSE OF ACTION
Fourteenth Amendment—Due Process Clause
Deprivation of Federal Benefits
42 U.S.C. §1983

138. Plaintiffs have a liberty interest in exercising their property rights under the CDC Program.

139. Shriners, acting under color of law under the CDC Program, deprived Plaintiffs of the liberty interest afforded by the CDC Program.

140. The federal government's executive branch implemented the CDC Program and offered it to Plaintiffs under the authority and prerogative of the State of Massachusetts as an emergency public function.

141. The federally funded CDC Program provided Plaintiffs with the opportunity to enjoy a federal benefit[42] provided or administered by Massachusetts under its immunization cooperative agreement with the USG. Specifically, Plaintiffs' benefits included free medical counseling to learn of the drugs' risks, benefits, and alternatives and to be informed of their right to accept or refuse without costs, penalties, losing a benefit, and to enjoy the CDC Program's benefits without coming under outside pressure to use the CDC Program.

142. All drugs available under the CDC Program were authorized under the EUA Statute, and therefore, the option to accept or refuse was incorporated into the federally funded

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

program as a property right held by Plaintiffs subject to the Fourteenth Amendment's due process clause.[43]

143. Shriners placed Plaintiffs under threat of penalty should they refuse to participate in the CDC Program. When Plaintiffs refused, Shriners deprived Plaintiffs' of their Fourteenth Amendment rights by requiring them to seek exemptions, placing them under severe emotional duress fearing for their physical and financial safety, and ultimately terminating their careers.

144. Shriners acted recklessly and with moral turpitude when mandating nonconsensual participation in the CDC Program, disregarding Plaintiffs' benefits under the CDC Program and their health and safety involving unlicensed investigational new drugs.

145. The CDC Program requires strict adherence to 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)(the right to refuse), 45 C.F.R. Part 45 (Protection of Human Subjects), 10 U.S.C. §980 (Limitation on Use of Humans as Experimental Subjects), the Belmont Report, the Provider Agreement, EUAs, and the Fourteenth Amendment, all of which provide Plaintiffs with the liberty interest to refuse unwanted investigational drugs and medical treatment, and violations of that liberty interest are enforceable under §1983. *Health and Hospital Corporation of Marion Cty. v. Talevski*, 599 U.S. 166 (2023).

146. Additionally, 45 C.F.R. §46.122, 10 U.S.C. §980, and the CDC Program derive from spending legislation providing Plaintiffs with the right to refuse federally owned and funded INDs, which right is enforceable under §1983.

147. Shriners, acting under color of law under the CDC Program and while acting pursuant to Massachusetts' State-enforced custom of penalizing individuals who refused the drugs, engaged in a series of actions and/or omissions that deprived Plaintiffs' fundamental property right

[43] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)

to enjoy a benefit, service, privilege, program, facility, or activity provided or administered by the United States under Massachusetts' authority.

148. Shriners' transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such actions by others, and/or failures to perform legally mandated duties.

149. Shriners created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs' statutorily protected right to refuse.

150. This deprivation of a fundamental right guaranteed under the CDC Program constitutes a significant breach of Shriners' legal obligations when acting under color of law and is a deprivation of the Plaintiffs' Fourteenth Amendment right to refuse the CDC Program's services, necessitating judicial remedy for the damages described below.

SECOND CAUSE OF ACTION
Fourteenth Amendment—Due Process Clause
Unwanted Use of EUA Drugs
42 U.S.C. §1983

151. The Due Process Clause of the Fourteenth Amendment guarantees that no State shall "deprive any person of life, liberty, or property without due process of law." U.S. CONST. amend. XIV, §1, cl. 3.

152. Plaintiffs have a fundamental liberty interest in exercising their property rights under the EUA Statute's right to refuse.

153. Shriners acted pursuant to a State-enforced custom of penalizing individuals who refused the EUA drugs and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their liberty interest to refuse EUA drugs.

154. All drugs and devices available to Plaintiffs to comply with Shriners' IND Mandate were introduced into commerce under emergency use authorization pursuant to 21 U.S.C. §360bbb-3 (the EUA Statute).

155. The right to be informed of the risks, benefits, and alternatives of an EUA product without financial costs and to be free from outside pressure when considering whether to receive the drug are property interests created by Congress for Plaintiffs' benefit.

156. Plaintiffs' fundamental liberty interest of bodily autonomy is further strengthened by Congress mandating that the HHS Secretary establish conditions under which Plaintiffs are informed of their unqualified right to accept or refuse an unlicensed emergency use drug without penalty or pressure.

157. Plaintiffs are entitled to proceed pursuant to 42 U.S.C. §1983 to seek redress for deprivation of their property rights and liberty interests under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) because the right to refuse is a right conferred upon individuals by the EUA Statute and because the EUA Statute does not contain a remedial scheme for violations of those rights. See *Health and Hospital Corporation of Marion Cty. v. Talevski*, 599 U.S. 166 (2023).[44]

158. The Supreme Court holds that legislation conferring an unambiguous right for Plaintiffs is a "legitimate claim of entitlement" as defined in *Board of Regents of State Colls. v. Roth*, 408 U.S. 564, 576-77, 92 S.Ct. 2701, 33 L.Ed.2d 548 (1972), *overruled in part and on other grounds in Paul v. Davis*, 424 U.S. 693, 96 S.Ct. 1155, 47 L.Ed.2d 405 (1976), elevating the right to a protected property interest subject to the Due Process Clause.

[44] Plaintiffs specifically allege that this action is not a private right of action to enforce the EUA Statute. Rather, this action is a §1983 action for the deprivation of Plaintiffs' conferred rights listed in the EUA Statute.

159. Congress authorized only the HHS Secretary to establish emergency expanded access protocols under the EUA Statute but restricted the Secretary from requiring nonconsensual use of EUA drugs, and his authority is nondelegable.

160. Shriners is not the HHS Secretary and is not authorized to amend an EUA. Nor can it amend acts of Congress or misrepresent its authority when issuing the IND Mandate, establishing conditions conflicting with the EUA Statute, the EUA letters, and the required conditions mandated by Congress.

161. The requirement of all persons administering EUA drugs to ensure that Plaintiffs are informed of their right to accept or refuse under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) demonstrates that Congress unambiguously created a statutory entitlement specifically for "individuals" which is subject to the Due Process Clause and cannot be deprived outside of procedural due process.

162. Neither Massachusetts nor Shriners can constitutionally mandate what Congress prohibits – nonconsensual use of EUA drugs.

163. The Supremacy Clause prohibits Shriners from amending the EUA Statute and any EUA, which it did when establishing the IND Mandate punishing employees, contractors, and volunteers who refused the EUA drugs.

164. Shriners, choosing to offer Plaintiffs an opportunity to use products authorized only for emergency use, was under a duty by the USG and Massachusetts to ensure that:

> "All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling" and must "conspicuously [] state that: This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus."[45]

[45] See Exhibit C, August 23, 2021 EUA Letter, Sections X and Y

165. When issuing the IND Mandate, Shriners failed to perform the governmental function of informing Plaintiffs that the drugs were investigational and not approved or licensed by the FDA for any indication, or of the drug's risks, benefits, and alternatives, or of their right to accept or refuse them without penalty or pressure, or accept their freely given consent, all as required by the CDC Program and applicable federal laws.

166. Despite not being empowered to amend any EUA, Shriners did so when mandating nonconsensual use of EUA drugs and requiring Plaintiffs to seek a medical or religious exemption despite Plaintiffs already having the right to refuse the EUA products, thereby violating Plaintiffs' Fourteenth Amendment due process rights.

167. Shriners is not Congress, and it is not authorized to amend the Food, Drug, and Cosmetic Act ("FDCA") to establish a prohibited act under 21 U.S.C. §331 of refusing a drug not licensed under 21 U.S.C. §355, and only offered under 21 U.S.C. §360bbb-3, which Shriners did when establishing and enforcing the IND Mandate, nor can Shriners amend the EUA Statute to punish the option to refuse by creating a penalty under 21 U.S.C. §333.

168. The "option" is not subject to Shriners' authority; rather, Shriners is obligated to protect Plaintiffs' property rights under the statute on behalf of the State, which Shriners failed to do when establishing and enforcing the IND Mandate.

169. The drugs under Shriners' IND Mandate were listed as countermeasures under the PREP Act, which expressly preempted Shriners from issuing the official policy.

170. The PREP Act states that Shriners, acting under color of law, cannot establish or continue in effect with any legal requirement relating to "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")[46] (emphasis added). (42 U.S.C. §247d-6d(b)(8))

171. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) is under the FDCA and thus subject to the PREP Act's express preemption legal requirement.

172. Shriners was at all times material preempted from establishing a legal requirement conflicting with the option to refuse, which requirement nullified the constitutional authority of Congress to completely prohibit the nonconsensual use of federally owned EUA drugs.

173. Shriners willfully assumed the role as "vaccination provider" under any EUA requiring the "Organization"[47], as a state actor, to inform Plaintiffs of their right to refuse, which Shriners failed to perform by depriving that right from Plaintiffs when punishing them for exercising their right to refuse.

174. Shriners, acting under color of law, engaged in a series of actions and/or omissions that deprived Plaintiffs' fundamental right to refuse EUA investigational drugs without penalty or pressure.

175. Shriners' transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such acts by others, and/or failures to perform legally mandated duties.

176. Shriners created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs' statutorily protected right to refuse.

[46] 21 U.S.C. §301 *et seq*.
[47] The "Organization" is the person required to sign the Provider Agreement and thus, Shriners, as the "Organization," agreed to execute the conditions of authorization outlined under any EUA as required under "12(a)" of the Provider Agreement.

177. This deprivation of a fundamental right, guaranteed under the EUA Statute, constitutes a significant breach of Shriners' legal obligations when acting under color of law and a direct assault on Plaintiffs' Fourteenth Amendment property right to refuse EUA investigational drugs funded by the federal government, necessitating judicial remedy for the damages described below.

THIRD CAUSE OF ACTION
Fourteenth Amendment—Due Process Clause
Unwanted PREP Act Countermeasure
42 U.S.C. §1983

178. Plaintiffs have a liberty interest in exercising their right to refuse PREP Act countermeasures involving the Fourteenth Amendment's due process clause, which Shriners' actions deprived them of.

179. Shriners, acting under color of law relative to the PREP Act countermeasures under the CDC Program, deprived Plaintiffs of that liberty interest.

180. Shriners acted pursuant to a State-enforced custom of penalizing individuals who refused the PREP Act countermeasures and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their liberty interest to refuse PREP Act countermeasures.

181. All drugs and devices available to Plaintiffs to comply with Shriners' IND Mandate were listed as countermeasures under 42 U.S.C. §247d-6d ("PREP Act").

182. The PREP Act significantly impacts Plaintiffs' fundamental legal rights, particularly in the context of the Fourteenth Amendment's Due Process Clause. This legislation places considerable restrictions on individuals' ability to pursue various common-law causes of action, including product liability claims, medical malpractice suits, fraud allegations, and battery charges. Moreover, the Act limits Plaintiffs' capacity to seek tort remedies for bodily harm inflicted by other members of society if related to PREP Act countermeasures, and constrains their

right to be made whole for financial damages and emotional distress. These restrictions deprive Plaintiffs' fundamental rights under the Due Process Clause of the Fourteenth Amendment.

183. It is crucial to note that the Fourteenth Amendment sets a stringent standard for due process rights. According to this constitutional provision, if even a single due process right is denied to Plaintiffs under the PREP Act, it triggers the fundamental protections enshrined in the Fourteenth Amendment's Due Process Clause. This interpretation underscores the gravity of any infringement on individual rights, even if it occurs in isolation, and clearly demonstrates why Congress requires the HHS Secretary to "ensure…that potential participants are educated with respect to …the voluntary nature of the program…" 42 U.S.C. §247d-6e(c)

184. The PREP Act itself does not deprive a person of their Fourteenth Amendment rights since that right must be voluntarily surrendered under the Act. It was Shriners' IND Mandate issued pursuant to a State-enforced custom, and Shriners' threat and enforcement of penalty, that deprived Plaintiffs of their fundamental rights by penalizing the option of refusing PREP Act countermeasures (i.e., Pfizer-BioNTech COVID-19 Vaccine and masking devices), thus penalizing Plaintiffs for refusing to surrender their fundamental due process rights under the Fourteenth Amendment.

185. In *Logan v. Zimmerman Brush Co*., 455 U.S. 422 (1982), the Supreme Court held,

> The hallmark of property is an individual entitlement grounded in state law, which cannot be removed except "for cause," and appellant's right shares this characteristic.
>
> * * *
>
> The first question, we believe, was affirmatively settled by the *Mullane* case itself, where the Court held that a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause.

See also, Tulsa Prof. Collection Svcs. v. Pope, 485 U.S. 478 (1988); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985).

186. The Act's significant forfeiture of a person's due process rights must result from voluntary surrender, not mandatory compulsion. Congress unambiguously preempted Massachusetts and Shriners from interfering with that due process right, stating

> "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 counter-measure 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")[48] (emphasis added). (42 U.S.C. §247d-6d(b)(8))

187. Massachusetts' State-enforced custom of penalizing individuals who refused the PREP Act countermeasures and EUA drugs is a legal requirement that is "different from, or is in conflict with" the voluntary nature of a PREP Act program and the right to refuse under the EUA Statute.

188. Shriners, as a state actor under the CDC Program and while acting pursuant to Massachusetts' State-enforced custom of penalizing individuals who refused the PREP Act countermeasures, is not authorized to constitutionally mandate that Plaintiffs surrender their fundamental right to due process as required under the PREP Act. Therefore, the IND Mandate and its enforcement violated plaintiffs' Fourteenth Amendment substantive due process right when Shriners punished Plaintiffs for refusing to surrender that right without providing Plaintiffs with a hearing before an impartial decision maker.

[48] 21 U.S.C. §301 *et seq*.

189. Under the PREP Act's express preemption language, the right to refuse (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)) is incorporated into the PREP act because it is a "requirement applicable to the covered countermeasure" under the FDCA and is a property interest enforceable under §1983. *Health and Hospital Corporation of Marion Cty. v. Talevski*, 599 U.S. 166 (2023).

190. Moreover, Shriners' requirement that Plaintiffs use a PREP Act countermeasure is an unconstitutional condition requiring Plaintiffs to surrender their fundamental right to due process (i.e., access to the courts to file common law tort actions in the event of injury) guaranteed to them under the Fourteenth Amendment.

191. Despite the Supreme Court holding that a public entity cannot "produce a result which it could not command directly,"[49] Massachusetts used Shriners to accomplish a result that Massachusetts could not command directly: involuntary surrender of Plaintiffs' Fourteenth Amendment due process rights to bring common law causes of action should they incur injury from the PREP Act countermeasure.

192. Therefore, neither Massachusetts nor Shriners can constitutionally mandate that Plaintiffs use a PREP Act countermeasure as a condition of enjoying a public benefit (i.e., using their State-issued healthcare licenses).

193. The PREP Act expressly preempts interference in Plaintiffs' option to accept or refuse under the EUA Statute.

194. Shriners, acting under color of law under the CDC Program and while acting pursuant to Massachusetts' State-enforced custom of penalizing individuals who refused the PREP Act countermeasures, engaged in a series of actions and/or omissions that deprived Plaintiffs of their fundamental right to refuse PREP Act countermeasures without penalty or pressure.

[49] *Perry v. Sindermann*, 408 U.S. 593 (1972) quoting *Speiser v. Randall*, 357 U.S. 513 (1958)

195. Shriners' transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such actions by others, and/or failures to perform legally mandated duties.

196. Shriners created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs' statutorily protected right to refuse.

197. This deprivation of a fundamental right to refuse, guaranteed under the PREP Act and its express preemption language, constitutes a significant breach of Shriners' legal obligations when acting under color of law and is a deprivation of Plaintiffs' Fourteenth Amendment right to refuse PREP Act countermeasures, necessitating judicial remedy for the damages described below.

FOURTH CAUSE OF ACTION
Fourteenth Amendment—Due Process Clause
Unwanted Investigational Drugs and Unwanted Medical Treatment
42 U.S.C. §1983

198. The Due Process Clause of the Fourteenth Amendment guarantees that no State shall "deprive any person of life, liberty, or property without due process of law." U.S. CONST. amend. XIV, §1, cl. 3.

199. Plaintiffs have a fundamental liberty interest to refuse unwanted investigational drugs and unwanted medical treatments.[50]

200. Shriners acted pursuant to a State-enforced custom of penalizing individuals who refused the investigational drugs and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their liberty interest to refuse unwanted investigational drugs and unwanted medical treatments.

[50] *Cruzan, supra; Albright, supra*; *Washington v. Glucksberg*, *supra*; *Missouri v. McNeely*, 569 U.S. 141, 148 (2013).

201. Shriners' *discretionary* authority relating to Plaintiffs was limited to presenting the offer to be administered federally funded investigational drugs. Shriners was under a *ministerial* duty to accept Plaintiffs' freely given consent pursuant to its FWA.

202. Shriners' enactment and enforcement of the IND Mandate deprived Plaintiffs of their fundamental right to give their legally effective informed consent.

203. The right to refuse unwanted investigational drugs is "deeply rooted" and "implicit in the concept of ordered liberty," such that "neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, *supra*.

204. Shriners recklessly and with willful and wanton disregard for Plaintiffs' health,[51] safety, and legal rights, failed to perform the ministerial function of obtaining Plaintiffs' legally effective informed consent; rather, Shriners punished Plaintiffs when they exercised their right to refuse, which conduct was outside the scope of Shriners' authority.

205. Shriners, acting under color of law, engaged in a series of actions and/or omissions that deprived Plaintiffs of their fundamental right to refuse investigational drugs and unwanted medical treatments without penalty or pressure.

206. Shriners' transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such acts by others, and/or failure to perform legally mandated duties.

207. Shriners created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs of their constitutionally protected right to refuse investigational drugs and unwanted medical treatments.

[51] 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) severe injuries for the new and unvetted mRNA drugs listed under Shriners' IND Mandate.

208. This deprivation of a fundamental right, guaranteed under the aforementioned federal statutes and constitutional provisions, constitutes a significant breach of Shriners' legal obligations when acting under color of law and is a direct assault on Plaintiffs' Fourteenth Amendment right to refuse unwanted investigational drugs and unwanted medical treatments, necessitating judicial remedy for the damages described below.

FIFTH CAUSE OF ACTION
Fourteenth Amendment—Equal Protection Clause
Deprivation of Equal Protection Rights
42 U.S.C. §1983

209. The Equal Protection Clause of the Fourteenth Amendment, U.S. CONST. amend. XIV, §1, cl. 4, guarantees Plaintiffs equal protection of the laws, "which is essentially a direction that all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985).

210. Plaintiffs have a fundamental liberty interest in being treated equally before the law.

211. Shriners was a state actor under the CDC Program and acted pursuant to a State-enforced custom of penalizing individuals who refused the EUA drugs and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their fundamental liberty interest in being treated equally before the law.

212. Shriners deprived Plaintiffs of that liberty interest.

213. When a government action resulting in an equal protection claim interferes with the exercise of a fundamental right, the government must satisfy strict scrutiny. *Nat'l Rifle Ass'n of Am., Inc. v. McCraw*, 719 F.3d 338, 350 (5th Cir. 2013).

214. Plaintiffs are similarly situated to other citizens who were given the same opportunity to be injected with the federally funded INDs.

215. Alternatively, Plaintiffs assert a "class of one" equal protection claim. They are licensed healthcare workers similarly situated as all other healthcare workers in Massachusetts.

216. Plaintiffs were denied the equal protection of the laws when Shriners punished Plaintiffs' option to refuse under the EUA Statute (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)), CDC Program, and 45 C.F.R. §46.116, but did not punish other healthcare workers choosing the equal option to accept.

217. Plaintiffs were denied the equal protection of the laws when Shriners punished their right to refuse the INDs but did not punish other healthcare workers who chose to accept the INDs.

218. Plaintiffs were denied equal protection of the laws when Shriners punished Plaintiffs who chose not to use the federally funded CDC Program but did not punish other healthcare workers who chose to participate.

219. Shriners knew that persons acting on behalf of the USG as vaccination providers under the CDC Program were required to ensure that no person was under outside pressure to use the INDs and was required to ensure that the options to accept and to refuse were treated equally without discrimination against one option.

220. Shriners, acting under color of law under the CDC Program and while acting pursuant to Massachusetts' State-enforced custom of penalizing individuals who refused the drugs, engaged in a series of actions and/or omissions that unlawfully infringed upon Plaintiffs' fundamental Fourteenth Amendment right to Equal Protection of Laws described above.

221. Shriners' transgressions include affirmative and direct individual and collective acts, participation in or facilitation of such actions by others, and/or failures to perform legally mandated duties.

222. Shriners created an environment of undue pressure through threats and enforcement of unlawful penalties, discriminating against Plaintiffs for their statutorily protected choice to refuse.

223. This deprivation of the Fourteenth Amendment Equal Protection of Laws constitutes a significant breach of Shriners' constitutional obligations when acting under color of law. They are a direct assault on Plaintiffs' Fourteenth Amendment rights, necessitating judicial remedy for the damages described below.

SIXTH CAUSE OF ACTION
Fourteenth Amendment—Right To Privacy
Deprivation of Right to Privacy
42 U.S.C. §1983

224. The Fourteenth Amendment provides Plaintiffs with a fundamental liberty interest in the right of privacy from unwanted, unwarranted, and unjustified governmental intrusion. *Griswold v. Connecticut*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965).

225. Plaintiffs have a fundamental right of privacy.

226. Shriners was a state actor under the CDC Program and acted pursuant to a State-enforced custom of penalizing individuals who refused the EUA drugs [ACCURATE?] and thus acted under color of law when it issued an IND Mandate that deprived Plaintiffs of their fundamental right to privacy.

227. Shriners, acting under color of law, deprived Plaintiffs of that right.

228. Plaintiffs have a legally protected interest in their bodily integrity and whether to receive investigational or non-investigational medical treatments.

229. Moreover, Plaintiffs have the fundamental right to refuse public disclosure of their private health information as required by the CDC Program. Specifically, the CDC Program required Plaintiffs to disclose their private identifiable and health information to the authorized

vaccination provider that it, the USG, and the drugs' manufacturer could use for unknown purposes and length of time. Shriners is not authorized to condition the right to enjoy the benefits of a federal program they conduct on behalf of Massachusetts upon Plaintiffs' publicly disclosing their private health information.

230. Shriners, acting under color of law, continually invaded Plaintiffs' privacy by demanding that Plaintiffs inform Shriners when, where, and from whom Plaintiffs were or were not injected with investigational drugs.

231. Plaintiffs have a liberty interest in refusing to become human subjects in the federally funded research activities required under the CDC Program. Specifically, the CDC Program required the drug manufacturer, Massachusetts, and the State's vaccination providers to monitor and report adverse events that individuals encounter with the investigational drugs which constitute becoming a human subject pursuant to 45 CFR §§46.102(e)(1), 46.102(e)(5), and 46.102(l).

232. Plaintiffs possess a liberty interest in refusing the collection, study, sharing, and usage of data concerning their involvement with the CDC Program and any adverse reactions to the Investigational New Drugs (INDs). This privacy interest extends to protecting their information from being handled by unspecified individuals for undisclosed purposes and for an indefinite period, as mandated under the CDC Program.

233. Massachusetts used Shriners to invade Plaintiffs' right to privacy from governmental intrusion[52] when it allowed Shriners to engage in its State-enforced custom to establish and enforce the IND Mandate.

[52] *Griswold v. Connecticut, supra*.

234. Shriners had no authority to invade the privacy of Plaintiffs when they were considering whether to receive investigational drugs or unwanted medical treatments; nor did Shriners have authority to mandate that Plaintiffs disclose such private health information under threat of penalty. This form of governmental invasion by Massachusetts through its state actors is precisely what the Supreme Court addressed in *Griswold*, *supra*.

235. Shriners has no authority to compel Plaintiffs to subject themselves to federally funded research activities and assume greater health risks than they would be subjected to by contracting the virus that Shriners' IND Mandate purported to prevent.

236. Shriners has no authority to legally mandate disclosure of Plaintiffs' private health information to be used for undisclosed legal purposes.

237. Shriners, acting under color of law, engaged in a series of actions and/or omissions that unlawfully infringed upon Plaintiffs' fundamental Fourteenth Amendment right to Privacy as described above.

238. Shriners' transgressions include affirmative and direct individual acts, participation in or facilitation of such actions by others, and/or failures to perform legally mandated duties.

239. Shriners created an environment of undue pressure through threats and enforcement of unlawful penalties, depriving Plaintiffs' statutorily protected right to enjoy Fourteenth Amendment Privacy protections.

240. This deprivation of the Fourteenth Amendment right to privacy constitutes a significant breach of Shriners' constitutional obligations when acting under color of law. They are a direct assault on Plaintiffs' Fourteenth Amendment rights, necessitating judicial remedy for the damages described below.

SEVENTH CAUSE OF ACTION
Unlawful Termination

241. Massachusetts has a general law that an employment relationship is terminable by either the employee or employer without notice for almost any reason. *Jackson* v. *Action for Boston Community Dev., Inc.,* 403 Mass. 8, 9 (1988).

242. An exception to this at-will employment law is that an employer may not terminate an employee if that termination is contrary to a well-defined public policy.

243. Thus "[r]edress is available for employees who are terminated for asserting a legally guaranteed right (e.g., filing workers' compensation claim), for doing what the law requires (e.g., serving on a jury), or for refusing to do that which the law forbids (e.g., committing perjury)." *Smith-Pfeffer* v. *Superintendent of the Walter E. Fernald State Sch.,* 404 Mass. 145 at 149-150 (1989).

244. "To qualify as an exception to the general rule, '[t]he public policy must be well defined, important, and preferably embodied in a textual law source.' *Ryan v. Holie Donut, Inc*., 82 Mass. App. Ct. 633, 636 (2012). *See Mello v. Stop & Shop Cos*., 402 Mass. 555, 557 (1988) (public policy must be 'sufficiently important and clearly defined')." *Meehan v. Medical Information Technology*, 488 Mass. 730, 177 N.E.3d 917 (2021)

245. Massachusetts agreed to perform on behalf of the USG under the CDC Program to obtain Plaintiffs' legally effective informed consent.

246. Massachusetts, under its prerogative, agreed to the express preemption language under the PREP Act when agreeing to use covered countermeasures which states:

> "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 counter-measure 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")[53] (emphasis added). (42 U.S.C. §247d-6d(b)(8))

247. Massachusetts cannot continue in effect with its at will employment law when the use of the law is to solely "enforce" a legal requirement that "conflict[s]" with the option to accept or refuse, a "requirement applicable" under the FDCA (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)), an option the State agreed to protect on behalf of the USG.

248. The Supremacy Clause preempts Massachusetts from using its at will employment law to conflict with the federal goal of introducing into commerce unlicensed drugs during a nationally declared emergency only under voluntary conditions.

249. Massachusetts agreed to ensure that the CDC Program would be offered to the public on behalf of the USG only under voluntary conditions.

250. Massachusetts owes the public Fourteenth Amendment duties relating to the CDC Program.

251. Shriners prospectively agreed to administer the CDC Program to the public on behalf of the State and could not establish a policy conflicting with the State program, which Massachusetts was legally obligated to ensure was lawfully implemented on behalf of the USG.

252. The public policy that no person can be compelled to use unlicensed investigational new drugs under federally funded research conditions is well defined in Massachusetts.[54]

253. The CDC Program requires a person to forfeit their fundamental right to privacy by publicly disclosing their private health information and their interaction with the drugs to unknown

[53] 21 U.S.C. §301 *et seq*.
[54] Exhibit G, Massachusetts IRB Protocol.

persons for unknown reasons and length of time. Massachusetts and its recruited state actor, Shriners, were under a ministerial duty to accept Plaintiffs' chosen option under the CDC Program. Upon Plaintiffs exercising their statutory and programmatic property rights to refuse, Shriners no longer had the authority to invade Plaintiffs' privacy by requiring nonconsensual use of the drugs and involuntary disclosure of their private identifiable information. Shriners cannot use the State's at will employment law to punish Plaintiffs for refusing to participate in a federal program requiring loss of privacy. Massachusetts General Law, Chapter 214, Section 1B is an unambiguous public policy that "[a] person shall have a right against unreasonable, substantial or serious interference with his privacy."

254. Plaintiffs have a fundamental right under the Fourteenth Amendment and Massachusetts General Law, Chapter 214, Section 1B to determine whether to participate in a federal program, receive an investigational medical treatment, or use a PREP Act countermeasure without being punished for exercising that right under the State's at-will employment law.

255. Massachusetts Constitution Part 1, Article XI

> Every subject of the commonwealth ought to find a certain remedy, by having recourse to the laws, for all injuries or wrongs which he may receive in his person, property, or character. He ought to obtain right and justice freely, and without being obliged to purchase it; completely, and without any denial; promptly, and without delay; conformably to the laws.

256. The State cannot use the PREP Act in conjunction with its at will employment law as a procedural device (*Perry v. Sindermann*, 408 U.S. 593 (1972) quoting *Speiser v. Randall*, 357 U.S. 513 (1958)) to deprive an individual of his right to bring a common law cause of action if injured by another member of society under the CDC Program. Such loss of rights must come from voluntary participation, not mandatory forfeiture.

257. Shriners' IND Mandate required Plaintiffs to commit fraud against the USG. A COVID-19 Provider must obtain Plaintiffs' legally effective informed consent, meaning Plaintiffs must only participate after giving their legally effective informed consent to obtain the government benefit. Shriners' IND Mandate required Plaintiffs to obtain federally owned drugs "under fraudulent pretenses" (i.e., lying to the provider that Plaintiffs are providing legally effective informed consent when in fact they are doing so under threat of penalty).

258. Shriners unlawfully discharged Plaintiffs in violation of "well defined" and "important" public policy. *Smith-Pfeffer* v. *Superintendent of the Walter E. Fernald State Sch., supra.*

SEVENTH CAUSE OF ACTION
Intentional Infliction of Emotional Damage

259. When Plaintiffs exercised their right to refuse the EUA/PREP Act COVID-19 investigational drugs, Shriners engaged in a scorched-earth policy and inflicted, with malicious intent, emotional distress to the fullest extent that one in their positions of authority and power could inflict, all to the detriment of Plaintiffs' emotional well-being.

260. Shriners has long used drugs classified as investigational and knew, or should have known, that it is not authorized to punish a person for refusing the drugs.

261. Shriners promised the USG it would never place an individual under coercion, unjustifiable pressures, sanctions, or undue influence to use federally owned INDs, which Shriners' IND Mandate did. Moreover, Shriners placed Plaintiffs under moral duress to compel them to surrender their Fourteenth Amendment right to refuse the INDs, which conduct was committed with reckless and wanton disregard for Plaintiffs' safety, health, and rights.

262. Shriners' conduct, committed with gross negligence, recklessness, or intent, as described above, gives rise to a claim of outrageous conduct and intentional infliction of emotional

distress under the common law of the State of Massachusetts against Shriners for the damages described below.

VII. Damages Recoverable and Demanded

263. As a direct and proximate result of the Shriners' 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 Shriners is liable in compensatory, legal, equitable, and all other damages that this Court deems necessary and proper.

264. When a defendant's behavior reaches a sufficient threshold, which occurred in this case regarding Shriners Defendants, in their individual capacities, punitive damages are recoverable in §1983 cases. *Smith v. Wade*, 461 U.S. 30 (1983)

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

VIII. Jury Trial Demand

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

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

Dated: November 29, 2024

Respectfully submitted,

/s/ Brian Unger
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