UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

BRENDA HORSLEY *et al,*	*	
	*	
Plaintiffs,	*	
	*	
VERSUS	*	CIVIL ACTION
	*	
KAISER FOUNDATION HOSPITALS, INC	*	
GREG ADAMS, ANDREW BINDMAN, MD,	*	
TOMAS ARAGON, AND GOV. GAVIN	*	
NEWSOM	*	
Defendants,	*	

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

COMPLAINT
(JURY TRIAL REQUESTED)

NOW INTO COURT, through undersigned counsel, come Plaintiffs, Brenda Horsley, *et al*, (hereinafter "Plaintiffs"), who file this Complaint against Defendants, Kaiser Foundation Hospitals, Greg Adams, CEO of Kaiser Foundation Hospitals, Inc., Andrew Bindman MD, CMO of Kaiser Foundation Hospitals, Tomas Aragon, Director and State Public Health Officer for the California Department of Public Health, and Gov. Gavin Newsom (hereinafter "Defendants[1]"), presenting allegations and causes of action as follows:

DESCRIPTION OF CAUSE OF ACTION

This is a §1983 case seeking redress from Defendants for the deprivation of Plaintiffs' Constitutional and federal statutory right to refuse an EUA investigational drug without incurring a penalty or loss of benefits to which Plaintiffs were otherwise entitled.

[1] Kaiser, its CEO Greg Adams, and its CMO Andrew Bindman, MD, will be collectively referred to as "Kaiser PolicyMakers."

This lawsuit is being brought under 42 U.S.C. §1983 seeking redress for deprivation of rights granted to Plaintiffs by the United States Constitution, 21 U.S.C. §360bbb-3 *et seq* (the EUA statute), 42 USC §247d-6d *et seq* (the PREP Act), 45 CFR Part 46, 18 U.S.C. §242, ICCPR Treaty, and the common laws of the State of California to hold accountable Kaiser Foundation Hospitals, Inc., a State Actor at all times pertinent herein, and its PolicyMakers, the Chief Executive Officer (CEO) Greg Adams, Chief Medical Officer (CMO) Andrew Bindman, MD, Tomas Aragon, Director and State Public Health Officer for the California Department of Public Health, and Gov. Gavin Newsom, for damages arising out of their unconstitutional, unlawful, malicious, unequal and contractually violative COVID-19 investigational drug mandate. Special laws apply to the drugs designated for compliance with Governor Newsom's and Kaiser's vaccine mandates because the FDA defines the available drugs as "investigational with no license for any indication." And even though Defendants' mandates were instituted during and in response to a pandemic emergency, as the U.S. Supreme Court noted since the beginning of the pandemic: "**even in a pandemic, the Constitution cannot be put away and forgotten**." *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct. 63, 208 L.Ed.2d 206 (2020).

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I. Introduction

1. In early 2020, the nation and the world faced a novel coronavirus called SARS-CoV-2, which caused the highly contagious disease COVID-19.

2. On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency. The President declared a national emergency on March 13, 2020, of which led to the development of investigational new drugs designed to perform as a vaccine from the virus, i.e., cause the body to produce antibodies to the virus so that the person is immune from infection when exposed to the true virus.

3. To implement the nationwide distribution and administration of these investigational new drugs, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization pursuant to 21 U.S.C. 360bbb-3 (Section 564 of the Food, Drug & Cosmetic Act.)

4. The FDA made clear on its website:

> FDA believes that terms and conditions of an EUA issued under Section 564 preempt state or local law, both legislative requirement and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564…**In an emergency, it is critical that the conditions** that are part of the EUA or an order or waiver issued pursuant to section 564A – those that FDA has determined to be necessary or appropriate to protect public health – **be strictly followed**, and no additional conditions be imposed. (Emphasis added)

5. In August 2020, the Centers for Disease Control (CDC) published the transcript of a meeting of the Advisory Committee on Immunizations and Respiratory Diseases, at which Dr. Amanda Cohn stated (@1:14:40):

> I just wanted to add that, just wanted to remind everybody, that **under an Emergency Use Authorization, an EUA, vaccines are not allowed to be mandatory**. So, early in the vaccination phase, individuals will have to be **consented** and **they won't be able to be mandated.** (Emphasis added)

6. In August 2021, Gov. Newsom usurped the authority of the United States Congress by issuing a Health Order in defiance of federal law when he mandated the use of investigational new drugs by healthcare workers. Additionally, Gov. Newsom engaged in outrageous tyrannical conduct by mandating that healthcare facilities deny employment to healthcare workers who exercised their federal statutory right to refuse investigational drugs.

7. Kaiser PolicyMakers decided that the suffering of the few was justified by the windfall such suffering had on Kaiser's financial bottom line. Thus, Kaiser PolicyMakers prescribed their own "required conditions" in defiance of Congress and the rights of individuals under Defendants' authority as secured by the Constitution.

8. In August of 2021, Kaiser PolicyMakers issued a despicable illegal mandate that shocked the conscience. During the height of the pandemic, when hospitalization rates soared, and SARS-CoV-2 variants abounded, and in direct contravention to federal law governing investigational drugs, Kaiser PolicyMakers subjected a workforce of more than 200,000 people to investigational drug use under threat of penalty and outside of their free will and voluntary consent. Should those individuals not comply with Kaiser PolicyMakers' fraudulent usurpation of authority, they would be segregated, penalized, humiliated, terminated, and denied unemployment benefits, thus depriving Plaintiffs of their Constitutional and federal statutory right to refuse an investigational drug without penalty.

9. Gov. Newsom used his office as official cover in hopes of obtaining for himself immunity from liability in future legal actions. Similarly, attempting to hide behind the PREP Act as a liability cover, Kaiser PolicyMakers willfully chose to engage in violations of federal law.

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 pursuant to 28 U.S.C. 1367.

15. This Court has personal jurisdiction over Defendants 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 Defendants in the State of California 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 California, which is situated within this Court's jurisdiction, and all Defendants are domiciled in the State of California.

III. Plaintiffs

18. The following individuals are plaintiffs herein:

18.1. Plaintiff, Brenda Horsley, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.2 Plaintiff, Cynthia Anderson, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.3 Plaintiff, Maria Samantha De La Cruz, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.4. Plaintiff, Jeff Folkes, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.5. Plaintiff, Michael Jang, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.6. Plaintiff, Vincent Lanchinebre, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.7. Plaintiff, Michelle Massa, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.8 Plaintiff, Joshua Pacheco, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.9. Plaintiff, Justin Rawson, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.10. Plaintiff, Daniel Ruvalcaba, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.11. Plaintiff, Patricia Underhill, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

18.12. Plaintiff, Courtney Wolfenstein, is an adult individual who all times pertinent resided in the State of California, and was previously an employee of Kaiser in California.

IV. <u>Defendants</u>

19. The following are named as defendants herein:

19.1. Defendant, Kaiser Foundation Hospitals, is a non-profit, public-benefit corporation formed according to the laws of the State of California and headquartered in Oakland, California. It operates 39 hospitals and more than 700 medical offices, with over 300,000 personnel, including more than 87,000 physicians and nurses across the country.

19.2. Defendant, Greg Adams, was at all times pertinent, the Chief Executive Officer and PolicyMaker of Kaiser Foundation Hospitals 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 Kaiser. Mr. Adams is named as a defendant in his official and individual capacities.

19.3. Defendant, Andrew Bindman, MD, was at all times pertinent, the Chief Medical Officer and PolicyMaker of Kaiser Foundation Hospitals 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 Kaiser. Dr. Bindman is named as a defendant in his official and individual capacities.

19.4. Defendant, Tomas J. Aragon, was at all times pertinent, the Director and State Public Health Officer for the California Department of Public Health, and is an individual of the full age of majority and a resident of California. Mr. Aragon is named as a defendant in his official and individual capacities.

19.5. Defendant Gavin Newsom is the Governor of the State of California. Mr. Newsom is named as a defendant in his official and individual capacities.

V. History and Facts

20. Plaintiffs make no assertions regarding whether it is lawful for a public or private entity to mandate a ***licensed*** vaccine. Plaintiffs' allegations herein only relate to Defendants'

mandating the use of drugs, biologics, and devices that are authorized under 21 U.S.C. §360bbb-3 (the EUA statute) and the PREP Act.

21. Plaintiffs adamantly assert that an individual has the absolute Constitutional and federal statutory right to refuse the administration of an Emergency Use Authorization (EUA) drug (e.g., Pfizer BioNTech COVID-19 Vaccine), biologic, or device (e.g., EUA testing articles and masks) or a "covered countermeasure" under PREP Act immunity without incurring a penalty or losing a benefit to which they are otherwise entitled and that such a right is not dependent upon a person seeking a religious or medical exemption.

22. Because the EUA statute was created to allow the Secretary of HHS to authorize the use of a product for a purpose for which it is not already licensed, 21 U.S.C. §360bbb-3 products fall under the investigational classification by statute.[2]

23. This classification was illustrated in the May 10, 2021, Scope of Authorization letter issued to Pfizer, Inc. wherein the FDA advised Pfizer that its product is "an investigational vaccine not licensed for any indication." The same is true for the Moderna and Jannsen injections.

24. Because EUA products are, by definition, used only during times of emergency, the laws regulating these products are not litigated as much as more commonly used statutes, so a brief recitation of the origin and history of these laws is in order.

25. The laws regulating the investigational new drug industry were largely created after Senator Edward Kennedy held live hearings in 1973 detailing the industry's abuses against the American people. In 1974, Congress enacted the National Research Act[3] in response to those

[2] 21 U.S.C. §360bbb-3(a)(2)(A) and (B)
[3] Public Law 93-348-July 12, 1974 National Research Act

hearings, establishing laws, regulations, and mandatory guidelines to protect Americans from future abuses.

26. The 1974 National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research[4] (hereinafter referred to as the "Commission").

27. Congress required the Commission to:

A. "conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects,"

B. "develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles," and

C. "make recommendations to the [HHS] Secretary" for "such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary."

28. Congress further required the Commission to consider "the nature and definition of informed consent in various research settings."[5]

29. On April 18, 1979, the Commission published its findings in the Federal Register in a report titled, "The Belmont Report."[6]

A. <u>The Belmont Report</u>

30. The Belmont Report outlined what the Commission considered "the nature and definition of informed consent" as follows:

A. "An autonomous person is an individual capable of deliberation about personal goals and acting under the direction of such deliberation. To

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[4] Title II of the National Research Act - https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf

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

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

respect autonomy is to give weight to autonomous persons 'considered opinions and choices while refraining from obstructing their actions…" (Emphasis added);

B. "To show lack of Respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments…"(Emphasis added);

C. "Respect for persons requires subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied" (Emphasis added).

31. The Belmont Report defined those adequate standards of informed consent as follows:

A. An agreement to participate in research constitutes valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence; (Emphasis added)

B. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance;

C. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable;

D. Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject," (emphasis added), and;

E. …undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

32. The Commission determined that if an individual is under outside pressure to participate in an investigational medical activity, then obtaining that individual's informed consent was legally impossible.

33. Congress mandated in the National Research Act that "[i]f the Secretary determines that administrative action recommended by the Commission should be undertaken by him, he shall undertake such action as expeditiously as is feasible."

34. Congress required the HHS Secretary to act upon the Commission's recommendations as outlined in the Belmont Report by establishing regulations to protect humans involved in biomedical research activities. **Therefore, given the complexity, the intent of Congress was not to draft those laws but to allow the HHS Secretary to promulgate regulations on its behalf** to protect humans involved with investigational drugs. Therefore, these regulations are unique in that they were expressly requested by Congress to fulfill the intent of Congress via the National Research Act.

35. In the early 1980s, HHS acted upon the Commission's recommendations, stating, "Based on the Belmont Report and other work of the National Commission, HHS revised and expanded its regulations for protecting human subjects…The HHS regulations are codified at 45 Code of Federal Regulations (CFR) 46, subparts A through D."[7]

B. <u>45 CFR Part 46</u>

36. 45 CFR Part 46 is entitled, "Protection of Human Subjects." Subpart A is entitled, "Basic HHS Policy for Protection of Human Research Subjects" and establishes that (a) the policy

[7] 45 CFR 46 FAQs. HHS.gov. Published 2018. Accessed May 18, 2023. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html

(for protection of human research subjects) "applies to **all research**[8] involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency..." (Emphasis added).[9]

37. HHS designed a very broad definition of research when, at 45 CFR § 46.102 (Definitions): "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes"[10] (emphasis added). Research under this policy includes medical chart reviews by students or periodic studies of medical products under 21 U.S.C. §360bb-3 authorization.[11]

38. A "human subject" is broadly defined as (1) a living individual, (2) from whom data is obtained and used,[12] and (3) from whom identifiable private information is known.[13]

39. HHS regulations define[14] the term "human subject" at 45 CFR 46.102(e) as follows:

> (1) ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research:

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[8] Research under 45 CFR Part 46 includes clinical trials but is not limited in scope to only clinical trials. College students studying medical charts of patients constitutes "research" requiring 45 CFR Part 46 adherence.

[9] 45 CFR 46.101(a)

[10] 45 CFR 46.102(l)

[11] https://www.hhs.gov/ohrp/sites/default/files/human-subject-regulations-decision-charts-2018-requirements.pdf

[12] 45 CFR 46.102(e)(1)(i)

[13] 45 CFR 46.102(e)(1)(ii)

[14] " Coded Private Information or Biospecimens Used in Research (2018)." HHS.gov. Published January 19, 2018. https://www.hhs.gov/ohrp/coded-private-information-or-biospecimens-used-research.html#:~:text=Identifiable%20private%20information%20is%20private,is%20associated%20with%20the%20information (Last accessed June 5, 2023)[**PRACTICE NOTE**: If the hyperlink does not work, cut and paste the entire three-line link into a web browser and hit enter.]

(i) Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) ***Intervention*** includes physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) ***Interaction*** includes communication or interpersonal contact between investigator and subject.

(4) ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(5) ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the information.

(6) ***An identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the biospecimen. (Emphasis in original.)

40. Congress drafted broad definitions for "research" and "subjects" to comply with the recommendations of the Belmont Report, which declared that "the general rule is that if there is <u>any element</u> of research in an activity, that activity should undergo review (third-party review to ensure the health and rights of involved individuals are protected) for the protection of human subjects"[15] (emphasis added).

41. Therefore, if individuals are administered an investigational medical product and their private identifiable information is collected along with the details about their interaction with

[15] <u>The Belmont Report Part A: Boundaries Between Practice & Research</u>. "Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."

the product, and that information is monitored, studied, or analyzed for purposes of adding to the generalizable knowledge of the product, then the activity meets the definition of "research," requiring 45 CFR Part 46 compliance when the federal government is involved.

42. HHS ensured that all research activities involving the federal government must comply with Belmont Report's ethical requirements: (1) "Department or agency heads retain final judgment as to whether a particular activity is covered by this policy, and this judgment shall be exercised consistent with the ethical principles of the Belmont Report"[16] (emphasis added), (2) if the activity is considered exempt from the policy, then "the alternative procedures to be followed are consistent with the principles of the Belmont Report."[17]

43. Congress expressly prohibits the federal government from administering an investigational product to an individual without complying with the Belmont Report's ethical principles and 45 CFR §46.101, *et seq*.

44. Placing an individual under a "sanction" for refusing an EUA drug, biologic, or device patently violates the ethical principles of the Belmont Report.

45. The intent of Congress was to give the Belmont Report the force of law through 45 CFR §46.101, *et seq*. and the Federal Wide Assurance agreement (see discussion, *infra*) for the explicit purpose of protecting humans when they are offered a federally funded EUA investigational product.

46. To further protect Americans from medical research abuses in the future, Congress declared that, "Federal funds administered by a Federal department or agency may not be expended

[16] 45 CFR § 46.101(c)
[17] 45 CFR § 46.101(i)

for research involving human subjects unless the requirements of this policy have been satisfied."[18] (45 CFR § 46.122)

47. Moreover, Congress also prohibited the United States Military from abusing individuals again by enacting 10 U.S.C. § 980(a), which provides in pertinent part, "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless — (1) the informed consent of the subject is obtained in advance."

48. Therefore, pursuant to 45 CFR §46.101, *et seq*., "research" occurs when an individual is administered an investigational drug, the individual's private identifiable information is known, and data collected regarding their interaction with the drug is added to the generalizable knowledge about the drug.

49. The COVID-19 CDC Vaccination Program is a research activity requiring 45 CFR §46.101, *et seq*. compliance as well as each COVID-19 EUA's Scope of Authorization. (See *infra*)

50. At no time may the federal government offer or administer an investigational medical product to an individual if their "legally effective informed consent" is not obtained in advance.

C. <u>Legally Effective Informed Consent</u>

51. 45 CFR § 46.116 sets forth the Belmont Report's "adequate standards" of informed consent[19], and they include, but are not limited to:

> (a)(1) Before involving a human subject in research covered by this policy, an investigator <u>shall obtain the legally effective informed consent</u> of

[18] All COVID-19 EUA drugs and their administration have been fully funded by the federal government, requiring 45 CFR Part 46 adherence.

[19] The Belmont Report and 45 CFR §46.116 contain the only definition for what Congress deems legally effective informed consent. Therefore, when statutes explicitly or implicitly mandate a person to give their legally effective informed consent, these definitions must be understood as the intent of Congress for compliance purposes.

the subject or the subject's legally authorized representative; (Emphasis added)

(a)(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence; (Emphasis added)

(a)(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject;

(a)(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information;

(a)(5) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research;

(a)(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights;

(a)(7) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs…;

(a)(8) 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" (Emphasis added).

52. Legally Effective Informed Consent, according to the Belmont Report, can be broken down into its basic formula as:

A. the individual must not be under outside pressure to participate,

B. the only reason an individual participates is that he or she believes the product may benefit their personal health goals, and

C. the conditions of 1 and 2 are established before the individual participates in the investigational product.

53. Only when authorities comply with 45 CFR §46.101, *et seq*. and the ethical principles of the Belmont Report can an opportunity exist for an individual to give their legally effective informed consent according to 45 CFR § 46.116(a)(1).

54. Informed Consent must be legally effective and prospective, according to HHS.

55. 45 CFR Part 46 applies to all federal agencies, departments, and the military (45 CFR § 46.101(a)). Additionally, twenty federal agencies incorporated 45 CFR Part 46 specifically into their regulatory framework.[20]

56. Through the Federal Wide Assurance (FWA) agreement (see *infra*), all U.S. States and Territories (i.e., state health agencies have FWA agreements) have agreed to obtain the legally effective informed consent of individuals when involving them in investigational medical products.

57. Consensual medical experimentation involving investigational medical products can only exist under conditions that ensure individuals are free from outside pressures to participate.

58. Therefore, individuals have the explicit right to refuse an investigational drug, biologic, or device without incurring a penalty or loss of benefits to which they are otherwise entitled.

[20] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

59. When Defendants penalized Plaintiffs for refusing to inject a 21 U.S.C. §360bbb-3 investigational drug into their bodies, Defendants breached their fiduciary and statutory duties to obtain Plaintiffs 'legally effective informed consent. (See, *infra*)

D. COVID-19 Research Activities

60. The State of California and Kaiser PolicyMakers are in a symbiotic relationship to conduct 45 CFR §46.101, *et seq*. research activities pertaining to COVID-19 EUA drugs, biologics, and devices on behalf of the federal government. Moreover, they are in a symbiotic relationship to obtain legally effective informed consent from individuals offered participation in those experimental medical products.

61. The federal government's Executive Branch purchased all COVID-19 EUA drugs (see, *infra*) and, in conjunction with HHS[21] and the CDC, developed research activities that States and CDC Vaccination Program Providers must conduct on its behalf.

62. Drugs, biologics, and devices authorized under 21 U.S.C. §360bbb-3 (see discussion, *infra*) are classified by the FDA as investigational (experimental)[22],[23] according to their labeling. They have no legal indication to treat, cure, or prevent any disease according to their labeling.

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[21] The EUA Scope of Authorization assigns research activities to the person acting on behalf of the manufacturer of the drug (the federal government who purchased all of the inventory), and to "emergency stakeholders," and "health care providers."

[22] Investigational new drug means, "A substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people…Also called experimental drug, IND, investigational agent, and investigational drug." NCI Dictionary of Cancer Terms. National Cancer Institute. Published 2023. Accessed June 25, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/investigational-new-drug

[23] 21 CFR 312.3 21 CFR 312.3 (Definitions and Interpretations): See "Investigational new drug" and "Clinical investigation" Note that "clinical investigation" is distinct from "clinical trial." While all clinical trials are clinical investigations, not all clinical investigations are clinical trials.

63. Moreover, if a product is already licensed by the FDA for the intended use under the declared emergency, the FDA is prohibited from issuing an EUA. (21 U.S.C. §360bbb-3(c)(3))

64. The only COVID-19 drugs made available to Plaintiffs are classified by the FDA as investigational new drugs. No FDA-licensed COVID-19 vaccines have been introduced into commerce for general commercial marketing since the declaration of the pandemic in March 2020, through the filing of this Complaint.

65. A "marketed drug" is not the same as an "investigational drug."

66. A "marketed drug" is one that is licensed by the FDA for general commercial marketing and approved with an indication and usage for the treatment of a particular disease, which, via federal statute, EUA medical countermeasure products must not be. (See 21 USC 355a, *et seq*, 21 USC 360bbb-3(a)(2)(a,b))

67. Investigational new drugs are legally regulated entirely differently than licensed drugs. The FDA declared in its August 23, 2021 EUA to Pfizer that "Pfizer-BioNTech COVID-19 Vaccine" drug is legally distinct from its licensed „COMIRNATY" drug[24].

68. The distinction lies within the drug's classifications as assigned to them by the FDA. Those distinctions have <u>significant</u> legal consequences for the end user. (See discussion, *infra*)

69. EUA drugs, by their statutory definitions, are not licensed by the FDA for general commercial marketing and have no legal indication to treat, cure, or prevent any known disease.

[24] See Exhibit B, FDA EUA Letter to Pfizer, August 23, 2021

70. Investigational drug "means a new drug or biological drug that is used in a clinical investigation." (21 CFR 312.3 "Investigational new drug")

71. Clinical investigation "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." (21 CFR 312.3 "Clinical investigation") (Emphasis added).

72. Only the FDA is authorized by Congress to assign a drug, biologic, or device its classification for purposes of regulation.

73. Drugs are governed by their classification according to their labeling and not by their formulation.

74. Congress explicitly enacted laws governing investigational new drugs to prevent the executive branch from continuing its history of abusing the rights of individuals who participate in investigational medical products.

75. On December 11, 2020, the FDA issued to Pfizer-BioNTech the first COVID-19 EUA for its investigational drug (officially named Pfizer-BioNTech COVID-19 Vaccine[25]), and the FDA confirmed that Pfizer's product "is an investigational vaccine not licensed for any indication."[26]

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[25] *Id*. The FDA improperly allowed Pfizer to add the word "Vaccine" to its investigational name. The court should not confuse this name to mean the drug's legal indication. Pfizer-BioNTech COVID-19 Vaccine is an investigational drug having no legal indication to treat, cure, or prevent any known disease. The FDA classified the drug as an "investigational new drug."

[26] 86 Fed.Reg. 5200, Jan. 19, 2021

76. On December 18, 2020, the FDA issued to ModernaTX, Inc., an EUA for its investigational drug (officially named Moderna COVID-19 Vaccine), and the FDA confirmed that Moderna's product "is an investigational vaccine not licensed for any indication."[27]

77. On February 27, 2021, the FDA issued to Janssen Biotech, Inc., an EUA for its investigational drug (officially named Janssen COVID-19 Vaccine), and the FDA confirmed that Janssen's product "is an investigational vaccine not licensed for any indication."[28]

78. 21 U.S.C. §360bbb-3 requires the Secretary of HHS to "[a]ppropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product (research activity)."

79. The Secretary establishes the conditions under which the research activities will occur in each EUA letter, known as the Scope of Authorization.

80. As an example, on January 19, 2021[29] the Secretary established mandatory conditions that Pfizer and emergency stakeholders (distributors, manufacturers, etc.) must follow, which involve 45 CFR 46 research activities.

81. Under the EUA's "Conditions of Authorization," the Secretary mandates in part:

* * *

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):

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[27] 86 Fed.Reg. 5200, Jan. 19, 2021

[28] 86 Fed.Reg. 28608, May 27, 2021

[29] Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic; Availability. Federal Register. Published January 19, 2021. Accessed June 7, 2023. https://www.federalregister.gov/documents/2021/01/19/2021-01022/authorizations-of-emergency-use-of-two-biological-products-during-the-covid-19-pandemic-availability

- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer, Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals, within 15 days after the last day of a month…Each periodic safety report is required to contain descriptive information which includes:

- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest.
- Newly identified safety concerns in the interval.

* * *

N. Pfizer Inc. will conduct post-authorization observational study(ies) to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (16 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities.

* * *

T. Vaccination providers administering Pfizer-BioNTech COVID-19 Vaccine must report the following information…to VAERS…:

- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

82. VAERS reported 1,562,008 entries from December 2020 through May 26, 2023, including 35,272 deaths (1.6 per hour) and 263,462 (12.11 per hour) serious injuries. These

numbers demonstrate historical entries for a drug and the vast involvement of the medical community to add to the "generalizable knowledge" of the product.

83. Healthcare providers and Pfizer, Moderna, and Janssen must identify the person receiving the product, monitor their involvement with the product, and report whether or not they had an adverse reaction to the product for the express purpose of adding to the generalizable knowledge of the product.

84. COVID-19 drug manufacturers and government agencies use collected data to add to the generalizable knowledge about the product. These conditions meet 45 CFR 46, FWA, and the Belmont Report definitions of research activities.

85. The CDC Provider Agreement (see discussion, *infra*), EUA authorizations, and CDC's Advisory Committee on Immunization Practices (ACIP) recommendations demonstrate how the nationwide COVID-19 vaccination program is to be systematically investigated.

86. The federal government purchased all COVID-19 drugs and created the CDC COVID-19 Vaccination Provider Agreement for the administration of its property to individuals desiring to participate in the product. The Provider Agreement establishes additional research activities that Defendants must conduct on the government's behalf and "must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP)."

87. ACIP's Morbidity and Mortality Weekly Report from September 2021 confirms that in addition to "initial clinical trial data, ACIP…considered…real-world vaccine effectiveness studies, and post-authorization vaccine safety monitoring," information came from entities that executed the CDC Vaccine Provider Agreement and submitted the below-described information

because the ONLY way to have authority to administer the COVID-19 Vaccines is by executing the CDC Vaccine Provider Agreement.[30] The use of this information by ACIP demonstrates how the data collected "contributes to generalizable knowledge."

88. The ACIP recommendations[31] referenced in Footnote 1 of the CDC Provider Agreement[32] instruct Defendants to:

A. Provide an EUA Fact Sheet to potential recipients before being administered the drug.

B. Counsel potential vaccine recipients about expected systemic and local reactogenicity.

C. Follow additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant or immunocompromised or who have severe allergies) based on advice from the CDC (https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/ pfizer/clinical-considerations.html)

D. Adverse events that occur in a recipient after receipt of COVID-19 vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS).

E. Report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under EUA.

F. Report any clinically significant adverse event, whether or not it is clear that a vaccine caused the adverse event.

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[30] ACIP, Morbidity and Mortality Weekly Report, "Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥ 16 Years: Recommendations of the Advisory Committee on Immunization Practices – United States, September 2021", Vol.70, No.38, p. 1344.

[31] *Id*., at 1347.

[32] The CDC Provider Agreement, at p.2, makes the ACIP Recommendations mandatory by the following language: "This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies through footnoted weblinks. Organization must monitor such identified guidance for updates. Organization must comply with such updates." See Exhibit A, CDC COVID-19 Vaccination Program Provider Agreement (hereinafter "Provider Agreement").

G. Inform vaccine recipients about V-Safe, the CDC's vaccine safety monitoring system that the CDC says "helps us monitor the safety of COVID-19 vaccines for everyone."[33]

89. The CDC Provider Agreement further instructs Defendants:

A. Within 24 hours of administering a dose of COVID-19 Vaccine, record in the vaccine recipient's record and report required information to the relevant state, local or territorial public health authority.

B. Submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state or local territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.

C. Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be available to any federal, state, local, or territorial public health department to the extent authorized by law.

D. Report the number of doses of COVID-19 Vaccine that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.

E. Provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient.

90. Based on the detailed, organized, and methodical way HHS and the CDC structured the nationwide COVID-19 Vaccination Program, it meets the criteria for "a systematic investigation…designed to develop or contribute to generalizable knowledge."

91. It cannot be reasonably argued that the required research activities under each COVID-19 EUA's Scope of Authorization and the CDC COVID-19 Vaccination Program Provider Agreement do not meet the conditions requiring 45 CFR §46.101, *et seq*. compliance.

[33] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/pdfs/v-safe-information-sheet-508c.pdf

E. ICCPR Treaty

92. In 1992, the United States Senate ratified the International Covenant on Civil and Political Rights Treaty (ICCPR).[34] Article VII states, "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." (Emphasis added)

93. Subjected means to be under the rule of law by one's authority.

94. Free consent means to be free from outside pressures to participate.

95. The U.S. Senate issued a resolution stating, "That the United States considers itself bound by Article 7 to the extent that 'cruel, inhuman or degrading treatment or punishment' means the cruel and unusual treatment or punishment prohibited by the Fifth, Eighth and/or Fourteenth Amendments to the Constitution of the United States."[35]

96. The U.S. Senate considered it to be a violation of Article 7 of the ICCPR Treaty and the 5th Amendment's Due Process Clause if individuals were forced to forfeit liberty and property without due process for refusing medical experimentation. The Senate also considered it to be a violation of Article 7 of the ICCPR Treaty and the 14th Amendment's Equal Protection Clause when individuals who refused medical experimentation were treated differently than those who accepted medical experimentation.

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[34] Treaty Document 95-20 - INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS. (2023, May 19). https://www.congress.gov/treaty-document/95th-congress/20/all-info

[35] See "Resolution" - Treaty Document 95-20 - INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS. Congress.gov. Published 2023. Accessed June 5, 2023. https://www.congress.gov/treaty-document/95th-congress/20/all-info

97. The United States Senate stated that Articles One through Twenty-Seven of the ICCPR Treaty are not "self-executing" but "that it is the view of the United States that States Party to the Covenant should, wherever possible, refrain from imposing any restrictions or limitations on the exercise of the rights recognized and protected by the Covenant, even when such restrictions and limitations are permissible under the terms of the Covenant."

98. Treatment by authorities debasing an individual's liberty, autonomy, and human dignity for the express purpose of coercing that individual to surrender their Constitutional rights, leading to feelings of fear, anguish, and inferiority, meets the international definition of cruel, inhumane, and degrading treatment or punishment.[36]

99. Whereas the "United Nations Convention Against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment" treaty deals specifically with physical torture or the threat of physical torture, Article VII of the ICCPR Treaty speaks to the political actions of governments and the laws of governments leading to a loss of rights, safety, and liberty, or the feelings that such actions will lead to those losses.

100. The UN Human Rights Committee spoke to Article IV of the ICCPR Treaty regarding the derogation of rights when states declare an emergency. "Article 4, paragraph 2, of the Covenant explicitly prescribes that no derogation from the following articles may be made:

[36] "Treatment that humiliates or debases an individual, showing a lack of respect for, or diminishing, their human dignity, or when it arouses feelings of fear, anguish or inferiority capable of breaking an individual's moral and physical resistance." - degrading treatment or punishment. Published 2023. Accessed June 6, 2023. https://home-affairs.ec.europa.eu/networks/european-migration-network-emn/emn-asylum-and-migration-glossary/glossary/degrading-treatment-or-punishment_en

article 6 (right to life), article 7 (prohibition of torture or cruel, inhuman or degrading punishment, or of medical or scientific experimentation without consent.)"[37] (Emphasis added.)

101. Article 4.2 of the ICCPR Treaty established the restriction of derogation of informed consent rights as a peremptory norm. Although Article VII of the ICCPR Treaty does not provide a private right of action, it is nonetheless enforceable under 42 U.S.C. §1983 because the treaty contains unambiguous rights enforceable language specific to the individual involved in experimental medical products or processes.

F. 21 U.S.C. §360bbb-3 (the EUA statute)

102. Congress expressly prohibits any manufacturer from introducing into commerce a drug, biologic, or medical device not licensed by the FDA for general commercial marketing (21 U.S.C. §355(a)) to ensure individuals are not subjected to medical experimentation outside of their free consent and or harmed by medical products not effectively researched for safety and efficacy.

103. Investigational drugs, biologics, and devices are strictly controlled by Congress. Only authorized persons may access, distribute, and administer the investigational products and only under the prescribed conditions established by Congress.

104. However, over time, Congress recognized the need to allow individuals to access unlicensed products for emergency, compassionate, and educational purposes (also known as "expanded access protocols"). Therefore, Congress established 21 U.S. Code §360bbb *et seq*., titled "Expanded Access to Unapproved Therapies and Diagnostics."

[37] "No justification or extenuating circumstances may be invoked to excuse a violation of article 7 for any reasons, including those based on an order from a superior officer or public authority." - Human Rights Committee in its General Comment No. 20 on article 7 (A/44/40)

105. Numerous conditions must be met before the legal administration of products authorized pursuant to the section can occur. The overriding requirement, irrespective of the authorized expanded access protocol, is that the individual must give their legally effective informed consent, whether the consent is under written or verbal conditions. This requirement means the authority sponsoring the product or acting on behalf of the sponsor must ensure the individual consenting to participate is under no outside pressure to do so.

106. Making it patently clear of their intent to protect Individuals from medical research abuses, Congress enacted legislation prohibiting federal funding for research activities if the informed consent obtained from the individual is not legally effective nor prospective for the civilian (45 CFR § 46.122) and for the military (10 U.S.C. §980).

107. The Food, Drug, and Cosmetic Act "FDCA"), 21 U.S.C §360bbb-3 authorizes the HHS Secretary to grant emergency expanded access protocols to (1) FDA-licensed products for unlicensed uses or (2) products the FDA has not licensed for general commercial marketing.

108. Congress requires the HHS Secretary to establish "appropriate conditions designed to ensure that individuals to whom the product is administered are informed" of:

> (ii)(II) the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown;
>
> (ii)(III) the option to accept or refuse administration of the product;
>
> (ii)(III) the consequences, if any, of refusing administration of the product, and
>
> (ii)(III) the alternatives to the product that are available and of their benefits and risks.[38]

[38] 21 U.S.C. 360bbb-3(e)(1)(A)

109. Informing the individual of the product risks, alternatives, benefits, and health consequences provides that individual with the quality information required to give legally effective informed consent.[39]

110. Congress requires healthcare professionals to inform the individual of "the option to accept or refuse administration of the product," meaning the healthcare professional is required by Congress to inform the individual of his or her legal rights under the EUA statute before participating in the product or activity.

111. A legal right is a power held by an individual resulting from a constitution, statute, regulation, or judicial precedent of which no other authority may interfere unless prescribed in law.

112. There are two legal rights conferred upon individuals considering whether to participate in a Section 564 medical countermeasure product, which are (1) the right to **accept** a Section 564 medical product, and (2) the right to **refuse** to take or use a Section 564 medical product.

113. The decision belongs exclusively to the individual, and it must be under conditions free of outside pressures. If individuals are under outside pressure to participate, then it is legally impossible for them to give their free consent; thus, their rights have been infringed upon.

114. There are three specific persons upon whom Congress confers a right under 21 U.S.C. §360bbb-3, which are:

[39] The requirements of informing the subject of risks, benefits, alternatives, and health consequences, and that the Secretary has authorized the use of the investigational drug mirrors 45 CFR §46.116 requirements.

A. the HHS Secretary, who is empowered to authorize access to investigational drugs, biologics, or medical devices and the conditions under which that access can occur,

B. the healthcare professional who is authorized to inform the individual of their Section 564 legal rights and to administer Section 564 medical products, and

C. the individual who is authorized to accept or refuse Section 564 medical products.

115. Congress established a required condition that "[w]ith respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health." (21 USC 360bbb-3(e))

116. Additionally, Congress conferred authority onto the Secretary so that he may "appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use."

117. These "appropriate conditions" and the "circumstances" are outlined in the Emergency Use Authorization (EUA) letter issued to the manufacturer of the emergency medical countermeasure under the "Scope of Authorization."

118. Therefore, the Scope of Authorization contained in each EUA letter has the force of law as it establishes the conditions under which the emergency activities can occur, prescribing duties for the manufacturer and rights of all persons involved in the administrative process of the product.

119. The Secretary determined that the COVID-19 pandemic required healthcare workers to provide individuals contemplating the use of one of the EUA products with a drug fact sheet *before the product is administered* to act as a function of informed consent. In other words, the Secretary thought it was practical that every person be afforded this right and, as such, mandated that requirement under the Scope of Authorization for each EUA.

120. To ensure individuals are protected when they are offered EUA medical products, Congress was explicit in that "[n]othing in this section [21 U.S.C. 360bbb-3] provides the Secretary <u>any authority to require any person to carry out any activity</u> that becomes lawful pursuant to an authorization under this section (21 U.S.C. 360bbb-3(l))." (Emphasis added)

121. For purposes of the case at bar, the "activity that becomes lawful pursuant to an authorization under this section" is the administration of the EUA COVID-19 investigational injections manufactured by Pfizer, Moderna, and Johnson & Johnson/Jannsen or the required use of EUA testing articles and masks.

122. Therefore, the Secretary may grant access to unlicensed medical products for use under the declared emergency, but the Secretary may not require any person to manufacture, distribute, store, administer, or receive the product.

123. The Secretary may not delegate his authority, so by extension, any person participating in a 21 U.S.C. §360bbb-3 activity is also restricted by Congress from requiring any other person to participate in "any activity that becomes lawful pursuant to an authorization under" 21 U.S.C. §360bbb-3.

124. **Congress, therefore, prohibits governments (e.g., governors, mayors, school boards) and voluntary participants (e.g., hospitals, manufacturers, doctors) from having the**

authority to require any person to participate in any 21 U.S.C. §360bbb-3 activity at any time, under any statute, regulation, or state policy or custom.

125. The explicit purpose of this statutory restriction is to ensure that no person is under a "sanction," "coercion," "undue influence," or "unjustifiable pressure"[40] to participate. If individuals are under those pressures, then no federal funds could be expended for the administration of a COVID-19 EUA product, nor could any healthcare provider acting on behalf of the federal government obtain an individual's Legally Effective Informed Consent.

126. The individual has the right to accept the product, and the healthcare professional has the authority to administer the product. Still, neither is required to act on the demands of the other. Congress established a guideline requiring both the healthcare professional and the individual to mutually agree to the process to meet the legal requirement of 21 U.S.C. §360bbb-3.

127. The purpose of this requirement is to ensure that the individual receives a quality standard of healthcare even under emergency conditions because not everyone is a proper candidate to take or use an investigational medical countermeasure.

128. Therefore, if the HHS Secretary is the only person authorized to establish the conditions under which persons can access 21 U.S.C. §360bbb-3 medical countermeasures and not even he can mandate participation, **then Defendants had no authority to amend the Scope of Authorization and require that which Congress prohibits**.

129. Therefore, when Defendants established a policy requiring individuals under their authority to become vaccinated against the COVID-19 virus, they were required by federal law to

[40] The Belmont Report's conditions that would nullify legally effective informed consent.

ensure that (1) licensed products existed to meet the legal requirements of the mandate, and (2) Plaintiffs were to be informed that they were under no obligation to inject an unlicensed COVID-19 EUA investigational drug into their body, nor would they incur a penalty or lose a benefit when refusing to do so. Defendants did neither.

G. HHS EUA Precedent

130. On January 28, 2005, HHS issued the first EUA[41] under its new Section 564 authority (i.e., 21 USC 360bbb-3). The military requested EUA protocols for Anthrax Vaccine Adsorbed (AVA), to be utilized by civilians and service members. HHS stated, "The issuance of this Authorization for the emergency use of AVA is the first time that the EUA authority is being used. FDA intends to explain clearly the reasons for each issuance, termination, or revocation of an EUA. The agency wishes to make its decision-making understandable to help ensure that members of the public, and particularly those individuals who may be eligible to receive a medical product authorized for emergency use, are informed about the basis of an EUA determination."

131. HHS mandated that individuals participating in the AVA investigational product must be informed of the following statements:

> A. Individuals (service members and civilians) who refuse anthrax vaccination will not be punished. (Emphasis added)
>
> B. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice.
>
> C. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination.

[41] https://www.govinfo.gov/content/pkg/FR-2005-02-02/pdf/05-2028.pdf

D. There may be no penalty or loss of entitlement for refusing anthrax vaccination,

E. This information shall read in the trifold brochure provided to potential vaccine recipients as follows: You may refuse anthrax vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination.[42]

132. The explicit instructions in the EUA language directly relate to AVA's classification as an investigational new drug not licensed by the FDA for any legal indication. Moreover, the language was designed to ensure that healthcare professionals could obtain the legally effective informed consent of the individual because it expressly informed the individual that no "sanction" would be imputed for refusal, thus nullifying all outside pressures to participate. No amendments to Section 564 have altered its requirements since HHS issued this first EUA.

133. The reason HHS was crystal clear about an individual's right to refuse an investigational drug was to respect court orders and the express authority of individuals to choose the available statutory options.

H. <u>Judicial EUA Precedent</u>

134. On October 27, 2004, U.S. District Court Judge Sullivan spoke to the individual's authority to refuse investigational drugs without consequence when he held in *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004), that:

A. Congress has prohibited the administration of investigational drugs to service members without their consent. This Court will not permit the government to circumvent this requirement; and,

B. Unless and until FDA properly classifies AVA [an anthrax vaccine] as a safe and effective drug for its intended use, an injunction shall

[42] Federal Register/Vol. 70, No. 21/Wednesday, February 2, 2005/Notices 5455 IV Conditions of Authorization

> remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. §1107. Accordingly, the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver." (Emphasis added.)

135. Immediately upon Judge Sullivan's ruling, the Department of Defense ended all punitive activities against service members and civilian employees because the federal court affirmed the individual's statutory authority to refuse investigational drugs without consequence. Except for 10 U.S.C. § 1107, the laws leading Judge Sullivan to his ruling apply to individuals irrespective of civilian or military service. No laws have changed to negate Judge Sullivan's 2004 ruling.

136. Judge Sullivan added clarity to the importance of what was argued before the court by stating: "The Court is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate." *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004).

137. *Doe* and the HHS provide judicial and administrative precedent affirming the right of individuals to refuse investigational products without incurring a penalty or losing a benefit to which they are otherwise entitled. Nothing in the law has changed to nullify that right since those precedents were firmly established.

I. Federal Wide Assurance (FWA)

138. In 2001, HHS created the Office of Human Rights Protection (OHRP), which established the Federal Wide Assurance (FWA) agreement. The FWA is an agreement by entities conducting business with HHS to comply with 45 CFR 46 and the Belmont Report's ethical guidelines.

139. HHS states, "The Federal Wide Assurance (FWA) is an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS). The FWA is also approved by OHRP for federal wide use, which means that other U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research they conduct or support. An FWA is the only type of assurance currently accepted and approved by OHRP. It is required whenever an Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule…"[43]

140. The OHRP assigns an FWA identification number to entities (hereinafter referred to as "Contracting Provider") that fulfill application requirements. An FWA identification number is issued only after the legally binding agreement between the Contracting Provider and the United States government has been signed.

141. The FWA's main purpose is to benefit a third-party beneficiary because the FWA agreement authorizes the Contracting Provider to participate in federally funded programs involving humans with investigational drugs if, and only if, the Contracting Provider agrees to protect the health and legal rights of the third-party beneficiaries (i.e., humans who are administered investigational drugs, biologics, or devices under the research conditions described above).

[43] Office for Human Research Protections. Federal Wide Assurance Instructions. HHS.gov. Published January 7, 2011. Last accessed May 19, 2023.

142. The fact that the entire FWA agreement hinges upon the intended rights of third-party beneficiaries means that Contracting Providers have a fiduciary duty to the third-party beneficiaries under the terms of the FWA agreement.

143. The intended benefit to the third-party beneficiary is the right to accept or refuse participation in investigational products, clinical trials, and other research activities without fearing consequences for refusal and to know that independent Institutional Review Boards will provide oversight, ensuring their health, safety, and rights are protected.

144. Although the third-party beneficiaries are not signatories to the contract, they are the intended third-party beneficiaries of the agreement, and their rights were violated the moment Defendants penalized Plaintiffs for refusing to take EUA products (i.e., investigational drugs, and testing articles).

145. The FWA agreement requires the Contracting Provider to ensure that no third-party beneficiary is under outside pressure to participate in an investigational drug, biologic, or medical device.

146. The FWA agreement requires Defendants to assure potential participants that they will not incur a penalty or lose a benefit to which they are otherwise entitled when refusing participation.[44]

147. The duty placed upon the Contracting Provider is owed to those who refuse as well as those who accept the administration of investigational drugs.

148. Therefore, when Defendants punished Plaintiffs (third-party beneficiaries) for refusing the administration of an investigational drug, they:

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[44] "The Federal Wide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46." - HHS. 45 CFR 46.116(b)(8) requires the individual to be informed they will not be penalized for refusing participation in a research activity.

A. activated the terms and conditions of the contract,

B. violated the terms of the contract, causing injury to the legal rights of the third-party beneficiary,

C. created a cause of action for breach of fiduciary duty in favor of the third-party beneficiary.

149. The Fourteenth Amendment's Equal Protection Clause provides additional protections by requiring all persons involved in federally funded COVID-19 countermeasure programs to be treated equally before the law, irrespective of the chosen option.

J. <u>Preemption of State Law – PREP Act and EUA Statute</u>

150. In 2005, Congress passed the Public Readiness and Emergency Preparedness Act, hereafter referred to as the PREP Act (42 USC 247d-6d and 42 USC 247d-6e), to provide immunities for persons volunteering for "covered" activities. In accordance therewith, the HHS Secretary issued a COVID-19 PREP Act declaration in February 2020.[45]

151. The first provision of the PREP Act (42 USC 247d-6d) is entitled "Targeted liability protections for pandemic and epidemic products and security countermeasures."

152. The second provision of the PREP Act (42 USC 247d-6e) is entitled "Covered countermeasure process."

153. Congress expressly crafted language preempting state and local law conflicting with the PREP Act (42 USC 247d-6d(b)(8)), which provides, in pertinent part:

(8) Preemption of State law

> During the effective period of a declaration under subsection (b)…no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

[45] 85 FR 15198

> (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 [21 U.S.C. 301 et seq.].

154. Congress expressly established that participation in the administration of the covered countermeasure (i.e., any EUA COVID-19 investigational drug) shall be voluntary. Specifically, Congress stated the following at 42 USC 247d-6e(c), in pertinent part:

> (c) Voluntary program
>
> The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 247d–6d of this title…and that potential participants are educated with respect to contraindications, <u>the voluntary nature of the program</u>, and the availability of potential benefits and compensation under this part. [Emphasis added.]

155. The CDC COVID-19 Vaccination Provider Program exclusively utilizes "the relevant state, local, or territorial immunization's cooperative agreement with CDC" as the means to distribute the federal government's "covered countermeasure[s]" (COVID-19 EUA drugs) (see, *infra*).

156. Therefore, when the State voluntarily agreed to use its immunization program to distribute the federal government's property, it was required to ensure all participants were only involved under strictly voluntary conditions.

157. Congress informed the State that if it planned to "administer or use a covered countermeasure," then it may not "establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that…is different from, or is in conflict with…**any 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."

158. One such **matter included in a requirement applicable to the covered countermeasure** is contained in 21 U.S.C. §360bbb-3 (the Emergency Use Authorization statute) whereby Congress, in unambiguous rights-conferring language, conferred upon the individual considering participation in a "covered countermeasure" may choose to "accept" or "refuse" participation.[46]

159. Therefore, by the express language of the PREP Act, and its incorporation of the option to choose contained in the EUA statute, and also based on the Supremacy Clause in the U.S. Constitution, any State laws, ordinances, regulations, or customs that are "different" from or in "conflict" with an individual's authority to freely choose to accept or refuse participation in the medical countermeasure are preempted.

160. Therefore, States are preempted by Congress from mandating participation in a PREP Act "covered countermeasure."

161. Similarly, the State and private employers in that State are prohibited from enforcing any at-will employment doctrine when employees refuse participation in a "covered countermeasure" because using the threat of penalty of loss of employment benefits, or even employment itself, "conflict[s]" with the employee's federal statutory right to accept or refuse participation in the covered countermeasure (e.g., drugs, biologics, masks, testing articles, etc.) without consequence.[47]

162. The purpose of informing the individual of "the significant known…risks of such use, and of the extent to which such benefits and risks"[48] and of "the alternatives to the product

[46] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)
[47] *Id.*
[48] (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(II))

that is available and of their benefits and risks"[49] is because the individual is not only consenting to be *irreparably* injected with an investigational drug but to also participate in a legally binding agreement under the terms and conditions established by Congress.

163. Individuals who consent to receive one of the COVID-19 EUA investigational drugs must agree to the following terms and conditions, including but not limited to:

A. forfeiture of civil litigation rights resulting from injuries;[50]

B. allowing their private identifiable information to be collected and used for a variety of purposes by unknown persons;[51]

C. allowing their involvement with the EUA product to be cataloged by various persons for unknown purposes,

D. allowing the data collected about their adverse events to be utilized by researchers for unknown purposes and eternity,[52]

E. assuming greater risks to their safety, health, and legal rights.[53]

164. The FDA issued an opinion[54] regarding federal preemption of the State's authority to interfere with 21 U.S.C. §360bbb-3 (aka section 564):

> FDA anticipates that conflicts between federal and state law may arise when FDA acts under sections 564, 564A, and 564B if states have existing requirements governing the shipment, holding, dispensing, administration, or labeling of unapproved medical products or approved medical products for unapproved uses. Courts have stated that the Supremacy Clause of the U.S. Constitution can operate to nullify both state legislative requirements and state common-law duties. Under the legal principles of implied conflict

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[49] (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III))

[50] PREP Act forfeits all civil actions for damages in most situations.

[51] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Agreement requires manufacturers and/or emergency stakeholders to obtain private identifiable information.

[52] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Agreement requires manufacturers and/or emergency stakeholders to monitor, report and study a variety of adverse reactions to EUA products.

[53] Section 564 (21 U.S.C. 360bbb-3) requires potential recipients to be made aware of the risks, alternatives, and the fact that the product is only authorized by the Secretary under emergency conditions. These elements provide potential recipients with the required information to make a quality and legally effective decision to consent. Therefore, consent means the individual agrees to assume more than minimal risk as defined above.

[54] "Emergency Use Authorization of Medical Products and Related Authorities," Section VII. U.S. Food and Drug Administration. Published 2022. Accessed June 6, 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#preemption

> preemption, courts have found state law preempted where it is impossible to comply with both federal and state law, or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Consistent with this case law, section 4(a) of Executive Order 13132 states that "[a]gencies shall construe... a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." FDA states that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564. Similarly, an order or waiver issued under section 564A and pre-positioning under section 564B preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements related to the activity authorized under sections 564A or 564B. To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular medical product within the scope of the declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," and "conflicts with the exercise of Federal authority under [§ 564]." The same rationale applies to an order or waiver issued under section 564A and pre-positioning of an MCM under section 564B. (Emphasis added)

165. The Supreme Court has long held that "the test of applicability of state laws [conflicting with the Supremacy Clause] is whether the matter on which the State asserts the right to act is in any way regulated by the Federal Act."[55]

166. 21 U.S.C. §360bbb-3 and the PREP Act can only be executed by the United States HHS Secretary under the prescribed conditions established by Congress.

167. The State and subordinate private parties may only participate in "covered countermeasures" and the use of 21 U.S.C. §360bbb-3 medical products by volunteering to adhere to the conditions established by the HHS Secretary under the respective statutes, which includes

[55] *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 236 (1947)

the federal statutory requirement to obtain Plaintiffs' legally effective informed consent when considering participation in programs authorized by the above statutes.

168. If Defendants can punish Plaintiffs for *refusing* to participate in using a 21 U.S.C. §360bbb-3 product, they must also have the authority to punish Plaintiffs *accepting* the product. In such a scenario, one can easily see that Plaintiffs are damned if they accept and damned if they refuse because the option no longer belongs to the Plaintiffs; rather, it belongs to Defendants disagreeing with the Plaintiffs' choice. Granting Defendants that power deprives Plaintiffs of their Constitutional rights (Equal Protection of Laws and Due Process) and undermines the authority of Congress to determine the conditions under which access to unlicensed drugs, biologics, and devices can occur.

169. Moreover, should Defendants be allowed to interfere in the Federal Acts by penalizing Plaintiffs for refusing to participate, and Plaintiffs are injured, having no judicial recourse for remedy, then Plaintiffs are deprived of their Due Process rights resulting from the sustained losses of their injury. Should a person be informed of the risks of participating in a covered countermeasure and still choose to participate, resulting in injury, then courts are satisfied that their Due Process rights are not violated when denied judicial relief under the statute's immunity clauses because they were made aware of the risks and consequences prospectively.

170. This irrefutable fact is why Congress preempts the State and Defendants (as State Actors) from having any authority to interfere with the right of Plaintiffs to either accept or refuse participation in "medical countermeasures" under 21 U.S.C. §360bbb-3 and "covered countermeasures" under the PREP Act.

171. In the case at bar, Defendants' use of the state at-will employment doctrine to terminate Plaintiffs' employment as a penalty for refusing administration of an EUA

investigational drug conflicts with the federal law's goal of ensuring that only truly willing participants are involved in the use of "covered countermeasures" and 21 U.S.C. §360bbb-3 medical products, and as a result of that conflict, the State's at-will employment doctrine is preempted for purposes of the administration of those countermeasures. It is thereby inapplicable as a defense to Defendants' unlawful actions described herein by Plaintiffs.

K. CDC COVID-19 Vaccination Program Provider Agreement

172. The Centers for Disease Control (CDC) states that "[a]t this time, **all COVID-19 vaccine in the United States has been purchased by the U.S. government** (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remains U.S. government property until administered to the recipient. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law." [See Exhibit A, Provider Agreement]

173. Although the program states it is a "Vaccination Program" (hereinafter referred to as "CDC Vaccination Program"), the federal government has not distributed any FDA-licensed COVID-19 vaccines. Instead, it has relied exclusively on unlicensed COVID-19 EUA drugs for the program's administration.

174. Before the CDC accepts a person or entity as a Provider in the CDC Vaccination Program, that person or entity is required to sign the CDC COVID-19 Vaccination Program Provider Agreement (See Exhibit A, Provider Agreement).

175. The Provider Agreement informs the person or entity that, "Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement (Section A)" (See Exhibit A, Provider Agreement.)

176. The Provider Agreement requires the organization to assign a person or persons who will be under a legal obligation to ensure the program is carried out effectively, declaring, "For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements."

177. "This program is a part of collaboration <u>under the relevant state, local, or territorial immunization's cooperative agreement with CDC</u>. To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 Vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements…" (Emphasis added).

178. Therefore, the CDC clearly states that the Provider Agreement works in conjunction with "relevant state" and other municipality immunization agreements. This requirement denotes state action involving private parties acting in the capacity of a state actor.

179. HHS requires any entity conducting business with its organization to submit and be approved for a Federal Wide Assurance agreement (see discussion, *supra*) in advance of participating in any program involving humans with investigational drugs under its authority. The fact that the medical products in question are under an EUA does not exempt entities conducting

business with HHS from first agreeing to obtain an FWA before participation. This fact is why the CDC chose only to distribute the program via the State's existing immunization program. Each state already has an HHS FWA agreement in place.

180. The Executive Branch of the government is required to comply with 21 U.S.C. §360bbb-3's requirements and all other laws and regulations protecting humans involved in investigational medical products under emergency access protocols.

181. When the Executive Branch chose to purchase all COVID-19 vaccines (i.e., licensed and unlicensed COVID-19 drugs), it was required to ensure that all applicable laws associated with each drug's classification were adhered to by all volunteering participants.

182. The Executive Branch chose to establish the Provider Agreement as the mechanism to ensure those legal obligations were followed.

183. While the Provider Agreement does not replace the laws and regulations governing any EUA drug classification, it adds an extra layer of legal obligations required of volunteer participants.

184. The Provider Agreement requires that all volunteer participants:

A. must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative,

B. Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS),

C. 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,

D. Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.

185. The EUA Fact Sheet is required because the Executive Branch of the government is the sole sponsor of EUA products,[56] and federal law requires them to obtain the legally effective informed consent of each individual before the administration of the product. Moreover, the HHS Secretary requires each recipient to be given the Fact Sheet for each EUA COVID-19 investigational drug from which the federal branch of government cannot exempt itself. The required Fact Sheet acts as a function of the "informed consent" process for persons ascertaining whether or not they will participate in the EUA product.

186. The Executive Branch is required to report adverse events as part of the government's COVID-19 Vaccination Program because federal law requires this of every EUA product, which the HHS Secretary echoed in each of the EUA letters issued to pharmaceutical companies. Moreover, the requirement to monitor, collect, and report, adverse reactions (research activities) from the drugs' use denotes how these products are governed by 45 CFR 46, requiring both IRB and Belmont Report compliance.

187. The requirement that the "Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws" is because federal law declares:

A. "This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects." (45 CFR 46.101(f));

B. Additionally, federal law declares, "The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in

[56] The Federal government chose to purchase and retain ownership of all EUA COVID-19 drugs. However, that ownership does not negate their legal obligations under Section 564.

order for informed consent to be legally effective" (45 CFR 46.116(i));

C. This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research. (45 CFR 46.101(g)).

188. The Provider Agreement required Defendants to acknowledge the law before acceptance, as follows: "By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine understand and will comply with the agreement requirements listed above…" (Emphasis added)

189. Therefore, State governments and their authorized private parties agreed to participate in a joint effort to conduct research activities and obtain the legally effective informed consent of individuals on behalf of the United States Government when signing the CDC COVID-19 Vaccination Program Provider Agreement.

VI. Statement Of Facts

190. Plaintiffs make no assertions regarding whether it is lawful for a public or private entity to mandate taking a ***licensed*** vaccine. Plaintiffs' allegations herein only relate to Defendants' depriving Plaintiffs' of their right to refuse EUA investigational drugs and/or PREP Act products.

191. Plaintiffs adamantly assert that an individual has the absolute Constitutional and federal statutory right to refuse the administration of an Emergency Use Authorization (EUA) drug (e.g., Pfizer BioNTech COVID-19 Vaccine), biologic, or device (e.g., EUA testing articles and masks) without incurring a penalty or losing a benefit to which they are otherwise entitled. Moreover, such a right is not dependent upon a person seeking a religious or medical exemption.

192. Plaintiffs assert that they have the Constitutional and federal statutory right to refuse participation in any activity or product under the PREP Act.

193. Plaintiffs assert that Defendants are prohibited by Congress from establishing 21 U.S.C. §360bbb-3 and PREP Act conditions requiring Plaintiffs to surrender their statutory rights and Constitutional protections as a condition to enjoy the privileges and benefits offered under federal and California State laws, regulations, ordinances, and customs.

194. Plaintiffs were employed as healthcare workers licensed by the State of California, working in healthcare facilities also licensed by the State, which has the authority to deny healthcare facilities and workers the right to conduct commerce by revoking their respective State licenses.

195. On July 26, 2021, Governor Newsom, acting under color of law, published an official press release[57] outlining a new policy that, as applied, was unlawful and deprived Plaintiffs of their Fourteenth Amendment rights of Equal Protection of Laws and Due Process.

196. Governor Newsom's policy stated in part:

A. "'As the state's largest employer, we are leading by example and requiring all state and health care workers to show proof of vaccination or be tested regularly, and we are encouraging local governments and businesses to do the same. Vaccines are safe – they protect our family, those who truly can't get vaccinated, our children and our economy. Vaccines are the way we end this pandemic.'" — Governor Newsom

B. "The new policy for state workers will take effect August 2 and testing will be phased in over the next few weeks. The new policy for health care workers and congregate facilities will take effect on August 9, and health care facilities will have until August 23 to come into full compliance."

197. As a matter of law, no licensed COVID-19 vaccine existed for general commercial marketing in 2021, 2022, and for most of 2023. Therefore, the Governor's policy relied

[57] See Exhibit C, Governor Newsom Press Release

exclusively on EUA investigational drugs, which were also under the PREP Act authority, for compliance.

198. The Governor lacks Constitutional authority to mandate that which Congress prohibits, and Congress has prohibited the mandatory participation in federally funded investigational new drugs, biologics, and devices under EUA or the PREP Act.

199. Governor Newsom freely volunteered the State of California to participate in the CDC COVID-19 Vaccination Program. The Governor should have known that the Program required all persons administering the federal government's property to adhere to 21 U.S.C. §360bbb-3 (the EUA statute) and all other applicable laws. Those applicable laws include 45 CFR Part 46, the State's FWA, the Belmont Report, Article VII of the ICCPR Treaty, the Scope of Authorization for each COVID-19 EUA drug, and the PREP Act.

200. The express language of the PREP Act and the Supremacy Clause Doctrine as it relates to the EUA statute removed all authority from Governor Newsom to establish conditions conflicting or interfering with an individual's lawful authority to either accept or refuse a medical product under an EUA/EUI[58] or the PREP Act.

201. At all times pertinent, Governor Newsom concealed the material fact that 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) contained a required condition of Congress that he must "ensure that individuals to whom the product is administered are informed — of the option to accept or refuse administration of the product." Although the governor is not injecting the unlicensed drug into those under his mandate, he is acting on behalf of the sponsor (federal government). He owes a

[58] EUI means Emergency Use Instructions. The CDC has claimed the authority to create its own form of emergency use for drugs, biologics, and devices by creating emergency use instructions for those products. Until courts rule on that authority, persons in authority will claim the use of EUIs and treat those products as another form of an EUA operating under the same statutes.

duty to Plaintiffs to ensure they can give their legally effective informed consent as outlined under 45 CFR § 46.116 and the Belmont Report.

202. Governor Newsom claimed lawful authority to determine employment conditions for all healthcare workers in the State of California and, as such, he had a duty and legal obligation to inform the public of their lawful rights, but chose to conceal those rights in hopes of causing Plaintiffs to surrender their Constitutional and statutory rights and to participate in the federal government's EUA/PREP Act COVID-19 Vaccination Program outside of their free will and voluntary consent.

203. Governor Newsom concealed the material fact that persons submitting to a COVID-19 EUA injection must forfeit legal rights to seek judicial relief from any resulting injury.

204. Governor Newsom concealed the material fact that persons submitting to a COVID-19 EUA injection become a subject in the federal government's COVID-19 research project and must allow their private identifiable information to be collected and shared with unknown persons for unknown reasons for eternity.

205. Governor Newsom concealed the material fact that persons submitting to a COVID-19 EUA injection would also be monitored by the drug's manufacturers for adverse reactions to the products for as long as the manufacturer desired.

206. Governor Newsom's fiat mandate that Plaintiffs must "show proof of vaccination or be tested regularly" was a direct assault on the Plaintiffs' Constitutional and federal statutory rights.

207. Governor Newsom owed healthcare workers a Constitutional obligation. He could not treat persons who refused an EUA/EUI or PREP Act product differently from persons who accepted an EUA/EUI or PREP Act product. Governor Newsom violated the Fourteenth

Amendment when he deprived Plaintiffs of their liberties (freedom from unwanted experimental medical testing) because they exercised a federally protected right with which he disagreed.

208. Governor Newsom is bound by the Fourteenth Amendment to ensure all residents under his authority are treated equally before the law. If they are not, then due process is the mechanism by which that unequal treatment must be applied.

209. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) was established by a valid act of Congress conferring authority on Plaintiffs to choose one of two legally protected options.

210. Governor Newsom established a condition penalizing only one of those two options by depriving Plaintiffs of their liberty to be free from undesirable investigational COVID-19 testing protocols[59] as a condition to enjoy a privilege of the State to sell one's labor in the medical profession.

211. Governor Newsom's policy established an Unconstitutional Condition whereby Plaintiffs were required to surrender their Fourteenth Amendment protections as a condition to sell their labor in the marketplace.

212. Governor Newsom engaged in a police power by fiat rule in violation of the United States Constitution and in disregard for the authority of Congress to establish emergency uses of unlicensed drugs, biologics, and devices within the State of California.

213. Governor Newsom made a personal choice that he would decide who gets to enjoy the rights and privileges established by the United States Constitution and federal statutes. For those whom he disagreed with, he would demote them to a second-class citizen by fiat rule.

214. More concerning is Governor Newsom promoting unlicensed drugs as a "vaccine" and implying that the drugs he was mandating were "safe."

[59] All COVID-19 testing kits were only authorized under EUA to means they were investigational and not indicated for any intended use under the declared emergency.

215. Moreover, Governor Newsom concealed the material fact that the FDA had not licensed any drug to treat, cure, or prevent any known COVID-19 variant. COVID-19 drug manufacturers, to this day, do not claim to protect all individuals from COVID-19 variants.

216. Congress prohibits persons from promoting a drug outside of its legal indication or that an investigational drug is safe and effective for its intended use.[60] Such public promotions violate California's Business and Professions Code § 17500[61] and CA Health & Safety Code § 110390 (2018).[62]

217. The three available mRNA drugs at the time of Governor Newsom's mandate were only authorized under the EUA statute and the PREP Act. The drug manufacturers and persons administering them were also provided with near absolute immunity from sustained injuries. The mRNA drugs had in excess of one trillion potential adverse reactions to licensed drugs and known diseases, which the manufacturers, FDA, CDC, HHS, or the State of California had not studied for safety or efficacy. The actions of Governor Newsom represent a moral turpitude of leadership not common in modern societies.

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[60] 21 CFR 312.7(a)

[61] California's Business and Professions Code § 17500 provides: "It is unlawful for any person, firm, corporation or association, or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services, professional or otherwise, or anything of any nature whatsoever or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatever, including over the Internet, any statement, concerning that real or personal property or those services, professional or otherwise, or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading, or for any person, firm, or corporation to so make or disseminate or cause to be so made or disseminated any such statement as part of a plan or scheme with the intent not to sell that personal property or those services, professional or otherwise, so advertised at the price stated therein, or as so advertised. Any violation of the provisions of this section is a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars ($2,500), or by both that imprisonment and fine."

[62] CA Health & Safety Code § 110390 (2018) provides: "It is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular."

218. In August of 2021, Tomas J. Aragon, Director and State Public Health Officer for the California Department of Public Health, and Governor Newsom, acting under color of law, issued a public Health Order[63] stating in part:

A. "All workers who provide services or work in facilities described in subdivision (a) have their first dose of a one-dose regimen or their second dose of a two-dose regimen by September 30, 2021,"

B. "a. Health Care Facilities:

i. General Acute Care Hospitals

ii. Skilled Nursing Facilities (including Subacute Facilities)

iii. Intermediate Care Facilities

iv. Acute Psychiatric Hospitals

v. Adult Day Health Care Centers

vi. Program of All-Inclusive Care for the Elderly (PACE) and PACE Centers

vii. Ambulatory Surgery Centers

viii. Chemical Dependency Recovery Hospitals

ix. Clinics & Doctor Offices (including behavioral health, surgical)

x. Congregate Living Health Facilities

xi. Dialysis Centers

xii. Hospice Facilities

xiii. Pediatric Day Health and Respite Care Facilities

xiv. Residential Substance Use Treatment and Mental Health Treatment Facilities"

C. "Two-dose vaccines include: Pfizer-BioNTech, Moderna, or Novavax vaccines authorized by the World Health Organization. The one-dose vaccine is: Johnson and Johnson [J&J]/Janssen."

[63] See Exhibit D, California Department of Public Health Order

D. "All workers currently eligible for boosters, who provide services or work in facilities described in subdivision 1(a) must be 'fully vaccinated and boosted' for COVID-19 receiving all recommended doses of the primary series of vaccines and a vaccine booster dose…"

E. "Workers may be exempt from the vaccination requirements under sections (1) and (2) only upon providing the operator of the facility a declination form, signed by the individual, stating either of the following: (1) the worker is declining vaccination based on Religious Beliefs, or (2) the worker is excused from receiving any COVID-19 vaccine due to Qualifying Medical Reasons."

F. "Exempt workers must wear a respirator approved by the National Institute of Occupational Safety and Health (NIOSH), such as an N95 filtering facepiece respirator, or surgical mask, at all times while in the facility."

H. "This Order is issued pursuant to Health and Safety Code sections 120125, 120140, 120175,120195 and 131080 and other applicable law."

219. From the date Mr. Aragon issued his mandatory vaccination requirements through the termination of that requirement, no FDA-licensed COVID-19 vaccine had been introduced into commerce for general commercial marketing. Thus, no FDA-licensed COVID-19 vaccine was available for healthcare workers to comply with the Health Order. Therefore, the Health Order exclusively relied on investigational new drugs under 21 U.S.C. §360bbb-3 authorization and the PREP Act for compliance.

220. Mr. Aragon called his Health Order a vaccination requirement. However, such a declaration was a misrepresentation of facts. The Health Order was a requirement for healthcare workers to inject investigational new drugs into their bodies outside of their free will and constitutional[64] and federal rights[65] as a condition to enjoy the privilege of selling one's labor in

[64] The Fourteenth Amendment required Mr. Aragon to treat persons who chose the 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) option to refuse exactly the same as he treated persons who chose the other option to accept.
[65] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) provides Plaintiffs with absolute legal authority to accept or refuse EUA products free from outside pressures. Governor Newsom and Tomas J. Aragon had no authority to interfere with Plaintiffs' option because of the Supremacy Clause and the express language of the PREP Act.

the marketplace and to enjoy liberties (e.g., freedom from wearing a mask or COVID-19 testing) to which they were otherwise entitled.

221. Governor Newsom and Mr. Aragon's Health Order established an unconstitutional condition[66] depriving Plaintiffs of their lawful authority and Congress of its power[67]. Therefore, the Health Order was unlawful because it was only established by fiat authority, lacking the force of law, because Congress preempted the State of California from having lawful authority to interfere in a person's right to accept or refuse an EUA/EUI or PREP Act product or activity.

222. No person has the legal authority to require another person to inject an unlicensed EUA/EUI or PREP Act investigational drug into their body as a condition to earn, receive, or enjoy a privilege of the State or conduct commerce, including employment. (See, discussion *infra*)

223. On December 11, 2020, the FDA issued to Pfizer-BioNTech the first COVID-19 EUA for its investigational drug (officially named Pfizer-BioNTech COVID-19 Vaccine[68]), and the FDA confirmed that Pfizer's product "is an investigational vaccine not licensed for any indication."[69]

224. On December 18, 2020, the FDA issued to ModernaTX, Inc., an EUA for its investigational drug (officially named Moderna COVID-19 Vaccine), and the FDA confirmed that Moderna's product "is an investigational vaccine not licensed for any indication."[70]

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[66] One cannot be required to choose between forfeiting either a federal right or a Constitutional right as a condition to enjoy a privilege of the State. The Health Order required Plaintiffs to either forfeit their right to refuse or their right to be treated equally before the law as a condition to continue selling their labor in the marketplace.

[67] Congress created 21 U.S.C. §360bbb-3 (the EUA statute) and the PREP Act and expressly preempted governors and state health agencies from establishing conditions they prohibit.

[68] The FDA improperly allowed Pfizer to add the word "Vaccine" to its investigational name. The court should not confuse this name to mean the drug is legally indicated for use as a vaccine. Pfizer-BioNTech COVID-19 Vaccine is an investigational drug having no legal indication to treat, cure, or prevent any known disease. The FDA classified the drug as an "investigational new drug." See Exhibit E, FDA's EUA Scope of Authorization Letter to Pfizer, December 11, 2020.

[69] 86 Fed.Reg. 5200, Jan. 19, 2021

[70] 86 Fed.Reg. 5200, Jan. 19, 2021

225. On February 27, 2021, the FDA issued to Janssen Biotech, Inc., an EUA for its investigational drug (officially named Janssen COVID-19 Vaccine), and the FDA confirmed that Janssen's product "is an investigational vaccine not licensed for any indication."[71]

226. Investigational new drugs[72] (IND) have no FDA-licensed legal indication to treat, cure, or prevent any known disease and are experimental by their very nature.[73]

227. Therefore, since no licensed COVID-19 vaccine existed within the marketplace at all times pertinent, it is indisputable that Governor Newsom and Mr. Aragon deprived Plaintiffs of their Constitutional and federal statutory rights to refuse an EUA/EUI/PREP Act product when they required California healthcare workers to inject an unlicensed investigational new drug into their bodies on or before September 30, 2021, as a condition to sell their labors in the state's healthcare industry or enjoy the liberties and benefits they were otherwise entitled.

228. As a matter of law, Plaintiffs would never have been able to provide proof of true vaccination because no FDA-licensed vaccines existed to vaccinate persons from any SARS-CoV-2 (COVID-19) variant.

229. Drugs and biologics are regulated according to their classification and not their formulation, and the EUA/EUI classification has no legal indication as a "vaccine." That is why the FDA stated in its respective EUA letters to the manufacturers that the drugs were

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[71] 86 Fed.Reg. 28608, May 27, 2021

[72] Investigational drug "means a new drug or biological drug that is used in a clinical investigation." (21 CFR 312.3 "Investigational new drug") Clinical investigation "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, <u>an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice</u>." (21 CFR 312.3 "Clinical investigation") (Emphasis added).

[73] Investigational new drug means, "A substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people…Also called experimental drug, IND, investigational agent, and investigational drug." NCI Dictionary of Cancer Terms. National Cancer Institute. Published 2023. Accessed June 25, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/investigational-new-drug

"investigational vaccines not licensed for any indication," meaning they were under investigation to receive the vaccine classification potentially.

230. Governor Newsom willfully enrolled the State of California in the CDC COVID-19 Vaccination Program. The CDC informed Governor Newsom and Mr. Aragon that,

> "[a]t this time, **all COVID-19 vaccine in the United States has been purchased by the U.S. government** (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remains U.S. government property until administered to the recipient. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine **outside the parameters of the Program** constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law." (Emphasis added) [See Exhibit A – CDC Covid-19 Vaccination Program Provider Agreement ("Provider Agreement").]

231. The Provider Agreement is an agreement between the federal government, the state government, and the healthcare providers who contractually agree to administer the injections to the public in accordance with the terms and conditions of the Provider Agreement and the federal statutes referenced therein.

232. The Provider Agreement states, "This program is a part of **collaboration** <u>under the relevant state, local, or territorial immunization's cooperative agreement with CDC</u>. To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 Vaccine), constituent[74] products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements…" (emphasis added).

[74] 21 CFR 312. §4.2 "constituent…is part of a combination product" defined in 21 CFR § 3.2(e).

233. The "Organization" refers to the healthcare facility signing the Provider Agreement and agreeing to administrate the federal government's property. The "Organization" is either a state health clinic, health care professional licensed by the State, healthcare facility licensed by the State, or other person authorized by the State to administer the federal property on the State's behalf.

234. The CDC informed Governor Newsom and Mr. Aragon that "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."[75] This requirement not only applied to the State of California and its various health agencies and clinics, but it also applied to all State-licensed private healthcare facilities (and their employees) that signed the Provider Agreement, which the State authorized to participate.

235. Therefore, since the COVID-19 drugs available to persons under the State's health order were only authorized under the EUA statute, and were given PREP Act immunity, the state was legally bound to ensure that its mandate complied with "all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA[76] that covers COVID-19 Vaccine."

236. The CDC contract informed Gov. Newsom and Mr. Aragon that "Each time Organization submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose….Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and

[75] See 12(a) in the Provider Agreement.
[76] 21 U.S.C. §360bbb-3

civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq*., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349."

237. Therefore, the Health Order, as applied, required healthcare facilities to commit fraud against the United States Government as a condition to comply with the Governor's mandate. This is because Governor Newsom and Mr. Aragon ordered those facilities to ignore the legal authority of Plaintiffs to accept or refuse the products without consequence in violation of federal law, state law, and the State's voluntary agreement with the federal government.

238. Congress was explicit that only the HHS Secretary can establish conditions with respect to the administration of Investigational (i.e., experimental) drugs.[77]

239. 21 U.S.C. §355(a) states that "no person shall introduce or deliver for introduction into interstate commerce any new drug unless an approval of an [FDA marketing] application." (Emphasis added).[78]

240. Congress carved out exemptions to that restriction under 21 U.S.C. §360bbb *et. seq.,* to allow individuals access to unlicensed drugs and biologics under compassionate, educational, and emergency conditions.[79]

241. Congress established **a required condition** before expanded access protocols could be issued under 21 U.S.C. §360bbb-3, "[w]ith respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), **shall**, for a person who carries out any activity for which the authorization is

[77] 21 U.S.C. §360bbb-3(l) [CITATION NOTE: lowercase "L", not a number one]
[78] 21 U.S.C. §355 (New Drugs) is part of Chapter 9 – Federal Food, Drug, and Cosmetic Act, Subchapter VI – Drugs and Devices, Part A – Drugs and Devices.
[79] The EUA statute is also part of Chapter 9 – Federal Food, Drug, and Cosmetic Act.

issued, **establish such conditions** on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health." (21 USC 360bbb-3(e)) (emphasis added)

242. Congress also conferred authority onto the Secretary that he may "appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, **and the circumstances under which**, the product may be administered with respect to such use." (21 U.S.C. §360bbb-3(e)(1)(B)(ii)) (Emphasis added).

243. However, for many years prior to 2021, it was clearly established that any medical product authorized under an EUA must provide individuals with the legal authority to determine participation free from outside pressure. Governor Newsom and Mr. Aragon should have been aware that "[n]othing in this section provides the Secretary **any authority to require any person to carry out any activity** that becomes lawful pursuant to an authorization under this section (21 U.S.C. 360bbb-3(l))" (Emphasis added). In other words, not even the Secretary of HHS may require any person to manufacture, distribute, administer, or receive an EUA product. Still, Gov. Newsom and Mr. Aragon asserted they had such authority but refused to show by law where that belief was established.

244. Governor Newsom, acting with moral turpitude,[80] removed the Constitutional and federal statutory right of healthcare workers to refuse the administration of an unlicensed investigational drug. Ironically, the Governor ordered healthcare professionals to act in a manner that was not professional and to forgo their oath to do no harm by ignoring potentially trillions of contraindications of the three mRNA investigational new drugs available when he issued his edict.

[80] "This phrase is used to describe the violation of decent, moral, and honest behavior and an act of depravity or vileness." Black's Law Dictionary 2nd Ed.

245. Therefore, Congress provided only the HHS Secretary authority to grant expanded access protocols to unlicensed medical products undergoing clinical trials or products not licensed for their intended use under a declared emergency. However, Congress restricted the Secretary from requiring anyone to manufacture, distribute, administer, or receive the product simply because the product was granted emergency access. Moreover, Congress did not authorize the HHS Secretary to delegate his authority to another person. By extension, any person involved in an EUA activity is also restricted from requiring any person to participate in that activity.

246. The moment Governor Newsom volunteered the State of California to participate in the CDC COVID-19 Vaccination Program, he agreed to the terms and conditions of the program, which required him to comply with all protocols under the EUA statute, including the restriction that no person can be required to participate in any EUA activity.

247. However, even if the CDC COVID-19 Vaccination Provider Agreement did not exist, the Governor was bound to abide by the EUA statute anytime the State involved an individual with an EUA investigational drug.

248. Therefore, when the Health Order was issued, Gov. Newsom and Mr. Aragon violated their statutory and constitutional duties. They deprived Plaintiffs of their Constitutional and federal statutory rights because the Health Order relied exclusively on EUA and PREP Act products for compliance. Those deprivations directly led to Plaintiffs' legal and financial injuries.

249. Specifically, when Governor Newsom and Mr. Aragon issued the Health Order requiring Plaintiffs to inject an investigational drug into their body no later than September 30, 2021, they fraudulently misrepresented their authority to Plaintiffs. They established EUA protocols that Congress legally prohibited (mandatory participation). Moreover, the Health Order

required facilities to stop purchasing the labor of persons refusing the experimental injections in violation of federal law and the U.S. Constitution (Due Process & Equal Protection).

250. Moreover, Governor Newsom freely volunteered to comply with the CDC COVID-19 Vaccination Program Provider Agreement, which contains third-party beneficiary rights for Plaintiffs.

251. Neither Governor Newsom nor Mr. Aragon provided Plaintiffs with information about their legal right to either accept or refuse EUA/EUI/PREP Act products without consequence. The Health Order intentionally refrained from referencing 21 U.S.C. §360bbb-3 because the requirement to inject unlicensed drugs into Plaintiffs' bodies infringes upon the authority of Plaintiffs to freely choose their preferred "option" under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III), among other Constitutional rights.[81]

252. The Supremacy Clause doctrine establishes that 21 U.S.C. §360bbb-3 supersedes Governor Newsom's and Mr. Aragon's authority to establish conditions conflicting with the federal statute. Because Congress restricted the HHS Secretary from delegating his authority, Governor Newsom and Mr. Aragon unlawfully enacted laws in defiance of the authority of the United States Congress, creating a Constitutional crisis within the State of California and the nation by issuing health orders that led to severe deprivation of Plaintiffs' Constitutional and federal statutory rights to choose an option without penalty.

253. Should a governor be authorized to penalize a person choosing the option to refuse, it also stands to reason that a governor can penalize a person choosing the option to accept. Though this argument is nonsensical, it aptly demonstrates that when a governor penalizes either option,

[81] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) requires that individuals to whom the product is being administered are informed "of the option to accept or refuse administration of the product."

the choice no longer belongs to an individual but to a third party who either agrees or disagrees with it, fundamentally altering the EUA statute.

254. When a "right" conferred upon an individual, in unambiguous language, by a valid act of Congress is penalized, it is not a right.

255. Moreover, the penalty violates the U.S. Constitution because it deprives a person of lawful authority outside of Due Process, and it deprives Plaintiffs of equal protection of laws as guaranteed under the Fourteenth Amendment because some individuals are not penalized while others are, even though they all acted under the same federal statute and are under the same federal jurisdiction.

256. Congress expressly required Governor Newsom and all licensed healthcare facilities and workers in the State "to inform" Plaintiffs of their **legal rights** under the EUA statute, which are that they can either "accept" or "refuse" without penalty.

257. Governor Newsom unlawfully amended the EUA statute by removing Plaintiffs' legal option to "refuse" participation in a 100% federally funded program (CDC COVID-19 Vaccination Program) without consequence.

258. Governor Newsom and Mr. Aragon exclusively relied on emergency medical countermeasures for compliance, which are also under PREP Act authority. The PREP Act also expressly restricts state executives and legislatures from issuing laws, regulations, and ordinances that conflict with or interfere with the statute's provisions.[82]

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[82]" Preemption of State law During the effective period of a declaration under subsection (b)…no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that— (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the…administration…of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]." - 42 USC 247d-6d(b)(8) See

259. Congress expressly wrote into legislation that state officials like Governor Newsom and Mr. Aragon could not establish a "legal requirement" interfering with "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 [21 U.S.C. 301 et seq.]" (emphasis added). The "any matter" directly links to the authority of Plaintiffs to either accept or refuse the medical countermeasures without consequence under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) (Federal Food, Drug, and Cosmetic Act).

260. Governor Newsom and Mr. Aragon intentionally ignored the PREP Act's restriction of their authority, even though the CDC Provider Agreement provides, "Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization **if** it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services"[83](Emphasis added). Clearly, Governor Newsom did not comply with the PREP Act; therefore, immunity protections under the PREP Act do not extend to the State.

261. Although the PREP Act does not provide for a private right of action, the PREP Act's restrictions demonstrate that Governor Newsom and Mr. Aragon acted under fraudulent pretense. Thus, the Health Order, as applied, was illegal and directly led to Plaintiffs' legal, financial, and health injuries.

262. While there is no private right of action under the PREP Act, Plaintiffs' injuries provide for a cause of action under 42 U.S.C. §1983 and other federal and Constitutional rights (see discussion, *infra*).

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#preemption

[83] CDC COVID-19 Vaccination Program Provider Agreement

263. Governor Newsom and Mr. Aragon deceptively used the fact that the COVID-19 EUA drugs were granted EUA and PREP Act status as the means to push their political agenda while ignoring the restrictions of their powers contained within those same statutes.

264. It is well-established California common law that Plaintiffs exercising a legal right may not be terminated or prohibited from employment for exercising such a right.

265. It cannot be disputed that Plaintiffs considering participation in a medical countermeasure authorized under the EUA statute have the exclusive legal right to determine which option to choose. Congress prohibits all other authorities from penalizing one of the two options.

266. Chaos has reigned within the State of California because Governor Newsom and Mr. Aragon completely disregarded the right of Plaintiffs to be treated equally before the law as guaranteed to them under the Fourteenth Amendment. The "option" is the right. Governor Newsom should have known that Plaintiffs were afforded the option, yet by fiat rule, he chose to demote Plaintiffs to second-class citizens for no other reason than he disagreed with their choice.

267. Governor Newsom declared by his actions that he, not the United States Congress, would determine which option Plaintiffs would choose. Such wanton disregard for the U.S. Constitution, the Supremacy Clause, and the Separation of Powers Doctrine is unheard of in the modern-day Republic.

268. Governor Newsom's and Mr. Aragon's wanton disregard for the rights of Plaintiffs led them to conceal their right to refuse without consequence to such a degree that securing Plaintiffs' substantive and procedural Due Process rights was legally impossible. **If persons in authority, such as Governor Newsom, refuse to acknowledge rights conferred upon Plaintiffs by valid acts of Congress, then due process is legally impossible to secure.**

269. Governor Newsom's and Mr. Aragon's Health Order violates the well-established Unconstitutional Conditions Doctrine. The Supreme Court has held that a person "may not barter away his life or his freedom, or his substantial rights" (*Home Ins. Co. of New York v. Morse*, 87 U.S. 455, 451 (1874))

270. The State of California holds licensing power over the right of Plaintiffs to enjoy their profession, and Governor Newsom and Mr. Aragon unlawfully utilized the powers of their office to prevent Plaintiffs from enjoying the equal protection of laws because of their personal preference in direct violation of their oath of office.

271. Governor Newsom's and Mr. Aragon's Health Order required Plaintiffs to surrender their Constitutional Rights of Equal Protection of Laws and Due Process as a condition to sell their labor in their chosen profession. The US Supreme Court held:

> "It would be a palpable incongruity to strike down an act of state legislation which, by words of express divestment, seeks to strip the citizen of rights guaranteed by the federal Constitution, but to uphold an act by which the same result is accomplished under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to withhold. It is not necessary to challenge the proposition that, as a general rule, the state, having power to deny a privilege altogether, may grant it upon such conditions as it sees fit to impose. But the power of the state in that respect is not unlimited; and **one of the limitations is that it may not impose conditions which require the relinquishment of constitutional rights.** If the state may compel the surrender of one constitutional right as a condition of its favor, it may, in like manner, compel a surrender of all. **It is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence** (emphasis added)."[84]

272. The Health Order established a condition that Plaintiffs must inject an investigational new drug into their bodies before September 30, 2021 to continue their employment

[84] *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593-94 (1926)

under the State's licensing requirements or to enjoy privileges and benefits they were otherwise entitled. The U.S. Supreme Court held:

> "Broadly stated, the rule is that the right to continue the exercise of a privilege granted by the state cannot be made to depend upon the grantee's submission to a condition prescribed by the state which is hostile to the provisions of the federal Constitution.[85]

273. Governor Newsom and Mr. Aragon unlawfully utilized the powers of their office to "produce a result which the State could not command directly" (*Speiser v. Randall*, 357 U.S. 513 (1958)). The State cannot demand by law that Plaintiffs inject an investigational new drug into their bodies[86] as a condition to participate in employment, education, the National Guard, or any licensed profession the State oversees, including healthcare.

274. Because the HHS Secretary prescribed research conditions meeting 45 CFR 46 requirements in each COVID-19 EUA, Governor Newsom and Mr. Aragon were bound to obtain Plaintiffs' legally effective informed consent. This consent requirement applies to any person acting on behalf of the sponsor[87] of the emergency medical countermeasure (e.g., COVID-19 drugs, masks, testing articles) program and not only to persons administering the product.

275. 45 CFR §46.116 and the Belmont Report describe the conditions by which legally effective informed consent must be obtained. The burden on Governor Newsom and Mr. Aragon when presenting Plaintiffs with the offer to participate in the federal government's property

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[85] *Western Union Tel. Co. v. Kansas*, 216 U.S. 1, 47, 48 S., 30 S. Ct. 190; *Western Union Tel. Co. v. Foster*, 247 U.S. 105, 114, 38 S. Ct. 438, 1 A. L. R. 1278. (*U.S. v. Chicago, M., St. P. &P. Railway Co*., 282 U.S. 311, 328-329 (1931)).

[86] 45 CFR § 46.116, 45 CFR §46.122, the Belmont Report (45 CFR § 46.101(c,i)), 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, PREP Act, 10 U.S.C. §980.

[87] The Federal Government is the sole sponsor of all COVID-19 EUA drugs, biologics, and devices, paying for 100% of their costs. Therefore, California is acting on behalf of the sponsor when establishing mandatory participation in the government's property.

required them to ensure Plaintiffs were not under "sanctions, "coercion," "undue influence," or "unjustifiable pressures" to participate.[88]

276. Therefore, Governor Newsom and Mr. Aragon deprived Plaintiffs' of legally effective informed consent rights by establishing a "sanction" for non-participation in investigational new drugs under "coercive" conditions. Moreover, Governor Newsom and Mr. Aragon should have known of the requirement to obtain Plaintiffs' legally effective informed consent when volunteering to participate in the CDC COVID-19 Vaccination Program immunization project.[89]

277. Governor Newsom and Mr. Aragon, acting with moral turpitude, placed Plaintiffs under moral duress[90] to inject an unlicensed investigational drug into their bodies, knowing they relied on their chosen profession to access living wages and would be under extreme emotional distress to comply with his unlawful usurpation of authority.

278. Long before the COVID-19 pandemic started, the State of California provided HHS with an "assurance" that it would comply with 45 CFR 46 and the Belmont Report anytime it offered an individual participation in an investigational new drug under federal authority or utilizing federal funds (e.g., CDC COVID-19 Vaccination Program).

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[88] The publication of the Belmont Report was a required condition of the 1974 National Research Act. Congress required the HHS Secretary to act on the Belmont Report and issue regulations providing for the Protection of Human Subjects. 45 CFR §46.116 is the only federal definition of informed consent, and therefore, whether federal law explicitly or implicitly requires informed consent, this is the only known meaning of that requirement demonstrating the intent of Congress.

[89] CDC COVID-19 Vaccination Program Provider Agreement (Exhibit A) Clause 12(a) states, "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." Therefore, 21 U.S.C. §360bbb-3 (under Food, Drug, and Cosmetic Act) requires adherence to 45 CFR §46.116 and the Belmont Report.

[90] Moral duress consists of imposition, oppression, undue influence, or the taking of undue advantage of the business or financial stress or extreme necessity or weakness of another. *Lafayette Dramatic Productions v. Ferentz*, 306 Mich. 193, 9 N.W.2d 57, 66; See also Black's Law Dictionary, Sixth Edition, p. 1008.

279. This assurance is a requirement by the Federal Government of the State of California as a condition for the State to receive federal funds to be expended on research activities.[91]

280. The agreement is why the CDC chose to use the State's existing immunization agreement because Governor Newsom and Mr. Aragon were already bound by duty to protect the rights of individuals under their authority when it agreed to the Federal Wide Assurance[92] (FWA) agreement administered under the Office of Human Rights Protection within HHS.

281. In exchange for the assurance to comply with the ethical principles of the Belmont Report and 45 CFR Part 46 when involving humans with investigational new drugs, HHS assigned the State FWA00000681, denoting a legally binding agreement between the State of California and the United States Government for the explicit benefit of third-party participants.

282. Governor Newsom and Mr. Aragon deprived Plaintiffs' third-party beneficiary rights[93] under the State's FWA agreement when they issued the requirement that Plaintiffs inject investigational new drugs into their bodies as a condition to continue employment in their chosen healthcare profession.[94]

283. In direct violation of 45 CFR §46.116 and the Belmont Report and deprivation of Plaintiffs' rights thereunder, Governor Newsom and Mr. Aragon purposefully placed Plaintiffs

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[91] 45 CFR § 46.122

[92]" The Federal Wide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46." - 1. Office. Federal Wide Assurances (FWAs). HHS.gov. Published June 16, 2009. Accessed August 31, 2023. https://www.hhs.gov/ohrp/federalwide-assurances-fwas.html#:~:text=The%20Federalwide%20Assurance%20(FWA)%20is,at%2045%20CFR%20part%2046.

[93] The right to give legally effective informed consent according to 45 CFR § 46.116 and the Belmont Report is but one of the rights conferred upon the Plaintiffs.

[94] 45 CFR §46.116

under "sanctions," "coercion," and "undue influence" to participate in an EUA medical countermeasure.

284. Governor Newsom pledged that the State would protect individuals considering participation in the CDC COVID-19 Vaccination Program. Before the ink dried from his affirmation, he turned around and deprived the third-party beneficiary rights belonging to Plaintiffs under that agreement and the State's FWA.

285. Although the federal government purchased all COVID-19 EUA drugs, they are not exempt from 21 U.S.C. §360bbb-3 requirements. Moreover, simply because the CDC has a program whereby the State of California can access the Federal Government's EUA property does not exempt the State from complying with its legal obligations under 21 U.S.C. §360bbb-3. The CDC COVID-19 Provider Agreement is an additional layer of responsibility for organizations to comply with, not an exemption from their statutory legal obligations.

286. Therefore, Governor Newsom and Mr. Aragon should have known that 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) contained a required condition of them "to ensure that individuals to whom the product is administered are informed— of the option to accept or refuse administration of the product."

287. At all times pertinent, Governor Newsom and Mr. Aragon concealed this right from Plaintiffs in their Health Orders. They intentionally refrained from guiding the healthcare community on this right because it undermined their desire to push an EUA investigational drug onto Plaintiffs outside of their free will and voluntary consent.

288. The Health Order's statement that: "Vaccination against COVID-19 is the most effective means of preventing infection with the COVID-19 virus" and "Unvaccinated persons are more likely to get infected and spread the virus" was meant to deceptively mislead Plaintiffs into

participating in drugs having no FDA legal indication that the drugs are either safe or effective.[95] In fact, as of August 5, 2021, the CDC had acknowledged that the COVID-19 EUA shots did not prevent either infection or transmission, so Gov. Newson's Health Order conflicted with what the CDC had already told the American public. Moreover, such a statement directly violates federal law.[96]

289. Moreover, at no time did Governor Newsom nor Mr. Aragon provide information Plaintiffs would want to know when considering participation.[97] For example, COVID-19 mRNA drugs also had historical reports of adverse events, were not manufactured according to standards licensed drugs are manufactured, and had heart-related and blood clotting issues that were not common side effects of a typical "vaccine." Additionally, they failed to inform recipients that Pfizer's BioNTech COVID-19 Vaccine trial lost 93% of its participants by the sixth month of a 24-month trial. Most importantly, Governor Newsom intentionally concealed that a person choosing to volunteer as an EUA drug recipient is prohibited from seeking any meaningful judicial relief when injured by the medical countermeasure, specifically because they are under PREP Act authority.

290. Most concerning is Governor Newsom's and Mr. Aragon's concealment of the legally binding agreement Plaintiffs must agree to before injecting an EUA investigational drug into their bodies. Congress was explicit that any person receiving a medical countermeasure under

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[95]" Unless and until FDA properly classifies AVA [an anthrax vaccine] as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug…" *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004)

[96] "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 CFR 312.7(a)

[97] 45 CFR 46.116(a)(4)

EUA and PREP Act authority must agree to the following terms and conditions, including, but not limited to:

A. forfeiture of civil litigation rights resulting from injuries,[98]

B. allow their private identifiable information to be collected and used for a variety of purposes by unknown persons,[99]

C. allow their involvement with the EUA product to be cataloged by various persons for unknown purposes,

D. allow the data collected about their adverse events to be utilized by researchers for unknown purposes and eternity,[100]

E. assume greater risks to their safety, health, and legal rights.[101],[102]

291. Governor Newsom and Mr. Aragon violated their duties to Plaintiffs that they must "Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision."[103]

292. **ANY** drug, biologic, or device authorized under 21 U.S.C. §360bbb-3 (the EUA statute) is classified by the FDA as investigational for its intended use under the declared emergency. (See, *supra*)

293. The State agreed to conduct research on behalf of the federal government when distributing the federal government's EUA COVID-19 investigational drugs (see, *supra*). All

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[98] PREP Act forfeits all civil actions for damages in most situations.

[99] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to obtain private identifiable information.

[100] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to monitor, report and study a variety of adverse reactions to EUA products.

[101] 21 U.S.C. §360bbb-3 requires potential recipients to be made aware of the risks, alternatives, and the fact that the product is only authorized by the Secretary under emergency conditions. These elements provide potential recipients with the required information to make a quality and legally effective decision to consent. Therefore, consent means the individual agrees to assume more than minimal risk.

[102] 21 CFR 50.3(k) (Protection of Human Subjects; Definitions) defines minimal risk as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

[103] CA Health & Safety Code § 24172(j) (2013)

persons who received a COVID-19 EUA drug, biologic, or device are lawfully considered "subjects" under 45 CFR § 46 because (1) the federal government funds the product, (2) their private identifiable information is collected, (3) their involvement with the product is monitored and studied for safety and efficacy, and (4) the person is a human.

294. Governor Newsom and Mr. Aragon should have known that "Except as otherwise provided in this section, no person shall be subjected to any medical experiment unless the informed consent of such person is obtained."[104]

295. Governor Newsom and Mr. Aragon should have known that depriving a California resident of their informed consent rights and or failure to inform the person involved in a medical research project of the associated risks can result in a fine of up to $50,000 and imprisonment in county jail up to one year per incident.[105]

296. Governor Newsom cannot produce a treaty, statute, regulation, or other legal power affording him authority to ignore Congress, abuse the Constitution, or defy his oath of office by requiring an individual under the authority of his office to inject an investigational drug into their body as a condition of anything.

297. Congress preempted Governor Newsom's and Mr. Aragon's actions, restricted their authority, denied their power, and still, they acted as if the rule of law did not apply to them, their office, or those state actors under their authority.

298. Governor Newsom's and Mr. Aragon's actions are more akin to an authoritarian dictatorship than duly elected officers acting for the public's benefit by upholding their respective oaths to respect Plaintiffs' rights as guaranteed to them by the United States Constitution and the California State Constitution and laws.

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[104] CA Health & Safety Code § 24175(a) (2013)
[105] CA Health & Safety Code § 24176 (2013)

299. Therefore, the Health Order, as applied, deprived Plaintiffs:

(1) of their Fourteenth Amendment right to Equal Protection of Laws because the health order only penalized persons choosing the statutory option to refuse and only required the same persons to wear a mask or engage in experimental COVID-19 medical testing.

(2) of their Fourteenth Amendment substantive and procedural Due Process Rights because the Health Order refused to acknowledge Plaintiffs' statutory rights and provide them with a time, place, and date to air their complaint before the State deprived them of their liberty and property.

(3) of their 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) legal authority to choose one of the two federal statutory options without consequence.

(4) of their rights under 45 CFR § 46.122[106]

(5) of their rights under 45 CFR § 46.116[107]

(6) of their rights under the Belmont Report

(7) of their rights under Article VII of the ICCPR Treaty[108]

(8) of their third-party rights under the CDC COVID-19 Vaccination Program Provider Agreement.

300. Governor Newsom's and Mr. Aragon's actions directly led to Plaintiffs experiencing life-altering emotional trauma, financial destruction, and loss of life's goals, dreams, and aspirations, including engaging in the professions of their choice. Governor Newsom and Mr.

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[106] *Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002), "the Court has found that spending legislation gave rise to rights enforceable under §1983."

[107] COVID-19 EUA drugs were fully funded by the federal government under the HHS and CDC research program requiring adherence to 45 CFR § 46.116 and the Belmont Report.

[108] Although the ICCPR Treaty provides no private right of action, it is enforceable under § 1983.

Aragon intentionally inflicted emotional distress on Plaintiffs for the express purpose of deceptively compelling them to surrender their Constitutional protections and statutory rights and to participate in the federal government's COVID-19 investigational drug program outside of their free will and voluntary consent.

Kaiser Foundation Hospitals

301. Kaiser Foundation Hospitals ("Kaiser") is a network of not-for-profit hospitals incorporated in California.

302. Kaiser's CEO is Greg Adams.

303. Kaiser's Chief Medical Officer (CMO) is Andrew Bindman, MD.

304. At all times pertinent, Plaintiffs were under the authority of Kaiser.

305. Kaiser PolicyMakers (Greg Adams and Andrew Bindman, MD) signed the CDC COVID-19 Vaccination Program Provider Agreement, assured HHS it would comply with its FWA00025698 agreement, established institutional review boards under 45 CFR Part 46 authority, and instituted and enforced Kaiser's COVID-19 policy.

306. Although Kaiser, and its PolicyMakers, at other times and in other circumstances, are private parties, they acted under color of law when, as collaborators with the State of California pursuant to the Provider Agreement and the State's Health Order, penalized and deprived Plaintiffs of their statutory and Constitutional rights for refusing to inject one of the mandated unlicensed investigational drugs into their bodies.

307. The Supreme Court and Ninth Circuit Court of Appeals utilize several tests to ascertain when a private party is engaged in state action. Kaiser is a state actor under the (1) Public

Function Test,[109] (2) State Compulsion Test,[110] (3) Symbiotic Relationship Test,[111] and (4) Customs Test.[112]

308. On August 27, 2021, Kaiser Policymakers issued a new company policy[113] that, as applied, violated federal law, state law, and deprived Plaintiffs' of their statutory and Constitutional rights.

309. The policy stated in part:

(1) "Kaiser Permanente is requiring all employees be fully vaccinated for COVID-19 by September 30, 2021, or to submit proof of a qualifying medical or religious exemption. Those who are not vaccinated by September 30 will be placed on unpaid administrative leave for up to 60 days until they are fully vaccinated."

(2) "Unvaccinated employees and those who have not provided proof of vaccination must follow workplace safety rules including routine proof of negative COVID-19 test results based on regional requirements."

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[109] The CDC COVID-19 Vaccination Program was exclusively a government function for the public, in which no private party could participate, administrate, or even charge the public for the Program. Though the Program was novel and new, it fits the historical definition of a governmental public function.

[110] The State issued a mandate impacting Plaintiffs' employment. Kaiser is a state actor under this test pursuant to *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982) (citing *Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 166 (1978); *Jackson*, 419 U.S. at 357; *Adickes v. S.H. Kress & Co*., 398 U.S. 144, 170 (1970); *Moose Lodge No. 107 v. Irvis*, 407 U.S. 163, 173 (1965)).

[111] Kaiser and California were required by the federal government to conduct medical research and obtain Plaintiffs' legally effective informed consent. These requirements demonstrate a symbiotic relationship between the State and Kaiser pursuant to: *Brunette v. Humane Society of Ventura County*, 294 F.3d 1205 (9th Cir. 2002): "Burton (*Burton v. Wilmington Pkg. Auth*, 365 U.S. 715, 81 S. Ct. 856 (1961)) teaches that substantial coordination and integration between the private entity and the government are the essence of a symbiotic relationship. Often significant financial integration indicates a symbiotic relationship. See *Rendell-Baker v Kohn*, 457 U.S. at 842-43, 102 S.Ct. 2764; *Vincent v. Trend W. Tech. Corp*., 828 F.2d 563, 569 (9th Cir. 1987). For example, if a private entity, like the restaurant in Burton, confers significant financial benefits indispensable to the government's "financial success," then a symbiotic relationship may exist. *Vincent*, 828 F.2d at 569. A symbiotic relationship may also arise by virtue of the government's exercise of plenary control over the private party's actions. See *Dobyns v. E-Systems, Inc*., 667 F.2d 1219, 1226-27 (5th Cir. 1982) (finding symbiotic relationship where the government-controlled a private peacekeeping force engaged in a government-directed field mission in the Sinai Peninsula).

[112] The Supreme Court noted in *Adickes v. S. H. Kress & Co*., 398 U.S. 144 (1970) that the "Petitioner will have established a claim under §1983 for violation of her equal protection rights if she proves that she was refused service by respondent because of a <u>state-enforced custom…</u>" (emphasis added). Governor Newsom and Kaiser PolicyMakers developed a state custom whereby a person's 21 U.S.C. §360bbb-3 statutory rights can be ignored "as if" they do not exist.

[113] Exhibit F, Kaiser Policy

(3) "Employees who are not fully vaccinated or who do not have an approved exemption will no longer be eligible to continue employment and will be terminated" by December 01, 2021.

310. As discussed *infra*, no COVID-19 drug was also licensed by the FDA to be introduced into commerce for general commercial marketing. Therefore, as applied, the policy relied exclusively on EUA investigational drugs for compliance in violation of federal law, contractual agreements, and Plaintiffs' constitutional rights.

311. Therefore, as a matter of law, Kaiser PolicyMakers did not issue a "vaccination" requirement. They issued a requirement that Plaintiffs inject EUA investigational drugs that had no legal indication to treat, cure, or prevent any known disease into their bodies as a condition to continue selling their labors to the company in violation of federal law, state law, and their contractual duties.

312. Kaiser PolicyMakers' COVID-19 Policy violated:

(1) their CDC COVID-19 Vaccination Program Provider Agreement having third-party beneficiary rights for Plaintiffs.

(2) their Federal Wide Assurance agreement under number FWA00002344, which has third-party beneficiary rights[114] for Plaintiffs.

(3) Plaintiffs' Fourteenth Amendment right to Equal Protection of laws under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) because Plaintiffs were only penalized (e.g., placed on admin leave, terminated, required to engage in experimental device use) because they chose the option to refuse whereas employees who chose the option to accept were not penalized.

(4) Plaintiffs' Fourteenth Amendment right to Due Process (substantive and procedural) because Kaiser PolicyMakers deprived Plaintiffs of their liberties (freedom from the requirement to use experimental masking and unwanted experimental COVID-19 testing) and property (PTO, wages, retirement funds, healthcare insurance, etc.) without providing them a time, place, and date to air their complaint resulting from

[114] The FWA requires Kaiser PolicyMakers to adhere to 45 CFR Part 46 and the Belmont Report including obtaining Plaintiffs legally effective informed consent.

Plaintiffs exercising their 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) statutory authority.

(5) Plaintiffs' right to be free from medical experimentation under Article VII of the ICCPR Treaty.

(6) Plaintiffs' 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) lawful authority to accept or refuse participation without interference from Kaiser PolicyMakers.

(7) Plaintiffs 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) option to accept or refuse participation as required under the PREP Act as a condition of Kaiser PolicyMakers and manufacturers of "covered countermeasures" receiving immunity.

(8) their lawful duties under its Institutional Review Board whenever Plaintiffs are involved in a federally funded investigational product. The IRB must adhere to 45 CFR Part 46 and the Belmont Report.

(9) Plaintiffs' legally effective informed consent rights under 45 CFR Part 46, the Belmont Report, CDC COVID-19 Vaccination Program Provider Agreement, 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III), and Defendants' respective FWAs.

313. At all times pertinent, Kaiser PolicyMakers did not inform Plaintiffs of their rights to refuse participation in an EUA/EUI/PREP Act product or activity without incurring a penalty or losing a benefit to which they are otherwise entitled. The purpose of concealing this right under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) was to deceptively cause Plaintiffs to surrender their Constitutional and statutory rights in hopes of causing them to unwillingly participate in the federal government's COVID-19 Vaccination medical research project.

314. Kaiser PolicyMakers are legally sophisticated in laws applicable to the investigational new drug classification.[115] They know they are legally restricted from applying

[115] Kaiser informs the public: "The Division is one of the nation's largest research facilities outside of a government or university setting. We are the primary professional home of more than 60 research scientists and 600 staff members who lead studies in epidemiology, health services, and clinical trials. Our studies cover a wide range of clinical topics, including cardiovascular disease, cancer, diabetes, substance abuse, mental health, maternal and child health, and women's health. Our research addresses broad issues, including the role of genes and the environment in health, the

outside pressure on Plaintiffs to participate in federally funded research projects, much less sanctioning them for refusing to participate. The same laws governing their research projects are the exact same laws governing the administration of EUA biomedical research products.

315. Kaiser PolicyMakers signed and/or approved the CDC COVID-19 Vaccination Provider Agreement and knew of its legal requirements prohibiting them from mandating participation in the Program's activities.[116] Moreover, they agreed to conduct joint medical research activities with the State and obtain Plaintiffs' legally effective informed consent.

316. Kaiser PolicyMakers assured HHS that they would **never** place an individual under "coercion," "undue influence," "sanction," or "unjustifiable pressure" to inject unlicensed drugs into their bodies, which were funded by the federal government when HHS awarded Kaiser its Federal Wide Assurance Agreement Number (FWA00002344). Kaiser PolicyMakers had to promise to comply with 45 CFR § Part 46 and the Belmont Report having intended benefits for Plaintiffs.

317. Kaiser PolicyMakers have an institutional review board (IRB) under 45 CFR Part 46 and the Belmont Report protocols overseeing all investigational new drug administration protocols, which prohibited the application of their COVID-19 policy.

318. Kaiser PolicyMakers knew of each COVID-19 EUA Scope of Authorization prohibiting mandatory participation. Even if the CDC did not implement the COVID-19

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influence of behavior on disease prevention and chronic illness management, drug safety, health care policy, health services delivery, and disparities. We have almost 400 ongoing projects and contribute more than 500 scientific papers to peer-reviewed journals each year." "The Division's work is funded primarily by federal agencies, such as the National Institutes of Health, Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality. The Permanente Medical Group and Kaiser Foundation Health Plan's Community Benefit Program are our major internal sponsors." - 1.About DOR. Kaiser Permanente Division of Research. Published June 21, 2023. Accessed October 23, 2023. https://divisionofresearch.kaiserpermanente.org/about/

[116] 12(a) of the contract states, "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." 21 U.S.C. §360bbb-3 contains the option to accept or refuse, which Joint Board Members voluntarily agreed to adhere to when involving Plaintiffs in the CDC COVID-19 Vaccination Program.

Vaccination Program, Kaiser PolicyMakers should have known that compliance with the EUA statute is a legal requirement they cannot violate.

319. Kaiser PolicyMakers oversaw the administration of drugs and biologics administered to patients under 21 U.S.C. §360bbb *et seq.,* for decades[117] and always obtained a patient's informed consent because they knew the statute's requirements.

320. Kaiser PolicyMakers' COVID-19 policy usurped the authority of the HHS Secretary by unlawfully amending the conditions established by the Secretary in the Scope of Authorization for each COVID-19 EUA drug. Moreover, Kaiser PolicyMakers ignored the authority of the U.S. Congress by requiring the very condition (mandatory) that Congress prohibits. The Supremacy Clause prospectively preempted Kaiser PolicyMakers' authority to establish their COVID-19 policy as applied. The policy was patently illegal, a fact with which Kaiser PolicyMakers were intimately familiar.

321. Kaiser Policymakers cannot produce a Constitution, treaty, statute, regulation, or any other authority providing them exemption from their lawful duties under the above-referenced laws, contracts, agreements, and Constitution. Moreover, Congress expressly preempted them from establishing contradictory conditions using fiat authority.

322. Kaiser PolicyMakers knew the Health Order established by Governor Newsom and Mr. Aragon was unlawful, and they had a duty to protect the rights of Plaintiffs despite the illegal requirements established by Governor Newsom and Mr. Aragon. Kaiser PolicyMakers were free to and, in fact, instructed to protect Plaintiffs' rights by complying with federal law, their contractual obligations, and HHS's legal obligations unabated, but they intentionally failed to do so.

[117] Hospitals routinely utilize investigational new drugs for cancer patients which require EUA authority.

323. The Supremacy Clause of the U.S. Constitution gave Kaiser PolicyMakers full authority to ignore the State's Health Order as applied without fear of consequence. However, they chose to ignore their lawful obligations for the age-old sin of greed because the federal government's cash cow was too great of a temptation to opt out of.

324. The moral turpitude of Kaiser PolicyMakers was painfully realized when they issued a requirement for Plaintiffs to seek exemption from investigational drug use by requesting a medical or religious exemption. The exemption requirement is a clear violation of federal law as the option to accept or refuse is absolute. It belongs exclusively to Plaintiffs in which Kaiser PolicyMakers are expressly prohibited from interfering, a fact with which they were intimately familiar.

325. One of the statements Kaiser PolicyMakers required Plaintiffs to sign seeking a medical or religious exemption is, "I understand that I may be required to take additional education on COVID-19 vaccines and safety training, routinely show proof of negative COVID-19 test results and wear a mask during work hours if I am not vaccinated" and " To be eligible for this exemption, I understand that I must disclose below the religion and identify the specific doctrine or teaching that prevents me from receiving any COVID-19 vaccine."

326. Kaiser PolicyMakers compelled Plaintiffs, under financial duress and intense emotional strain, to prospectively agree to certain conditions if they were exempted from Kaiser PolicyMakers' requirement to be injected with an EUA investigational drug. In other words, Kaiser PolicyMakers held the proverbial gun to Plaintiffs' head and said if you want us to consider your medical condition or religious beliefs, you must first sign this document waiving your Fourteenth Amendment rights. If you do not, we will deprive you of your Constitutional and federal statutory

rights by terminating your employment, irrespective of your medical condition, religious beliefs, and your Constitutional and statutory rights.

327. The policy and corresponding actions of Kaiser PolicyMakers demonstrate a culture of moral turpitude rampant throughout Kaiser, where the rule of law is ignored, the rights of Plaintiffs are trampled, and no one is held accountable for their lawlessness.

328. Kaiser PolicyMakers, with willful and wanton disregard for the rights, safety, and welfare of the Plaintiffs, intentionally ignored their lawful obligations, contractual duties, and federal agreements for no other reason than the age-old sin of greed. Worse yet, they used a pandemic to hide their malfeasance and willfully applied as much pressure on Plaintiffs as one in their positions of power could to set them as an example to all others that no one under their authority would ever have the freedom to exercise their Constitutional and statutory rights without severe life-altering consequences.

329. Kaiser PolicyMakers intentionally inflicted emotional distress upon Plaintiffs by destroying their dreams, careers, goals, housing, education, family life, healthcare, retirement, and feelings of dignity and equal treatment. Kaiser PolicyMakers subjected Plaintiffs to medical investigation outside of their free will and voluntary consent, and when Plaintiffs refused participation, Kaiser PolicyMakers terminated their employment, depriving them of their Fourteenth Amendment rights to Equal Protection of Laws and Due Process.

330. Kaiser PolicyMakers engaged in lawless activity that shocked the conscience, was outrageous, intolerable, and extreme, and placed Plaintiffs in severe emotional distress, fearing for their lives and livelihoods. Such debased leadership is unheard of in modern societies and exceeds the bounds of decency.

VII. Legal Claims

331. The facts described above constitute a deprivation of several rights guaranteed to Plaintiffs by the United States Constitution, federal statutes, and treaties. These deprivations are actionable under 42 U.S.C. § 1983 because the Defendants acted under color of state law when issuing their COVID-19 vaccination requirements and administrating the CDC COVID-19 Vaccination Program pursuant to the CDC COVID-19 Vaccination Program Provider Agreement and the federal statutes cited therein and acting on the State's Health Policy.

332. Court precedent demonstrates that federal statutes and regulations with rights conferring language are enforceable under 42 U.S.C. §1983.[118]

333. Defendants were, and are, restricted from attempting to use state law to amend the above-referenced statutes, regulations, treaties, agreements, and contracts due to the Supremacy Clause Doctrine. The Supremacy Clause Doctrine, and the express preemption language in the PREP Act and 21 U.S.C. §360bbb-3, restrict public and private employers from using state laws to require individuals to participate in any EUA or PREP Act activity or use any EUA or PREP Act product. This extends to any at-will employment law, doctrine, or custom an employer would otherwise claim as the right to interfere in the CDC Vaccination Program, 21 U.S.C. §360bbb-3, or PREP Act protocols and to amend conditions established by Congress for Plaintiffs' benefit.

COUNT ONE

42 U.S.C. § 1983 – Subjected to Investigational Drug Use

334. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

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

335. The CDC COVID-19 Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR Part 46, the Belmont Report, 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, Federal Wide Assurance, 10 U.S.C. § 980, EUA Scope of Authorization letters, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

336. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) (the EUA statute) contains a required condition of the Secretary "to ensure that individuals to whom the product is administered are informed — 'of the option to accept or refuse administration of the product.'"

337. 21 U.S.C. §360bbb-3, the CDC COVID-19 Vaccination Program Provider Agreement, and each EUA's Scope of Authorization contains research conditions for COVID-19 medical products meeting 45 CFR 46.102(l)'s definition of research requiring adherence to 45 CFR § 46.101[119] *et seq.*

338. "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)

339. 45 CFR § 46.116 and the Belmont Report contain the only known definition of legally effective informed consent.

340. 45 CFR 46.116(b)(8) states: "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."

[119]" This policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency" 45 CFR 46.101(a).

341. The Belmont Report, having the force of law,[120] declares, "An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence" and "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."

342. Defendants breached their duties to establish "adequate standards" of informed consent when applying "sanctions," "coercion," "undue influence," and "unjustifiable pressures" on Plaintiffs to participate in COVID-19 investigational new drugs and devices (e.g., masks, testing articles). At all times pertinent, Defendants did not obtain Plaintiffs' legally effective informed consent.

343. Article VII of the ratified International Covenant on Civil and Political Rights (ICCPR) Treaty affirms that "…no one shall be subjected without his free consent to medical or scientific experimentation."

344. The Defendants' actions described above, individually and/or collectively, acting under color of state law, and in deprivation of the Constitutional rights and rights secured by the above federal statutes, regulations, and treaty, unlawfully subjected Plaintiffs to the use of investigational medical products under threat of penalty outside of their legally effective informed consent as described in the above facts, thereby causing them damages described in Paragraphs 418 through 424, *infra*.

[120] 45 CFR § 46.101(c), 45 CFR 46.101(i), 45 CFR § 46.122

COUNT TWO

42 U.S.C. § 1983 – Deprivation of Equal Protection Rights

345. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

346. The CDC COVID-19 Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR Part 46, the Belmont Report, 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, Federal Wide Assurance, the EUA Scope of Authorization letter, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

347. The Fourteenth Amendment to the U.S. Constitution guarantees equal protection of the laws.

348. At all times pertinent, Defendants intentionally only penalized individuals who exercised their federal statutory right to refuse administration of a product under the PREP Act or an EUA drug (e.g., Pfizer-BioNTech COVID-19 Vaccine), biologic, or device (e.g., masks, COVID-19 testing articles) thereby applying the laws unequally to and depriving Plaintiffs, of their Constitutional Equal Protection Rights.

349. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, have deprived the Plaintiffs of their equal protection rights as described in the above facts, thereby causing them damages described in Paragraphs 418 through 424, *infra*.

COUNT THREE

42 U.S.C. § 1983 – Deprivation of Constitutional Due Process Rights

350. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

351. The CDC COVID-19 Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR 46, the Belmont Report, 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, Federal Wide Assurance, the EUA Scope of Authorization letter, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

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

353. At all times pertinent, Defendants, having knowledge of Plaintiffs' Constitutional and federal statutory right to refuse administration of EUA drugs and medical products, intentionally ignored those rights in an attempt to increase the number of participants in the CDC COVID-19 Vaccination Program for purposes of greed, resulting in the deprivation of Plaintiffs' substantive and procedural Due Process rights.

354. "The fundamental requisite of due process of law is the opportunity to be heard." *Louisville & Nashville R. Co. v. Schmidt*, 177 U. S. 230, 177 U. S. 236. Defendants did not provide Plaintiffs with a date, time, place, or procedure to defend their right to refuse injection of an unlicensed drug before depriving them of their liberty and property.

355. Defendants' requirement that Plaintiffs inject unlicensed drugs into their bodies as a condition to sell their labor "is not a legitimate exercise of the police power of the State, but an

unreasonable, unnecessary and arbitrary interference with the right and liberty of the individual to contract in relation to labor, and, as such, it is in conflict with, and void under, the Federal Constitution." *Lochner v. New York*, 198 U.S. 45 (1905)

356. Plaintiffs have the Constitutional right "to present [their] case and have its merits fairly judged." *Logan v. Zimmerman Brush Co*., 455 U.S. 422 (1982). At all times pertinent, Defendants refused to acknowledge Plaintiffs' Constitutional and Statutory rights, thereby nullifying impartiality.

357. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, have deprived the Plaintiffs of their substantive and procedural due process rights as described in the above facts, thereby causing them damages described in Paragraphs 418 through 424, *infra*.

COUNT FOUR

42 U.S.C. § 1983 - Deprivation of Rights Under the Spending Clause

358. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

359. The laws cited in the CDC COVID-19 Vaccination Program Provider Agreement, along with 45 CFR §46.122, 10 U.S.C. §980, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

360. In *Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002), "the Court has found that spending legislation gave rise to rights enforceable under §1983 only in *Wright* v. *Roanoke Redevelopment and Housing Authority,* 479 U. S. 418, 426, 432, and *Wilder* v. *Virginia Hospital Assn.,* 496 U. S. 498, 522523, where statutory provisions explicitly conferred specific monetary entitlements upon the plaintiffs, and there was no sufficient administrative means of enforcing the requirements

against defendants that failed to comply." See also, *Health and Hospital Corporation of Marion County v. Talevski*, *supra*, 599 U.S. ____ (2023)

361. The federal government appropriated funds to the Department of Defense to enter into contracts with the manufacturers of the EUA investigational drugs to purchase 100% of the products and to distribute them to the Organizations that signed the CDC COVID-19 Vaccination Program Provider Agreement.

362. The federal government funds any charges associated with the administration of the COVID-19 EUA shots via Medicare.[121]

363. In the case at bar, the "specific monetary entitlement" to Plaintiffs, and any potential recipient, is that the EUA investigational drugs and their administrative costs are free of charge to the recipients.

364. 45 CFR §46.122 provides: "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."

365. 10 U.S.C. §980 states: "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless – the subject's informed consent is obtained in advance…"

366. Only Organizations who agreed to participate in the CDC Vaccination Program can bill the government for administering the shots.

367. The EUA statute and the PREP Act lack any enforcement scheme for a breach of a potential recipient's right to refuse administration of an EUA investigational drug without penalty that would preclude §1983 enforcement.

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[121] https://www.medicare.gov/medicare-coronavirus

368. Agreement Requirement Number 3 on the CDC Provider Agreement states, "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."

369. Agreement Requirement Number 4 states, "Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees."

370. These two provisions establish a specific monetary entitlement to the individual.

371. Agreement Requirement Number 5 states, "Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) Fact Sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative."

372. Agreement Requirement Number 5 complies with funding restrictions established by Congress in, 45 CFR § 46.122 and 10 U.S.C. § 980.

373. The compliance is found in the EUA Fact Sheet, notating the individual's right to refuse the administration of the product. This express right is the fundamental requirement in obtaining the legally effective informed consent of the individual.

374. Whether for civilians under 45 CFR § 46.122 or personnel under 10 U.S.C. § 980, Congress created a specific monetary entitlement for individuals considering whether or not to participate in a federally funded research activity. That entitlement means they have the explicit right to be informed of the risks, benefits, and alternatives to the research product and then consider whether to participate without incurring a fee or being under outside pressure to participate.

375. This monetary entitlement is most apparent in the CDC COVID-19 Vaccination Program Provider Agreement. An individual can seek out a participating COVID-19 Program healthcare professional, obtain medical counseling, ask questions, and read literature. If they choose not to participate, they will not incur a fee from the professional for the administrative time spent considering whether or not to participate since the healthcare professional must inform them of their legal right to refuse under 21 U.S.C. §360bbb-3.

376. The healthcare professional agreed to comply with the legally effective consent requirements via Agreement Number 12 on the CDC COVID-19 Vaccination Program Provider Agreement mandating that (1) "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," and (2) "Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws."

377. The "all applicable requirements as set forth by the U.S. Food and Drug Administration, including…any EUA" extends to 21 USC 360bbb-3 (Section 564), 45 CFR 46, the FWA, the IRB, the ICCPR Treaty, and the Scope of Authorization letter.

378. Defendants were under explicit legal obligations to comply with 45 CFR § 46.122, 10 U.S.C. § 980 via their FWA agreement and their CDC COVID-19 Vaccination Program participation.

379. Therefore, the laws cited in CDC COVID-19 Vaccination Program Provider Agreement, 21 U.S.C. §360bbb-3, 45 CFR § 46.122, and 10 U.S.C. §980 clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983 when federal funds are expended under those provisions of law.

380. The Defendants' actions described above, individually and/or collectively, and in deprivation of the rights and privileges secured by the Constitution and the above statutes and regulations, refused to obtain the legally effective informed consent of the Plaintiffs in violation of spending legislation as described in the above facts, thereby causing them damages described in Paragraphs 418 through 424, *infra*.

COUNT FIVE

Unconstitutional Conditions Doctrine - 42 U.S.C. § 1983

381. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

382. The CDC COVID-19 Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR §46, the Belmont Report, 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, Federal Wide Assurance, the EUA Scope of Authorization letter, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

383. "…[T]the state, having power to deny a privilege altogether, may grant it upon such conditions as it sees fit to impose. But the power of the state in that respect is not unlimited; and one of the limitations is that it may not impose conditions which require the relinquishment of constitutional rights. If the state may compel the surrender of one constitutional right as a condition of its favor, it may, in like manner, compel a surrender of all. It is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence (emphasis added)". *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593-94 (1926)

384. Governor Newsom and Kaiser PolicyMakers established conditions requiring Plaintiffs to surrender their Constitutional rights under the Fourteenth Amendment to enjoy privileges of the State, such as the ability to sell their labors in the marketplace freely.

385. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, manipulated the Constitutional rights of Plaintiffs out of existence as described in the above facts, thereby causing them damages described in Paragraphs 418 through 424, *infra*.

COUNT SIX

PREP Act - 42 U.S.C. § 1983

386. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

387. The PREP Act, the CDC COVID-19 Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR Part 46, the Belmont Report, 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, Federal Wide Assurance, the EUA Scope of Authorization letter, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

388. The PREP Act provides certain immunities to "covered countermeasures" when the HHS Secretary determines there is a public health emergency and makes a declaration of that emergency through the publication in the Federal Register specifying the conditions by which the covered countermeasure and covered persons can participate and the use of such covered countermeasure.[122]

[122] 42 USC 247d-6d(b)(1)

389. Congress preempted the State of California and medical facilities it licenses from establishing laws and continuing in effect with existing ones (i.e., at-will employment doctrine) that would otherwise interfere with Plaintiffs' authority with respect to "conduct undertaken" concerning "any matter included in a requirement applicable" to a "covered countermeasure" under the PREP Act or 21 U.S.C. §360bbb-3 including the required condition that ***Plaintiffs be informed of their legal right to either accept or refuse said countermeasure***.[123],[124](Emphasis added.)

390. Congress was explicit that the HHS Secretary must establish conditions ensuring that "potential participants are educated with respect to…the voluntary nature of the program…"[125]

391. The "program" consists of those agreeing to manufacture, distribute, administer ("covered person"), and receive[126] ("covered individual") the product.

392. Congress expressly restricted the HHS Secretary from having any authority to require any person to participate in any activity involving a "drug," "biologic," or "device" under 21 U.S.C. §360bbb-3[127] or any "covered countermeasure" under the PREP Act.

393. By extension, any person authorized to participate in the program is also restricted from mandating participation.

394. The State of California and Kaiser PolicyMakers established laws and policies that conflicted with the PREP Act and 21 U.S.C. §360bbb-3 when they required Plaintiffs to participate in the use of a covered countermeasure under threat of penalty.

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[123] 21 U.S.C. 301 is the Federal Food, Drug and Cosmetic Act, which ranges from §301 to §399, and thus includes 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).
[124] 42 USC 247d-6d(b)(8)
[125] 42 USC 247d-6e(c)
[126] 42 U.S.C. §247d-6e(e)(2)
[127] 21 U.S.C. §360bbb-3(l) " –Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section…"

395. Moreover, Defendants engaged in policy-making and conduct that conflicted with the PREP Act and the Fifth and Fourteenth Amendments of the United States Constitution.

396. Mandatory participation in PREP Act covered countermeasures is a severe violation of the Constitution's Due Process guarantees.

397. No person can be required to enter into a legally binding agreement requiring the forfeiture of legal rights under threat of penalty.

398. The terms and conditions associated with the PREP Act and 21 U.S.C. §360bbb-3 represent a legally binding agreement as established by the U.S. Congress. Those terms require Plaintiffs to forfeit their right to seek judicial relief from injuries sustained from the use of the countermeasure and injuries sustained from the countermeasure's administration. The agreement also requires Plaintiffs to divulge their private health information and private identity and assume greater risks to their health, safety, and legal rights.

399. Defendants' pronouncement that Plaintiffs must participate in covered countermeasures prospectively denies Plaintiffs their due process rights should they incur injury because the PREP Act denies them access to judicial relief for those injuries.

400. Governor Newsom's and Kaiser PolicyMakers' policies violated Plaintiffs' right to accept or refuse participation in PREP Act covered countermeasures without pressure or influence being placed upon them.

401. Governor Newsom's and Kaiser PolicyMakers' issued policies requiring participation in investigational drugs, testing articles, masks, and other devices under threat of penalty, violating Plaintiffs' right to voluntary participation and due process rights.

402. Defendants changing the voluntary nature of the program into an involuntary program endangers the immunities of existing covered countermeasures established by the HHS Secretary.

403. Defendants' interference is a direct assault on the Constitutional rights of Plaintiffs, which opens the doors to legal remedies not envisioned by Congress but required of the Constitution for resulting injuries sustained by individuals when under threat of penalty to participate.

404. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, deprived the Constitutional and federal legal rights of Plaintiffs as described in the above facts, thereby causing them damages described in Paragraphs 418 through 424, *infra*.

COUNT SEVEN

Breach of Contract, Third Party Beneficiary

405. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

406. The CDC COVID Vaccination Program Provider Agreement, and the federal statutes and regulations incorporated by reference, requires the interpretation of federal statutes and thus provides its own basis for the exercise of federal jurisdiction.

407. The CDC COVID Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR 46, 21 U.S.C. §360bbb-3, Title 21 of the US Code, the EUA Scope of Authorization letter clearly and unambiguously create third-party beneficiary rights.

408. The primary third-party beneficiary right intended for Plaintiffs is the freedom to consider participation in a federally funded EUA (drug, biologic, or device), PREP Act, or other emergency medical countermeasure products or activities that are free from "sanctions," "coercion," "undue influence," "unjustifiable pressures to participate.

409. The other third-party benefit intended for Plaintiffs is that they must not fear the loss of benefits to which they are otherwise entitled when considering participation.

410. Defendants issued a policy that was an "overt threat of harm"[128] to the financial and emotional well-being of Plaintiffs for the express purpose of coercing them to participate in the CDC COVID-19 Vaccination Program outside of their free will and voluntary consent.

411. The Defendants' actions described above, individually and/or collectively, and in breach of the CDC COVID-19 Vaccination Program Provider Agreement, deprived the Plaintiffs of the benefits intended to be conferred upon them through the terms and conditions of the CDC COVID Vaccination Program Provider Agreement as described in the above facts, thereby causing them damages described in Paragraphs 418 through 424, *infra*.

COUNT EIGHT

Intentional Infliction of Emotional Distress

412. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

413. When the United States Congress refused to allow Defendants to apply consequences to Plaintiffs refusing to participate in the use of COVID-19 investigational drugs, Defendants engaged in a scorched earth policy and inflicted with malicious intent severe emotional

[128]" Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance." — The Belmont Report

distress to the fullest extent that one in their positions of authority and power could inflict to the detriment of Plaintiffs' emotional well-being.

414. The Defendants' conduct committed with gross negligence, recklessness, or intent, as described above, give rise to a claim of outrageous conduct and intentional infliction of emotional distress under the common law of the State of California against the Defendants for the damages described in Paragraphs 418 through 424, *infra*.

COUNT NINE

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

415. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 333, as if fully set forth herein.

416. Should the court not agree that Kaiser PolicyMakers was engaged in State Action, Plaintiffs claim that 21 U.S.C. §360bbb-3 contains an implied private right of action pursuant to *Cannon v. University of Chicago*, 441 U.S. 677 (1979), *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498 (1990), and *Cort v. Ash*, 422 U.S. 66 (1975).

417. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty have deprived the Plaintiffs of their explicit right to refuse the administration of an emergency use authorized drug and/or medical product without penalty as described in the above facts, thereby causing them damages described in Paragraphs 418 through 424, *infra*.

VIII. Damages Recoverable and Demanded

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

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

420. When the Defendants' behavior reaches a sufficient threshold, punitive damages are recoverable in § 1983 cases. *Smith v. Wade*, 461 U.S. 30 (1983). Because Defendants' actions were intentional and willful, Plaintiffs are entitled to, and hereby demand, an award of punitive damages against each and every Defendant in an amount sufficient to deter them, individually and collectively, from repeating their unconstitutional actions. *Smith v. Wade*, 461 U.S. 30 (1983)

421. Because Defendants' actions involved reckless or callous indifference to the Plaintiffs' federally protected rights, Plaintiffs are entitled to, and hereby demand, an award of punitive damages against each and every Defendant in an amount sufficient to deter them, individually and collectively, from repeating their unconstitutional actions. *Smith v. Wade*, 461 U.S. 30 (1983)

422. Because Defendants' actions were motivated by evil motive or intent, Plaintiffs are entitled to, and hereby demand, an award of punitive damages against each and every Defendant in an amount sufficient to deter them, individually and collectively, from repeating their unconstitutional actions. *Smith v. Wade*, 461 U.S. 30 (1983)

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

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

IX. Jury Trial Demand

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

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

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