

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
TACOMA DIVISION

AILA CURTIS, *et al*,

*

Plaintiffs,

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VERSUS

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CIVIL ACTION

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PEACEHEALTH, LIZ DUNNE, DOUG,
KOEKKOEK, AND GOV. JAY INSLEE

*

*

Defendants,

*

* * * * *

COMPLAINT
(JURY TRIAL REQUESTED)

NOW INTO COURT, through undersigned counsel, come Plaintiffs, Aila Curtis, *et al*, (hereinafter “Plaintiffs”), who respectfully file this Complaint against Defendants, PeaceHealth; its policymakers, the CEO Liz Dunne, and Chief Physician Executive (CPE) Doug Koekkoek, in their individual and representative capacities; and Governor Jay Inslee, in his individual capacity and in his official capacity as Governor of the State of Washington, (hereinafter “Defendants”), presenting allegations and causes of action as follows:

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PRELIMINARY STATEMENT

This is an action brought under the United States Constitution, 42 U.S.C. § 1983, 21 U.S.C. §360bbb-3, 42 USC 247d-6d, 45 CFR 46, 18 U.S.C. §242, ICCPR Treaty, and the common laws of the State of Washington to hold accountable Governor Jay Inslee, PeaceHealth, a State Actor at all times pertinent herein, via its policymakers, the CEO Liz Dunne, Chief Physician Executive (CPE) Doug Koekkoek, for damages arising out of their unconstitutional, unlawful, malicious, unequal and contractually violative COVID-19 investigational drug mandate. Special laws apply to Governor Inslee and Liz Dunne’s vaccine mandates because the FDA defines the drugs at issue

as “investigational with no license for any indication.” And even though Defendant’s vaccine 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).

I. Introduction

1. On June 21, 1788, the United States Constitution became the supreme law of the land, serving as a beacon of hope worldwide.

2. The hope our forefathers enshrined in the Constitution is that everyone is created equal before the law, regardless of race, religion, nationality, or socioeconomic status.

3. An individual’s right to be treated equally before the law bestows a duty upon the government to ensure that its laws, regulations, ordinances, and customs neither conflict with nor cancel that right. However, history has shown that our government sometimes breaches its duties to the citizenry. The courts must be called upon to prevent future breaches from occurring and to issue remedies to those damaged due to those wrongs.

4. In 1972, the nation became aware of the human rights abuses by the Executive Branch of the United States government. Using federal funds and authority, medical researchers effectively denied African-American males treatment for syphilis for no other reason than to study how the disease progressed in human anatomy. One-hundred male participants were allowed to suffer until death, 40 of their wives contracted syphilis, and 19 of their children were born with congenital syphilis.

5. Hiding behind the belief that the benefit of the many justifies the suffering of the few, medical researchers chose to engage in horrific crimes against humanity to further their political agendas over the Constitutional rights of individuals under their authority.

6. Enraged upon the discovery of this news, Senator Edward Kennedy held live hearings in 1973 detailing medical research abuses by the government, pharmaceutical corporations, and healthcare professionals. The nation was stunned to learn that medical research abuses impacting millions over decades had gone under the radar without criminal prosecution.

7. Some of those research abuses included:

- A. the US Navy sprayed the entire city of San Francisco with a bacterial agent to study biological warfare (Operation Sea-Spray), injuring many unsuspecting residents;
- B. Chester M. Southam of Sloan-Kettering Institute injected live cancer cells into 300 healthy female prisoners without informing them or asking permission;
- C. In the early 1960s, Saul Krugman of Willowbrook State School in Staten Island, New York, deliberately infected children with viral hepatitis by feeding them extracts made from infected feces;
- D. In 1966, the U.S. Army injected gas infused with bacteria throughout the New York City Subway system to study the impact of biological warfare;
- E. In the 1950s, the Atomic Energy Commission (AEC) and Nebraska College of Medicine subjected healthy infants to radioactive iodine to test its effects on the thyroid gland;
- F. Throughout the 1960s, Inuit natives in Alaska were treated with radioactive iodine without being informed of the potential dangers, nor did the AEC conduct any long-term follow-up.
- G. The Department of Defense, in the late 1960s, funded non-consensual whole body radiation experiments on African-American, poor, and terminally ill persons, without informing them of the life-altering dangers.
- H. Other illegal research activities numbering in the thousands included irradiating thousands of male testicles, removing skull parts of babies still in the womb, sterilizing black females, chemical baths, irradiating entire

towns with nuclear material, and injection of live cancer cells into prisoners and terminally ill patients.

8. Senator Kennedy's heroic effort to shut down entire industries using humans as fodder resulted in Congress passing the National Research Act in 1974. The Act laid the foundation for many laws, regulations, and ordinances to protect individuals regarding investigational medical products.

9. In the early 1980s, Congress established "the Common Rule" (45 CFR 46) as required compliance by federal agencies, departments, and the military when involving humans with investigational medical products.

10. The Common Rule was explicit in that no individual can be under "coercion," "undue influence," "unjustifiable pressure," or a "sanction" to participate in the use of medical products classified by the FDA as experimental. (45 CFR § 46.116, the Belmont Report)

11. In 2005, Congress enacted 21 U.S.C. §360bbb-3 (Authorization for Medical Products for Use in Emergencies), providing individuals with legal authority to participate in the use of medical products classified by the FDA as investigational when the HHS Secretary declared an emergency.

12. Acutely aware of its obligation to protect humans involved in the use of experimental medical products even during an emergency, Congress established "required conditions" consisting of two rights of the people and, respectively, two duties upon the government. One right grants individuals access to medical products authorized for emergency use, not yet licensed by the FDA for general commercial marketing. The other right guarantees individuals the right to refuse participation in potentially deadly drugs without incurring a penalty or losing a benefit to which they are otherwise entitled.

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

14. On January 31, 2020, the Secretary of Health and Human Services (HHS) issued a declaration of a public health emergency. The President declared a national emergency on March 13, 2020, all 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.

15. In order 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.)

16. 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.

17. 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)

18. In 2021, individuals nationwide, exercising a federally secured right to refuse investigational medical products, were subjected to unconstitutional treatment by authorities disagreeing with the individual's chosen option. Those individuals were not allowed to enjoy the equal protection of laws. They were subjected to severe human rights abuses violating ratified treaties, federal laws, and the laws of all US States and Territories.

19. In August 2021, Governor Inslee usurped the authority of the United States Congress by issuing an official proclamation in defiance of federal law when he mandated the use of investigational new drugs by healthcare workers. Additionally, Governor Inslee engaged in outrageous tyrannical conduct by mandating that healthcare facilities deny employment to healthcare workers who exercised their federally secured right to refuse investigational drugs.

20. PeaceHealth, CEO Liz Dunne, as PeaceHealth's policymaker, and CPE Doug Koekkoek, decided that the suffering of the few was justified by the windfall such suffering had on PeaceHealth's financial bottom line. Thus, PeaceHealth prescribed its own "required conditions" in defiance of Senator Edward Kennedy, Congress, and the rights of individuals under their authority as secured by the Constitution.

21. In August 2021, CEO Dunne 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, CEO Dunne subjected 16,000 employees to investigational drug use under threat of penalty and outside of their free will and voluntary consent. Should employees not comply with CEO Dunne's fraudulent usurpation of authority, they were to be segregated, penalized, humiliated, and eventually terminated from employment, thus violating the federally secured rights of those individuals to refuse an investigational drug without penalty and causing harm to the

ability of the hospital to provide a quality standard of healthcare to communities within the state of Washington.

22. Governor Jay Inslee used his office as official cover in hopes of obtaining for himself immunity from liability in future legal actions. Similarly, hiding behind the PREP Act as a liability cover, PeaceHealth, its policymaker, CEO Dunne, and CPE Koekkoek willfully chose to engage in violations of federal law. Defendants' wanton conduct mirrors the abuses of power perpetrated against humanity that led Senator Kennedy and Congress to act in the early 1970s. Yet, half a century later, humanity in the United States still suffers due to the willingness of persons and entities such as Defendants to violate the lawful Constitutional ideal of treating all persons equally before the law.

II. Jurisdiction and Venue

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

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

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

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

27. This court has supplemental jurisdiction over Plaintiff's state law claims.

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

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

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

III. Plaintiffs

31. The following individuals are plaintiffs herein:

31.1. Plaintiff, Aila Curtis, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.2. Plaintiff, Shannon Lee Adams, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.3. Plaintiff, Ciera Agee, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.4. Plaintiff, Alison Archer, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.5. Plaintiff, Becky Barcenas, is an adult individual who all times pertinent resided in the State of Oregon, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.6. Plaintiff, Hannah Bernhardt, is an adult individual who all times pertinent resided in the State of Oregon, and was previously an employee of PeaceHealth or one of its DBA entities in Oregon.

31.7. Plaintiff, Kathy Bordeaux, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.8. Plaintiff, Christine Amber Bruce, is an adult individual who all times pertinent resided in the State of Oregon, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.9. Plaintiff, Susan Buchanan, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.10. Plaintiff, Kirsten Clarke, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.11. Plaintiff, Diane Clemans, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.12. Plaintiff, Jeff Coffey, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.13. Plaintiff, The Estate of Cherie Coiner, by and through Derek Coiner, is the estate of Cherie Coiner who was an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.14. Plaintiff, Sheila Craig, is an adult individual who all times pertinent resided in the

State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.15. Plaintiff, Rae Lynn Crocker, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.16. Plaintiff, Lisa Daluz, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.17. Plaintiff, Christina Dawson, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.18. Plaintiff, Margarita Demchenko, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.19. Plaintiff, Monica Dickinson, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.20. Plaintiff, Hayley Dixon, is an adult individual who all times pertinent resided in the State of Oregon, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.21. Plaintiff, Jason Dong, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.22. Plaintiff, Shanta Gervickas, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.23. Plaintiff, The Estate of Caleb Gervickas, by and through Shanta Gervickas, is the estate of Caleb Gervickas, who was an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.24. Plaintiff, Eduard Goncharuk, is an adult individual who all times pertinent resided in the State of Iowa, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.25. Plaintiff, Amy Haserot, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.26. Plaintiff, Betheny Hayden, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.27. Plaintiff, Rhonda Holmes, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.28. Plaintiff, Mikayla Holsinger, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.29. Plaintiff, Sumiko Kuba, is an adult individual who all times pertinent resided in

the State of Oregon, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.30 Plaintiff, Nadezhda Litvinenko, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.31. Plaintiff, Liliya Lopatin, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.32. Plaintiff, Misty Lyons, is an adult individual who all times pertinent resided in the State of Arkansas, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.33. Plaintiff, Sheila Lyons, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.34. Plaintiff, Irina Maksimenko, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.35. Plaintiff, Lyubov Melnychuk, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.36. Plaintiff, Ashley Mendoza, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.37. Plaintiff, Monica Miller, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.38. Plaintiff, Cheryl Mitchell, is an adult individual who all times pertinent resided in the State of Oregon, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.39. Plaintiff, Damaris Mocan, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.40. Plaintiff, Kathryn Morgan, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.41. Plaintiff, Nick Morzhov, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.42. Plaintiff, Dwain Nash, is an adult individual who all times pertinent resided in the State of Oregon, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.43. Plaintiff, Lysander Nerida, is an adult individual who all times pertinent resided in the State of Oregon, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.44. Plaintiff, Kathryn Ortega, is an adult individual who all times pertinent resided in the State of Alabama, and was previously an employee of PeaceHealth or one of its DBA entities

in Washington.

31.45. Plaintiff, Yvonne Quashie, is an adult individual who all times pertinent resided in the State of Tennessee, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.46. Plaintiff, Leslie Quintana, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.47. Plaintiff, Emma Ranson, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.48. Plaintiff, Shannon Ringnalda, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.49. Plaintiff, Mallory Schlang, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.50. Plaintiff, Melissa Smithdeal, is an adult individual who all times pertinent resided in the State of Florida, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.51. Plaintiff, Lori Souders, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.52. Plaintiff, Brooke Tanner, is an adult individual who all times pertinent resided in

the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.53. Plaintiff, Tracie Thomas, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.54. Plaintiff, Dena Thorp, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.55. Plaintiff, Jennifer Torres, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.56. Plaintiff, Lyubov Tshuprin, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.57. Plaintiff, Olga Tsytsyna, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.58. Plaintiff, Roxana Volynets, is an adult individual who all times pertinent resided in the State of Tennessee, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.59 Plaintiff, Hannah Wagar, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.60. Plaintiff, Vera Yadlovskiy, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.61. Plaintiff, Alla Kutsar Zabolotska, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.62. Plaintiff, Dina Zabolotska, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.63. Plaintiff, Nelya Zabolotska, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

31.64. Plaintiff, Kristine Zamudio, is an adult individual who all times pertinent resided in the State of Washington, and was previously an employee of PeaceHealth or one of its DBA entities in Washington.

IV. Defendants

32. Jay Inslee, is the Governor of the State of Washington. Mr. Inslee is named as a defendant in his official and individual capacities.

33. Defendant, PeaceHealth, is a not-for-profit healthcare system headquartered in Clark County, WA recognized as tax-exempt pursuant to Section 501(c)(3) of the Internal Revenue Code.

34. Defendant, Liz Dunne, is the President and Chief Executive Officer of PeaceHealth. Ms. Dunne is named as a defendant in her official and individual capacities.

35. Defendant, Doug Koekkoek, is the Chief Physician and Clinical Executive of PeaceHealth. Mr. Koekkoek is named as a defendant in his official and individual capacities.

V. History and Facts

36. Plaintiffs make no assertions regarding:

- A. whether it is lawful for a private employer to mandate taking a ***licensed*** vaccine,
- B. the safety or efficacy of any drug, biologic, or medical device, or
- C. natural immunity versus drug-induced immunization.

37. Plaintiffs adamantly assert, however, that an individual has the federally secured 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.

38. Additionally, Plaintiffs assert that they have the federally secured right to refuse any activity or product covered by the PREP Act.

39. 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, medical countermeasure products fall under the investigational or experimental classification by statute.¹

40. 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 should prove helpful.

¹ 21 U.S.C. §360bbb-3(a)(2)(A) and (B); See also the May 10, 2021, Scope of Authorization letter issued to Pfizer wherein the FDA advises Pfizer that its product is “an investigational vaccine not licensed for any indication.” The same is true for the Moderna and Janssen injections.

41. The aforementioned 1974 National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research² (hereinafter referred to as the “Commission”).

42. 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.”

43. Congress further required the Commission to consider “the nature and definition of informed consent in various research settings.”³

44. On April 18, 1979, the Commission published its findings in the Federal Register in a report titled, “The Belmont Report.”⁴

VI. The Belmont Report

45. 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 respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions...” (Emphasis added);

² Title II of the National Research Act - <https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf>

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

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

- 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).

46. 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.

47. 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.

48. 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.”

49. 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.

50. 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.”⁵

VII. 45 CFR 46

51. 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 (for protection of human research subjects) “applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency...” (Emphasis added).⁶

52. HHS designed a very broad definition of research when, at 45 CFR § 46.102 (Definitions): “Research means a systematic investigation, including research development,

⁵ 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>

⁶ 45 CFR 46.101(a)

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”⁷ (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.⁸

53. A “human subject” is broadly defined as (1) a living individual, (2) from whom data is obtained and used,⁹ and (3) from whom identifiable private information is known.¹⁰

54. HHS regulations define¹¹ 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:

(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.

⁷ 45 CFR 46.102(l)

⁸ <https://www.hhs.gov/ohrp/sites/default/files/human-subject-regulations-decision-charts-2018-requirements.pdf>

⁹ 45 CFR 46.102(e)(1)(i)

¹⁰ 45 CFR 46.102(e)(1)(ii)

¹¹ “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)

(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.)

55. 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 any element 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”¹² (emphasis added).

56. Therefore, if individuals are administered an investigational medical product and their private identifiable information is collected along with the details of their interaction with 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,” thus requiring 45 CFR 46 compliance when the federal government is involved.

57. HHS ensured that all research activities would 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”¹³ (emphasis added), (2) if the activity is considered

¹² The Belmont Report Part A: Boundaries Between Practice & Research. “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.”

¹³ 45 CFR § 46.101(c)

exempt from the policy, then “the alternative procedures to be followed are consistent with the principles of the Belmont Report.”¹⁴

58. Congress expressly prohibits the federal government from administering an investigational product to an individual without also complying with the ethical principles of the Belmont Report.

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

60. The intent of Congress was to give the Belmont Report the force of law through 45 CFR 46 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.

61. 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 for research involving human subjects unless the requirements of this policy have been satisfied.” (45 CFR § 46.122)

62. 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.”

63. 45 CFR 46 and the Belmont Report are conditions established by Congress for the express purpose of benefiting third-party beneficiaries (i.e., individuals considering the use of

¹⁴ 45 CFR § 46.101(i)

investigational medical products). The primary condition intended to benefit the third party is the requirement of authorities to prospectively obtain the third party's "legally effective informed consent" before administering to them federally funded investigational drugs (e.g., Pfizer-BioNTech COVID-19 Vaccine).

64. Therefore, pursuant to 45 CFR 46, "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.

65. When the federal government involves itself in research, it is required by law to comply with 45 CFR 46 and the ethical principles of the Belmont Report.

66. When the federal government determines that the activity does not require 45 CFR 46 oversight, then the activity is still required by federal law to comply with the ethical principles of the Belmont Report.

67. Moreover, federal research activity that is not deemed research for any other federal agency, statute, or regulation must still abide by 45 CFR 46 if the activity meets the definition of research set forth in 45 CFR 46.

68. The COVID-19 CDC Vaccination Program is a research activity requiring 45 CFR 46 compliance. (See *infra*)

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

VIII. Legally Effective Informed Consent

70. 45 CFR § 46.116 sets forth the Belmont Report’s “adequate standards” of informed consent¹⁵, and they include, but are not limited to:

- (a)(1) 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; (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

¹⁵ 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.

any time without penalty or loss of benefits to which the subject is otherwise entitled” (Emphasis added).

71. Legally Effective Informed Consent, according to the Belmont Report, can be broken down into its basic formula as (1) the individual must not be under outside pressure to participate, (2) the only reason an individual participates is that he or she believes the product may benefit their personal health goals, and (3) the conditions of 1 and 2 were established before the individual participated in the investigational product.

72. Only when authorities comply with 45 CFR 46 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).

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

74. 45 CFR 46 applies to all federal agencies, departments, and the military (45 CFR § 46.101(a)). Additionally, twenty federal agencies incorporated 45 CFR 46 specifically into their regulatory framework.¹⁶

75. 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 comply with 45 CFR 46 and the Belmont Report’s ethical guidelines.

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

¹⁶ <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>

77. Therefore, individuals have the explicit right to refuse an investigational drug, biologic, or device without incurring a penalty or losing a benefit to which they are otherwise entitled. When Defendants penalized Plaintiffs for refusing the administration of drugs undergoing clinical trials, they failed to comply with their duties to obtain the legally effective informed consent of Plaintiffs. Moreover, Defendants violated federal law and Plaintiff's federally secured rights via 45 CFR 46, the Belmont Report, 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, and the CDC COVID-19 Vaccination Provider Agreement (see discussion, *infra*) by failing to obtain Plaintiffs' legally effective informed consent.

78. The failure to obtain Plaintiffs' legally effective informed consent is evidenced in Governor Inslee's and PeaceHealth's EUA drug mandate containing pre-published sanctions for persons refusing participation. (See discussion, *infra*)

IX. COVID-19 Research Activities

79. PeaceHealth and the State of Washington are in a symbiotic relationship to conduct 45 CFR 46 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.

80. The federal government's Executive Branch purchased all COVID-19 EUA drugs and, in conjunction with HHS and the CDC, developed research activities that States and CDC Vaccination Program Providers must conduct on its behalf.¹⁷

¹⁷ Persons must volunteer to participate in 21 U.S.C. §360bbb-3 or PREP Act activities. Therefore, governors, hospitals, manufacturers, distributors, etc. must voluntarily agree to abide by the terms and conditions of the product's Scope of Authorization and associated laws. Those terms require research activities pursuant to 45 CFR 46.

81. Drugs, biologics, and devices authorized under 21 U.S.C. §360bbb-3 (see discussion, *infra*) are classified by the FDA as investigational (experimental)^{18, 19} according to their labeling. They have no legal indication to treat, cure, or prevent any disease according to their labeling.

82. Moreover, if a product is already licensed by the FDA for its intended use and can be used during a declared emergency, the FDA is prohibited from issuing an EUA. (21 U.S.C. §360bbb-3(c)(3))

83. 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.

84. A “marketed drug” is not the same as an “investigational drug.”

85. 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))

¹⁸ 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>

¹⁹ 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.

86. 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.

87. The distinction lies within the drug’s classifications as assigned to them by the FDA. Those distinctions have significant legal consequences for the end user. (See discussion, *infra*)

88. 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.

89. Investigational drug “means a new drug or biological drug that is used in a clinical investigation.” (21 CFR 312.3 “Investigational new drug”)

90. 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).

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

92. Drugs are governed by their classification and not by their formulation.

93. Congress explicitly drafted laws governing investigational new drugs to prevent the executive branch from continuing its history of abusing the rights of individuals who are administered investigational medical products.

94. 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 Vaccine²⁰), and the FDA confirmed that Pfizer’s product “is an investigational vaccine not licensed for any indication.”²¹

95. 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.”²²

96. 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.”²³

97. 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).”

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

²⁰ *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.”

²¹ 86 Fed.Reg. 5200, Jan. 19, 2021

²² 86 Fed.Reg. 5211, Jan. 19, 2021

²³ 86 Fed.Reg. 28608, May 27, 2021

99. As an example, on January 19, 2021²⁴ the Secretary established mandatory conditions that Pfizer and emergency stakeholders (distributors, manufacturers, etc.) must follow, which involve 45 CFR 46 research activities.

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

* * *

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

- 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

²⁴ 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>

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

101. 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.

102. 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.

103. As of August 2021, when Defendants issued their mandates, all COVID-19 drugs were undergoing clinical trials and were already under an Institutional Review Board, which must comply with 45 CFR 46 and the FWA (see discussion *infra*).

104. 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.

105. 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.

106. 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. The Provider Agreement states that Defendants “must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC’s Advisory Committee on Immunization Practices (ACIP).”

107. 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.²⁵ The use of this information by ACIP demonstrates how the data collected “contributes to generalizable knowledge.”

²⁵ 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.

108. The ACIP recommendations²⁶ referenced in Footnote 1 of the CDC Provider Agreement²⁷ 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.
- 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."²⁸

109. 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.

²⁶ *Id.*, at 1347.

²⁷ 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."

²⁸ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/pdfs/v-safe-information-sheet-508c.pdf>

- 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.

110. 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.”

111. The federal government’s purchase of all COVID-19 EUA drugs (see discussion, *infra*), demonstrates that it is automatically bound to 45 CFR 46 via 45 CFR § 46.122, 10 U.S.C. § 980, and the Belmont Report.

112. When Congress established a **required condition** of the Secretary under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) “to ensure that individuals to whom the product is administered are informed “of the option to accept or refuse administration of the product,” it intended compliance with 45 CFR §46.116 and the Belmont Report.

113. The nationwide CDC COVID-19 Vaccination Program authorized under 21 U.S.C. §360bbb-3 has elements of research activity requiring adherence to 45 CFR 46 and the Belmont Report. These activities provide individuals who are considering whether or not to participate the

statutory authority to accept or refuse without incurring a penalty or losing a benefit to which they are otherwise entitled.

114. Moreover, the COVID-19 immunization program is bound by statute to obtain the legally effective informed consent of the individual prospectively.

X. ICCPR Treaty

115. In 1992, the United States Senate ratified the International Covenant on Civil and Political Rights Treaty (ICCPR).²⁹ 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)

116. Subjected means to be under the rule of law by one’s authority.

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

118. 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.”³⁰

119. 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

²⁹ 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>

³⁰ 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>

to be a violation 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.

120. 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.”

121. 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.³¹

122. 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.

123. 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

³¹ “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

the Covenant explicitly prescribes that no derogation from the following articles may be made: article 6 (right to life), article 7 (prohibition of torture or cruel, inhuman or degrading punishment, or of medical or scientific experimentation without consent.)³² (Emphasis added.)

124. Article 4.2 of the ICCPR Treaty established the restriction of derogation of informed consent rights as a peremptory norm, potentially opening Defendants up to criminal liability for issuing and executing mandates involving non-consensual medical experimentation.³³

125. It cannot be reasonably disputed that Defendants subjected individuals under their authority to medical experimentation outside of their free will and voluntary consent. When Plaintiffs refused to participate, Defendants intentionally inflicted “cruel,” “inhumane,” and “degrading” treatment in violation of federal law and the International Covenant on Civil and Political Rights Treaty.

126. Specific examples of the cruel, inhumane, and degrading treatment that PeaceHealth inflicted upon the Plaintiffs herein include employment termination, leave without pay, mandatory COVID testing (even for teleworkers), public humiliation, defamation of character, segregation, isolation, gaslighting, emotional trauma, financial devastation, and forced public disclosure of private medical and employment information.

127. PeaceHealth’s COVID-19 immunization mandate, relying exclusively on experimental medical products, violated each plaintiff’s Constitutional rights under the Fourteenth Amendment, federal statutes under 21 U.S.C. § 360bbb-3, and 45 CFR 46, Article VII of the

³² “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)

³³ General comment no. 29 states of emergency (article 4) GE.01-44470 (E) 190901
GENERAL COMMENT ON ARTICLE 4 (adopted at the 1950th meeting, on 24 July 2001)

ICCPR Treaty, the Belmont Report, and their benefits under the CDC COVID-19 Vaccination Program Provider Agreement.

128. No treaty, Constitutional authority, a federal statute, regulation, or state law exempts Defendants from their duty of ensuring that Plaintiffs are not under political, legal, financial, social, or other degrading pressures to take a COVID-19 investigational drug.

XI. 21 U.S.C. §360bbb-3 (aka Section 564)

129. Congress expressly prohibits any person 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 protected against medical research abuses.

130. 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.

131. However, over time, Congress recognized the need to allow individuals to access unlicensed products for various medical reasons (also known as “expanded access protocols”). Therefore, Congress established 21 U.S. Code §360bbb, titled “Expanded Access to Unapproved Therapies and Diagnostics.”

132. Numerous conditions must be met before the legal administration of products authorized pursuant to the section can occur. The overriding requirement, irrespective of the granted expanded access protocol, is that the individual must give their legally effective informed consent, whether the consent is under written or verbal conditions.

133. Making it patently clear of their intent to protect Americans 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).

134. Section 564 of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C §360bbb-3³⁴ 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.

135. 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.³⁵

136. 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.³⁶

³⁴ 21 U.S.C. §360bbb-3 is commonly referred to as section 564.

³⁵ 21 U.S.C. 360bbb-3(e)(1)(A)

³⁶ 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.

137. 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 21 U.S.C. §360bbb-3.

138. 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.

139. 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.

140. 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.

141. Therefore, the right to accept or refuse an EUA medical countermeasure is absolute, and no authority may infringe upon that right. This understanding becomes vitally important when viewed in the light of Congress preempting state laws for PREP Act products and the COVID-19 Provider Agreement PeaceHealth signed with the Centers for Disease Control (CDC)(see *infra.*)

142. There are three specific persons upon whom Congress confers a right under Section 564, which are:

- 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.

143. 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))

144. 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.”

145. 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.”

146. 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.

147. 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

insert 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.

148. 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 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)

149. 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.

150. The explicit purpose of this statutory restriction is to ensure that no person is under a “sanction,” “coercion,” “undue influence,” or “unjustifiable pressure”³⁷ to participate. If individuals are under those pressures, then no federal funds could be expended for the administration of an EUA product, nor could any healthcare provider acting on behalf of the federal government obtain an individual’s Legally Effective Informed Consent.

151. The individual has the right to accept the product, and the healthcare professional has the authority to administer the product, but 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.

³⁷ The Belmont Report’s conditions that would nullify legally effective informed consent.

152. 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.

153. Therefore, if the HHS Secretary is the only person authorized to establish the conditions under which persons can take or use EUA medical products, **then by what authority did Defendants amend the Scope of Authorization and require that which Congress prohibits?**

154. Therefore, when Governor Inslee, PeaceHealth, Liz Dunne, and Doug Koekkoek established a policy requiring individuals under their authority to take a COVID-19 EUA investigational drug, they were required by federal law to 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 take unlicensed COVID-19 EUA drugs, nor would they incur a penalty or lose a benefit when refusing to participate in the PREP Act activity. Defendants did neither.

155. Defendants decided to violate federal law, contractual duties, and the Fourteenth Amendment rights of individuals under their authority when they issued a mandate with a compliance date before the availability of a licensed COVID-19 vaccine.

XII. HHS EUA Precedent

156. On January 28, 2005, HHS issued the first EUA³⁸ under its new Section 564 authority. 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

³⁸ <https://www.govinfo.gov/content/pkg/FR-2005-02-02/pdf/05-2028.pdf>

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.”

157. 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.
- 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.³⁹

158. 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”

³⁹ Federal Register/Vol. 70, No. 21/Wednesday, February 2, 2005/Notices 5455 IV Conditions of Authorization

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.

159. The reason HHS was crystal clear about an individual's right to refuse an investigational drug was to respect court orders.

XIII. Judicial EUA Precedent

160. 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 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.)

161. 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.

162. 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).

163. *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.

XIV. Federal Wide Assurance (FWA)

164. 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.

165. 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...”⁴⁰

166. 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.

167. 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).

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

169. 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.

170. Although the third-party beneficiaries are not signatories to the agreement, they are the intended third-party beneficiaries of the agreement, and their rights were violated the moment

⁴⁰ Office for Human Research Protections. Federal Wide Assurance Instructions. HHS.gov. Published January 7, 2011. Last accessed May 19, 2023.

PeaceHealth and Washington penalized Plaintiffs for refusing to take EUA products (i.e., investigational drugs, and testing articles).

171. 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.

172. The FWA agreement requires PeaceHealth to assure potential participants that they will not incur a penalty or lose a benefit to which they are otherwise entitled when refusing participation.⁴¹

173. The benefits to which potential participants are otherwise entitled include, but are not limited to:

- A. continued employment,
- B. 14th Amendment rights,
- C. 5th Amendment rights,
- D. paid time off,
- E. bonuses,
- F. raises,
- G. health insurance,
- H. 401k contributions,

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

⁴¹ “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.

175. Therefore, when PeaceHealth punished third-party beneficiaries for refusing the administration of an investigational drug, PeaceHealth:

- A. activated the terms and conditions of the contract,
- B. violated the terms of the contract causing injury to the rights of the third-party beneficiary,
- C. created a cause of action for breach of contract in favor of the third-party beneficiary.

176. 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.

177. Defendants violated the Equal Protection Clause by only punishing persons choosing one of two federally secured options (refuse).

178. Defendants violated the Equal Protection Clause when they coordinated with the Washington State Employment Security Department to deny unemployment benefits to Plaintiffs solely on the basis of workers exercising a federally secured option of refusing administration of an investigational drug, thus violating the Unconstitutional Conditions Doctrine.

179. The Unconstitutional Conditions Doctrine reflects the U.S. Supreme Court's repeated pronouncements that the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests."⁴²

180. The U.S. Supreme Court has held: "For at least a quarter-century, this Court has made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis

⁴² *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 133 S. Ct. 2586, 186 L. Ed. 2d 697, 24 Fla. L. Weekly Fed. S 435 (2013)

that infringes his constitutionally protected interests—especially, his interest in freedom of speech. For if the government could deny a benefit to a person because of his constitutionally protected speech or associations, his exercise of those freedoms would in effect be penalized and inhibited. This would allow the government to ‘produce a result which (it) could not command directly.’”⁴³ “Such interference with constitutional rights is impermissible.”⁴⁴

181. Based on longstanding Supreme Court precedent, the government is prohibited from denying individuals the right to receive unemployment benefits because the individual exercised his or her constitutionally protected right to bodily autonomy by refusing investigational drug administration. Such actions plainly violate the Fourteenth Amendment rights of equal protection of Plaintiffs.

182. Washington State Employment Security Department issued a letter to one Plaintiff demanding that monies paid to Plaintiff under unemployment benefits must be paid back, stating in part:

- A. “...your employer, PEACEHEALTH, said you were fired for breaking a company rule or policy. You harmed or could have harmed your employer’s business.”
- B. “We denied your unemployment benefits...until you requalify,”
- C. “We decided that your actions were misconduct because...”
 - (1) “Your employer required you to provide proof that you were fully vaccinated against COVID-19,”
 - (2) “You did not request an exemption,”
 - (3) “You did not provide proof that you were fully vaccinated,”
- D. “You must pay it back. The law says we can’t waive overpayments when you are fired for misconduct.”

⁴³ *Perry v. Sindermann*, 408 U.S. 593 (1972), citing *Speiser v. Randall*, 357 U.S. 513, 526, 78 S.Ct. 1332, 1342, 2 L.Ed.2d 1460.

⁴⁴ *Id.*

183. PeaceHealth enacted an illegal company policy violating federal laws resulting in Liz Dunne making false claims to⁴⁵ the United States Government and the State of Washington. PeaceHealth then stated that Plaintiffs violated the company policy when exercising a federally secured right to refuse investigational new drugs under 21 U.S.C. §360bbb-3 protocols. When determining Plaintiffs' rights to unemployment benefits, the State ignored federal law and the U.S. Constitution. Instead, the State acted on a custom and chose to impose sanctions and withhold benefits to "transform private predilections into compulsory rules of behavior no less than legislative pronouncements,"⁴⁶ thus violating the Unconstitutional Conditions Doctrine.

184. The State denying employment benefits to Plaintiffs on the sole basis of refusing 21 U.S.C. §360bbb-3 countermeasure products demonstrates State policy and custom (see *infra*) under which PeaceHealth acted when retaliating against Plaintiffs exercising their 21 U.S.C. §360bbb-3 option to refuse.

XV. PREP Act & Section 564 Preemption of State Law

185. 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. Accordingly, the HHS Secretary has issued a COVID-19 PREP Act declaration at 85 FR 15198.

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

⁴⁵ The CDC COVID-19 Vaccination Provider Agreement signed by PeaceHealth plainly states that, "Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and 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."

⁴⁶ *Adickes v. S. H. Kress & Co.*, 398 U.S. 144 (1970)

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

188. Congress expressly crafted language preempting state law (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

(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.].

189. Congress also expressly established that the plan to administer a 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...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, the voluntary nature of the program, and the availability of potential benefits and compensation under this part. [Emphasis added.]

190. The purpose of 21 U.S.C. §360bbb-3 informing the individual of “the significant known...risks of such use, and of the extent to which such benefits and risks” and of “the alternatives to the product that is available and of their benefits and risks” is because the individual is not only consenting to be injected with an investigational drug, but they must also consent to participate in a legally binding agreement under the terms and conditions established by Congress.

191. Individuals who consent to receive one of the COVID 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;⁴⁷
- B. allowing their private identifiable information to be collected and used for a variety of purposes by unknown persons;⁴⁸
- 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 for eternity,⁴⁹
- E. agree to assume greater risks to their safety, health, and legal rights.⁵⁰

192. Governor Inslee and PeaceHealth cannot coerce individuals under threat of penalty to enter into a legally binding agreement outside of their free will and voluntary consent. In fact, Congress expressly preempted all state and local laws, regulations, and rules to ensure no individual would be coerced into participating in the federal government's legally binding agreement.

193. Congress was explicit when it pronounced that “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... is different from, or is in conflict with, any requirement applicable under this section; and...or to any matter included in a requirement applicable to...the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]” (42 USC 247d-6d(b)(8),(A),(B)).

⁴⁷ PREP Act forfeits all civil actions for damages in most situations.

⁴⁸ Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to obtain private identifiable information.

⁴⁹ 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.

⁵⁰ Section 564 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.

194. 21 U.S.C. §360bbb-3 is under 21 U.S.C. 301. Therefore, the PREP Act preemption extends to “the option to accept or refuse,” which must only be under voluntary conditions.

195. Congress expressly preempted state laws interfering with the legal rights of individuals to decide whether or not to participate in the use of an EUA medical product under PREP Act authority. The preemption extends to at-will employment laws that private employers would otherwise utilize to interfere with an employee’s option to accept or refuse without consequence.

196. A private employer cannot lawfully establish 21 U.S.C. §360bbb-3 conditions contrary to Congress and those laid out by the HHS Secretary’s Scope of Authorization, and if they do so, the private employer would be usurping the authority of Congress to require that which Congress and the Secretary prohibit.

197. Congress, not the Defendants, determines who can participate in a PREP Act activity and the conditions under which they can participate. Defendants may not amend those conditions by usurping the authority of Congress.

198. Under § 247d-6d(b)(8)(A), “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...is different from, or is in conflict with, any requirement applicable under this section...and related to the...use...or administration...of the covered countermeasure...”

199. The FDA issued an opinion⁵¹ regarding federal preemption of 21 U.S.C. §360bbb-3 (aka section 564):

⁵¹“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>

“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 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)

200. However, although no express preemption language exists within 21 U.S.C. §360bbb-3, the field preemption doctrine demonstrates that Congress created a pervasive regulatory scheme designed only to be regulated by the federal government. Moreover, state laws in conflict with the regulatory scheme of 21 U.S.C. §360bbb-3 pose an obstacle to the goals of the federal government’s emergency countermeasure program.

201. State laws affording private employers ’legal authority to interfere with the federal statutory requirements of 21 U.S.C. §360bbb-3 and the PREP Act (e.g., at-will employment doctrine) violate the Supremacy Clause of the United States Government.

202. If PeaceHealth and Governor Inslee can punish citizens for refusing to participate in a PREP Act activity or product, then they must also have the authority to punish citizens participating in a PREP Act activity or product. Under that scenario, one can easily see that the “option to accept or refuse” no longer belongs to the individual but to a third party. The resulting chaos and unconstitutional conditions in such a scenario are explicitly why Congress preempted the authority of any person to interfere with either federally secured option granted to individuals considering participation.

203. Governor Inslee’s and PeaceHealth’s mandate of involuntary participation in a PREP Act activity and their corresponding actions to coerce, threaten, and unduly pressure Plaintiffs, changes the “voluntary nature of the program” into an obligatory condition, depriving Plaintiffs of their federally protected authority “to accept or refuse” without consequence. The defendants’ actions demonstrate that they attempted to unlawfully usurp the regulatory power of the United States government instead of properly implementing the emergency medical countermeasure protocols with which they voluntarily agreed to comply.

204. Congress expressly claimed preemption for the PREP Act and thereby 21 U.S.C. §360bbb-3. Thus Defendants are expressly prohibited from acting in a fiat manner to establish conditions regarding participation in the use of a covered countermeasure product contrary to federal statutes, agency regulations, and the Scope of Authorization outlined in the FDA-issued EUA letter to the manufacturer covering all EUA activities.

205. Those improper conditions include, but are not limited to:

- A. coercing employees to surrender their federally secured right “of the option to accept or refuse administration of the [PREP Act] product,”
- B. usurping the HHS Secretary’s authority to “[a]ppropriate 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,” (Emphasis added)
- C. requiring that which Congress explicitly prohibits: “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,”
- D. interfering with the explicit requirement of Congress that “[t]he Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure (e.g., Pfizer BioNTech COVID-19 Vaccine)...are educated with respect to contraindications, the voluntary nature of the program...”(Emphasis added) (42 U.S. Code §247d-6e(c)).

206. Healthcare professionals must obtain legally effective informed consent from voluntary participants **specifically because the participants are denied relief for any damages resulting from the EUA product or activity.**

XVI. CDC COVID-19 Vaccination Program Provider Agreement

207. 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 – CDC Covid-19 Vaccination Program Provider Agreement.]

208. 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.

209. 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 (hereinafter referred to as the “Provider Agreement”).

210. 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.)

211. 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.”

212. “This program is a part of collaboration under the relevant state, local, or territorial immunization’s cooperative agreement with CDC. 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).

213. 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.

214. 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 State’s existing immunization programs. Each state already has an HHS FWA agreement in place.

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

216. 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.

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

218. 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.

219. PeaceHealth, Liz Dunne, and Doug Koekkoek (or their authorized equivalent) signed the Provider Agreement agreeing to comply with all "applicable laws" regarding EUA products and PREP Act activities.

220. PeaceHealth agreed to inform individuals under their authority, of their legal rights to accept or refuse EUA medical products.

221. PeaceHealth agreed to ensure individuals were not under outside pressures to participate in obtaining the legally effective informed consent of participants in the COVID-19 drugs.

222. PeaceHealth, by signing the Provider Agreement, agreed to waive the applicability of all state and local laws that are "in conflict" with the terms and conditions of the Provider Agreement or requirements applicable to the PREP Act and Section 564 protocols. The waiver would include Governor Inslee's unlawful COVID-19 mandate. (see *infra*)

223. PeaceHealth agreed to directly benefit individual potential vaccine recipients under their authority by signing the Provider Agreement.

224. 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.”

225. The EUA Fact Sheet is required because the Executive Branch of the government is the sole sponsor of EUA products,⁵² 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.

226. 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

⁵² 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.

activities) from the drugs' use denotes how these products are governed by 45 CFR 46, requiring both IRB and Belmont Report compliance.

227. 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 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)).

228. The Provider Agreement required PeaceHealth 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)

229. Therefore, the State of Washington and PeaceHealth 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.

XVII. Nature of Case

230. This is a case for damages against Governor Jay Inslee, PeaceHealth, CEO Liz Dunne, and CPE Doug Koekkoek, who at all times pertinent herein served as State Actors for illegally and unconstitutionally penalizing individuals exercising their statutory right to refuse an investigational drug without incurring a penalty or losing a benefit to which they are otherwise entitled. The State of Washington had outsourced its Centers for Disease Control (CDC) emergency COVID-19 immunization program to PeaceHealth. Moreover, Governor Inslee issued a mandate under color of law establishing employment conditions based on COVID-19 vaccination status. As a result, PeaceHealth acted under color of state law at all times pertinent and abridged Plaintiffs' constitutional rights of equal protection and due process when Plaintiffs refused to participate in using those products.

XVIII. Statement Of Facts

231. PeaceHealth is a licensed "general hospital" provider under RCW 70.41.

232. PeaceHealth's employees include healthcare professionals licensed by the State of Washington.

233. The State of Washington licenses, regulates and oversees the operations of PeaceHealth.

234. PeaceHealth operates facilities throughout Washington and is a participating immunization provider for the Washington State Department of Health's immunization program.

235. Immunization program administration constitutes a public function of the State of Washington.

236. The Federal government owns all investigational and licensed COVID-19 drugs.

237. The executive branch of government established the CDC COVID-19 Vaccination Program to distribute its property (COVID-19 drugs) to volunteering participants.

238. The CDC works through existing state immunization programs whereby the State facilitates licensed medical facilities and healthcare professionals to administrate the federal government's COVID-19 program and administer the government's property under the PREP Act (42 USC 247d-6d) and 21 U.S.C. §360bbb-3 emergency authorization.

239. PeaceHealth willfully volunteered to participate in the CDC COVID-19 Vaccination Provider Program.

240. The CDC COVID-19 Vaccination Program constitutes an exclusive public function of the State.

241. Congress prohibits the HHS Secretary from requiring any person to participate in any activity that becomes lawful pursuant to 21 U.S.C. §360bbb-3 (i.e., the use of EUA products). Therefore, it also prohibits Washington State Governor Inslee from requiring any person to participate in any activity, including PeaceHealth Hospital or any healthcare worker.⁵³

242. The United States Constitution does not authorize Governor Inslee to amend treaties, federal statutes, and federal agency regulations by fiat rule.

243. Governor Inslee is prohibited by 21 U.S.C. §360bbb-3 from amending the conditions established by the HHS Secretary regarding the administration of any emergency medical countermeasure program or product.

244. Governor Inslee volunteered the State of Washington to participate in the CDC COVID-19 Vaccination Program.

⁵³ The "activity that becomes lawful pursuant to 21 U.S.C. §360bbb-3" is the use of the EUA COVID-19 drugs.

245. Emergency Use Authorization (EUA) COVID-19 drugs have been classified by the FDA as investigational new drugs and are not classified as “vaccines.”⁵⁴

246. Pursuant to its Federal Wide Assurance agreement with the federal government, Washington State agreed to comply with 45 CFR Part 46 protocols and the ethical principles of the Belmont Report when it involved a human with an investigational drug. Thus, HHS assigned the State of Washington Federal Wide Assurance Number FWA00000327, denoting a legally binding agreement between the State of Washington and the United States Government for the explicit benefit of third-party participants.

247. Governor Inslee is prohibited by Federal law from denying individuals the right to accept or refuse investigational new drugs funded by the Federal government or to apply consequences when accepting or refusing their administration.

248. The PREP Act and 21 U.S.C. §360bbb-3 preempt Washington State laws, regulations, ordinances, and executive proclamations that interfere or conflict with the emergency medical countermeasure program.

249. PeaceHealth, via its FWA, IRB, 21 U.S.C. §360bbb-3, and the CDC Vaccination Program Provider Agreement, is prohibited by Federal law from denying individuals the right to accept or refuse investigational new drugs funded by the Federal government or applying consequences when accepting or refusing their administration.

250. PeaceHealth is prohibited via the PREP Act from mandating that any person participates in any activity that becomes lawful pursuant to Section 42 USC 247d-6d.

⁵⁴ 26 U.S.C. § 4132(a)(2) “(2) Vaccine. The term “vaccine” means any substance designed to be administered to a human being for the prevention of one or more diseases.” EUA drugs do not have a legal indication for the “prevention” of any known disease.

251. PeaceHealth cited Governor Jay Inslee's Proclamation 21-14.1 as the reason PeaceHealth began conditioning employment upon Plaintiffs receiving a medical countermeasure product against their free will and voluntary consent (see, *infra*).

252. PeaceHealth volunteered to act on behalf of the State to provide the public function of administering the State's COVID-19 emergency immunization program.

253. The State of Washington and PeaceHealth are bound by law to conduct COVID-19 research activities, and also to obtain the legally effective informed consent of individuals, and to ensure that the Fourteenth Amendment rights of Plaintiffs are protected and secured at all times pursuant to the administrative functions of the CDC COVID-19 Vaccination Program.

254. On August 30, 2021, PeaceHealth, CEO Liz Dunne, and CPE Doug Koekkoek, conspiring with Governor Jay Inslee, and acting under the color of law, illegally subjected Plaintiffs to investigational drug use under threat of penalty outside of Plaintiffs' free will and voluntary consent.

255. PeaceHealth mandated Plaintiffs to inject an investigational drug into their bodies or face imminent punitive actions (see, *infra*)

256. Neither the State of Washington nor PeaceHealth referenced 21 U.S.C. § 360bbb-3 in their respective published mandates, the only statute authorizing them to administer an EUA drug. The statute also instructs Defendants that Plaintiffs have the legal authority to refuse EUA drugs, biologics, or devices without consequence.

257. Defendants intentionally usurped the federal government's authority by amending 21 U.S.C. § 360bbb-3 to cause Plaintiffs to surrender their Constitutional and statutory rights.

258. Defendants' actions led to:

- A. a deprivation of both substantive and procedural due process rights under the Fourteenth Amendment,

- B. a deprivation of equal protection rights under the Fourteenth Amendment,
- C. a deprivation of rights guaranteed under the Spending Clause,
- D. invasion of privacy under Washington State's common laws,
- E. unlawful public disclosure of Plaintiff's private health and employment information, and,
- F. outrageous conduct that shocks the conscience.

XIX. State Action Doctrine

259. Because of the pervasiveness of control exerted by the State's COVID-19 emergency immunization program, Defendants acted under the color of law at all times pertinent.

260. The State of Washington and PeaceHealth's COVID-19 immunization program relies exclusively on investigational new drugs, the administration of which is governed by federal statutes.

261. In *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."

262. Additionally, in a decision dated June 8, 2023, the United States Supreme Court in *Health and Hospital Corporation of Marion Cty. V. Talevski*, 599 U.S. ____ (2023)⁵⁵, stated, "Although federal statutes have the potential to create §1983-enforceable rights, they do so under this Court's precedents only when the statute unambiguously confers those rights."

263. The *Talevski* court spoke to its method of determining a statute's §1983 viability when it stated, "*Gonzaga* sets forth the Court's established method for ascertaining unambiguous

⁵⁵ Because the *Talevski* decision is so new, there was no page number assigned as of the date of the filing of this Complaint.

conferral. Courts must employ traditional tools of statutory construction to assess whether Congress has ‘unambiguously conferred’ ‘individual rights upon a class of beneficiaries’ to which the plaintiff belongs...Notably, it must be determined that ‘Congress intended to create a federal right’ for the identified class, not merely that the plaintiffs fall ‘within the general zone of interest that the statute is intended to protect.’ *Id.*, at 283 (emphasis omitted). The test for unambiguous conferral is satisfied where the provision in question is ‘phrased in terms of the persons benefited’ and contains ‘rights-creating,’ individual-centric language with an ‘unmistakable focus on the benefited class.’ *Id.*, at 284, 287 (emphasis omitted). If a statutory provision surmounts this significant hurdle, it ‘secures individual rights that are deemed ‘presumptively enforceable’ under §1983.”

264. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) 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.”

265. Therefore, the intended beneficiary class is those considering whether or not to be administered an EUA medical countermeasure. The “option to accept or refuse” is unambiguous conferral of power upon the individual considering participation.

266. 45 CFR 46 was developed by the express request of Congress to confer protective benefits for persons participating in medical research activities.

267. The CDC COVID-19 Vaccination Program Provider Agreement establishes required activities, including elements of medical research activity, thus requiring 45 CFR 46 compliance.

268. 45 CFR 46 §116 “uses clear rights-creating language, and speaks in terms of the persons benefited,” and has an “unmistakable focus on the benefited class.”

269. Article VII of the ICCPR Treaty states, in clear rights-conferring language, that no person may be subjected to medical experimentation without free consent. The FDA defines medical experimentation as “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”)

270. Defendant’s FWA agreement and the use of IRBs also exist for the express benefit of the individual and contain rights-conferring language.

271. The Scope of Authorization for each Emergency Use Authorization requires healthcare professionals to provide potential recipients with a drug Fact Sheet insert stating, “Under the EUA, it is your choice to receive or not receive” the product. This statement is the Secretary affirming the individual’s legal rights under 21 U.S.C. 360bbb-3.

272. The CDC COVID-19 Vaccination Program Provider Agreement requires “organizations” to “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.” This requirement aims to inform the individual of his or her legally effective informed consent rights and to meet the required conditions under 21 U.S.C. §360bbb-3.

273. 45 CFR 46 §122 states, “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.” By direct nexus, this restriction qualifies as a rights-conferring language for any spending legislation enacted by Congress involving this section of law.

274. 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 informed consent of the subject is obtained in advance.”

275. Obtaining legally effective informed consent is a required legal condition, and it means that no individual can be under a “sanction,” “coercion,” “undue influence,” or any other form of outside pressure to participate when considering whether or not to participate in a medical countermeasure.

276. The individual has the right, via the spending legislation, among other statutes, to accept or refuse the available COVID-19 EUA medical products without fearing any repercussions whatsoever because the federal government fully funds the entire program. Therefore, the spending restriction statutes “use clear rights-creating language, and speak in terms of the persons benefited” and have an “unmistakable focus on the benefited class.”

277. Although many rights-conferring items are contained in the above law provisions, the most notable is that no person can incur a penalty or lose a benefit when accepting or refusing an investigational medical product, as in any of the available COVID-19 EUA injections.

278. The purpose of those provisions directly relates to the Belmont Report’s ethical principles of (1) “Respect for Person,” (2) “Beneficence”, and (3) “Justice,” for persons involved in any research element. Every federal agency, department, and the military is required to comply with the Belmont Report. Moreover, no federal funds can be expended on research activities if the Belmont Report’s ethical principles are not established in the research activity’s protocol documents before the activity is even approved.⁵⁶

279. The U.S. Supreme Court has held that “to act ‘under color of’ state law for § 1983 purposes does not require that the defendant be an officer of the State. It is enough that he is a willful participant in joint action with the State or its agents. Private persons, jointly engaged with

⁵⁶ PeaceHealth and Washington State Department of Health’s FWA agreement are their promises to comply with the Belmont Report’s ethical principles and adherence to 45 CFR 46.

state officials in the challenged action, are acting ‘under color’ of law for purposes of § 1983 actions.”⁵⁷

280. In August 2021, Governor Inslee issued illegal official proclamations 21-14 and 21-14.1⁵⁸ **prohibiting:**

- A. “Any Health Care Provider from failing to be fully vaccinated against COVID-19 after October 18, 2021;” and,
- B. “Any operator of a Health Care Setting from permitting a Health Care Provider to engage in work for the operator as an employee, contractor, or volunteer in their capacity as a Health Care Provider after October 18, 2021 if the Health Care Provider has not been fully vaccinated against COVID-19 and provided proof thereof as required below. Providers who do not work in a Health Care Setting must provide proof of vaccination to the operator of the facility in which the Provider works, if any, or, if requested, to a lawful authority. A lawful authority includes, but is not limited to, law enforcement, local health jurisdictions, and the state Department of Health.”

281. Proclamation 21-14.1 also states in part:

- A. “A person is fully vaccinated against COVID-19 two weeks after they have received the second dose in a two-dose series of a COVID-19 vaccine (e.g., Pfizer-BioNTech or Moderna) or a single-dose COVID-19 vaccine (e.g., Johnson & Johnson (J&J)/Janssen) authorized for emergency use, licensed, or otherwise approved by the FDA or listed for emergency use or otherwise approved by the World Health Organization.”
- B. “Where required above, Workers for State Agencies, Workers for operators of Educational Settings, and Health Care Providers must provide proof of full vaccination against COVID-19”

282. Therefore, Governor Jay Inslee utilized his authority to mandate that healthcare facilities terminate the employment of individuals working in healthcare settings should those individuals exercise their statutory authority to refuse the administration of a COVID-19 EUA medical countermeasure. Therefore, the mandate was unlawful the moment it was published.

⁵⁷ *Dennis v. Sparks*, 449 U.S. 24 (1980)

⁵⁸ See Attachment Proclamation 21-14-1

283. PeaceHealth, CEO Liz Dunne, and CPE Doug Koekkoek, acting under the color of law, issued their mandate on August 30, 2021 stating in part:

- A. “It is the policy of PeaceHealth to require healthcare workers (HCWs) to be fully vaccinated against COVID-19.”
- B. “HCWs are considered fully vaccinated two weeks after they have received Pfizer or Moderna second dose, Johnson & Johnson single dose or other U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA), FDA approved, FDA authorized or World Health Organization (WHO) emergency use/approved COVID-19 vaccine/series.”
- C. “All new or returning HCWs must obtain a COVID-19 vaccination series/dose or submit a medical or religious exemption that is approved and can be accommodated before starting/restarting at PeaceHealth. If a new or returning HCW is scheduled to start before October 15, 2021, they may start/ restart at PeaceHealth if they are (1) fully vaccinated; (2) have an approved medical or religious exemption for which reasonable accommodations are made; or (3) if they have received at least one dose of a COVID-19 vaccination/series dose, have a second dose scheduled (if a two-dose series) and will be fully vaccinated by October 15, 2021.”

284. PeaceHealth’s COVID-19 policy references “Washington Proclamation 21-14-1” as an authoritative source for the policy.

285. PeaceHealth’s legal counsel notified some of the Plaintiffs that “Washington Proclamation 21-14.1 requires healthcare providers like PeaceHealth to require its employees to be vaccinated against COVID-19 or have an approved medical or religious exemption by October 18, 2021. PeaceHealth cannot allow employees to work after that date if they are not compliant with those requirements.”

286. Therefore, by issuing Proclamation 21-14.1, Washington Governor Jay Inslee unlawfully extended his authority and mandated that healthcare facilities violate the constitutional and statutory rights of Plaintiffs. PeaceHealth engaged in that state action when issuing and acting on the State’s COVID-19 vaccination policy.

287. Neither the state proclamation nor PeaceHealth's COVID-19 policy provided for a legal mechanism to ensure the due process rights of Plaintiffs were protected before they were robbed of their liberty and property.

288. As stated by the U.S. Supreme Court in *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345 (1974), "We have, of course, found state action present in the exercise by a private entity of powers traditionally exclusively reserved to the State."

289. The State's immunization program is both a historical and exclusive public function of the state.

290. The COVID-19 emergency medical countermeasure program is an exclusively public function of the State.

291. The federal government owns all doses of COVID-19 investigational drugs. The federal government created the CDC COVID-19 Vaccination Program to distribute its property. Because the federal government funds the emergency countermeasure program under research conditions, it is bound to 45 CFR §46.122 and 10 U.S.C. § 980 and must obtain the legally effective informed consent of volunteering participants. The federal government only works through Washington State's immunization program. Therefore, The State of Washington must obtain legally effective informed consent from volunteering participants. The State is required to treat all citizens equally before the law and ensure due process is secured before depriving a citizen of their liberty or property. Therefore, the State is bound to ensure that private parties administering the federal government's property fulfill the constitutional obligations of the State when engaged in the State Action of administrating the program and administering the product.

292. The State and PeaceHealth freely volunteered to participate in the federal government's COVID-19 Vaccination Program.

293. The State and PeaceHealth are required to obtain the legally effective informed consent of those considering participating in using federally owned investigational drugs.

294. PeaceHealth and the State are in a symbiotic relationship to obtain the legally effective informed consent of potential recipients for the success of the State's COVID-19 immunization program.⁵⁹

295. The State did not provide PeaceHealth with an alternative process to comply with federal statutory obligations of obtaining legally effective informed consent of Plaintiffs when engaged in the State action on its behalf.

296. PeaceHealth is required to update the vaccination status of individuals on behalf of the State.

297. PeaceHealth exclusively relies on the State for full reimbursement of COVID-19 vaccination patients.

298. The State relies on State agents, such as PeaceHealth, to achieve the goals of the State's COVID-19 immunization program.

299. 100% of all private parties participating in the State's COVID-19 immunization program are "clothed with the authority of state law" to access investigational medical products,

⁵⁹ *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*, [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).

administer those medical products, and bill the government for those activities on behalf of State authority.⁶⁰

300. Without the State, PeaceHealth could not participate in the CDC COVID-19 Vaccination Program Provider Agreement nor provide that governmental function to the public.

301. The State’s COVID-19 emergency medical countermeasure program is so intimately regulated, licensed, and funded that “[t]he State has so far insinuated itself into a position of interdependence...that it must be recognized as a joint participant in the challenged activity” *Burton v. Wilmington Pkg. Auth.*, 365 U.S. 715, 81 S. Ct. 856 (1961).

302. “If a private actor is functioning as the government, that private actor becomes the state for purposes of state action.”⁶¹

303. Defendants coordinated efforts to deny economic opportunities to individuals exercising a federally secured right to refuse an EUA product without penalty. Moreover, the State intimately relied on PeaceHealth to achieve its COVID-19 immunization goals.⁶²

304. The federal government exclusively funds Washington State’s COVID-19 Vaccination Program.

305. As the court held in *Modaber v. Culpeper Memorial Hospital, Inc.*, 674 F.2d 1023 (4tCir. 1982):

“we must inquire ‘whether there is a sufficiently close nexus between the State and the challenged action of the regulated entity that the action of the latter may fairly be treated as that of the State itself.’” *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 351, 95 S.Ct. 449, 453, 42 L.Ed.2d 477 (1974); accord, *Flagg Brothers, Inc. v. Brooks*, 436 U.S. 149, 157, 98 S.Ct. 1729, 1733, 56 L.Ed.2d 185 (1978). In holding that a privately-owned

⁶⁰ Misuse of power, possessed by virtue of state law and made possible only because the wrongdoer is clothed with the authority of state law, is action taken “under color of” state law. *United States v. Classic*, 313 U.S. 299 (1941), citing *Ex parte Virginia*, 100 U. S. 339, 100 U. S. 346; *Home Telephone & Telegraph Co. v. Los Angeles*, 227 U. S. 278, 227 U. S. 287, et seq.; *Hague v. CIO*, 307 U. S. 496, 307 U. S. 507, 307 U. S. 519; cf. 101 F.2d 774, 790.

⁶¹ *Terry v. Adams*, 345 U.S. 461, 469-70, 73 S. Ct. 809, 97 L. Ed. 1152 (1953); See *Jackson v. Metropolitan Edison Co.*, 419 U.S. at 353, 95 S. Ct. 449.

⁶² See Washington State Provider FAQ attachment

utility's termination of service is not "state action", the Court in *Jackson* makes it clear that state involvement without state responsibility cannot establish this nexus. *See* 419 U.S. 358, 95 S.Ct. 457. A state becomes responsible for a private party's act if the private party acts (1) in an exclusively state capacity, (2) for the state's direct benefit, or (3) at the state's specific behest. It acts in an exclusively state capacity when it "exercises powers traditionally exclusively reserved to the state[.]" 419 U.S. 352, 95 S.Ct. 454; for the state's direct benefit when it shares the rewards and responsibilities of a private venture with the state, *see id.*, 357-58, 95 S.Ct. 456-57, *Burton v. Wilmington Parking Authority*, 365 U.S. 715, 723-24, 81 S.Ct. 856, 860-61, 6 L.Ed.2d 45 (1961); and at the state's specific behest when it does a particular act which the state has directed or encouraged."

306. PeaceHealth is under express COVID-19 vaccination protocols by the State and the CDC to include⁶³:

- A. Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP),
- B. Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority,
- C. Organization must submit Vaccine-Administration Data through either [a] the immunization information system (IIS) of the state and local or territorial jurisdiction or [b] another system designated by CDC according to CDC documentation and data requirements,
- D. Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law,
- E. 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,
- F. Organization **must** administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees, (emphasis added)

⁶³ See Exhibit A, CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement.

- G. 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,
- H. Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines,"
- I. Organization must comply with CDC requirements for COVID-19 Vaccine management,
- J. Organization must report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction,
- K. Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses,
- L. Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS),
- M. Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards,
- N. Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine (emphasis added) and
- O. Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws. (emphasis added).

307. The State of Washington, via the CDC COVID-19 Vaccination Program Provider Agreement, must also ensure authorized agents of the State comply with 21 U.S.C. §360bbb-3's statutory requirements that the healthcare professional prospectively inform the recipient of:

- A. the significant known and potential benefits and risks of the use of the product,

- B. the option to accept or refuse administration of the product,
- C. the health consequences of refusing the product, and,
- D. the alternatives, risks, and potential benefits.

308. The State of Washington and PeaceHealth must comply with the HHS Secretary's regulatory framework outlined in each EUA's Scope of Authorization⁶⁴, adding additional entanglement between PeaceHealth and the State. See *Brentwood Academy v. Tennessee Secondary School Athletic Assn.*, 531 U.S. 288 (2001)

309. Therefore, "there is such a close nexus between the state and the challenged action that the seemingly private behavior may be fairly treated as that of the state itself." *Brentwood Academy v. Tennessee Secondary School Athletic Assoc.*, 531 U.S. 288, 295 (2001). See *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 351, (1974).

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

311. The CDC Provider Agreement 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 (emphasis added)."

⁶⁴ See "Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic; Availability," page 5208, Section "Emergency Stakeholders" continuing through "Vaccination Providers." <https://www.federalregister.gov/documents/2021/01/19/2021-01022/authorizations-of-emergency-use-of-two-biological-products-during-the-covid-19-pandemic-availability>

312. 21 U.S.C. §360bb-3 (a/k/a Section 564 of the FDCA, which authorizes EUA products under “applicable requirements” of the FDA) contains rights conferring language to accept or refuse EUA medical products without incurring a penalty or losing a benefit to which they are otherwise entitled.

313. Legally effective informed consent requires Defendants to ensure that they do not place individuals under a “sanction,” “coercion,” “undue influence,” or “unjustifiable pressures” when offering participation in the use of an investigational medical product.

314. The COVID-19 investigational drugs are federal property and may not be administered to persons without first obtaining their legally effective informed consent to ensure the government’s legal obligations under 45 CFR 46 (specifically §§ 116, 122) are met.

315. The CDC required Defendants to obtain the legally effective informed consent of individuals on its behalf when offering COVID-19 investigational new drugs via its Vaccination Program Provider Agreement.⁶⁵

316. The CDC informed Defendants that “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.⁶⁶” The Fact Sheet serves as a function of obtaining Plaintiffs’ legally effective informed consent.

317. Therefore, the federal government choosing to purchase all COVID-19 drugs under 21 U.S.C. §360bb-3 authority is Constitutionally obligated to obtain the legally effective informed

⁶⁵ Number 12(a) of the Agreement 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.” This section requires adherence to 21 U.S.C. §360bbb-3 (Section 564) protocols.

⁶⁶ Each EUA letter mandates that the manufacturer will provide the drug’s Fact Sheet to healthcare providers and that healthcare providers “will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination.” Accordingly, the CDC COVID-19 Vaccination Program Provider Agreement has the same requirement.

consent of individuals prospectively and equally. The State, by extension, is also required to comply with the federal requirement and may not delegate this function to a private party without also delegating the Constitutional obligation.

318. Obtaining the individual's legally effective informed consent is a legal procedure, and the State cannot delegate the COVID-19 immunization program without empowering the private party with legal authority to obtain Plaintiffs legally effective informed consent on the State's behalf.

319. Therefore, the Constitutional duty placed upon the State is to ensure that all persons choosing to accept or refuse are treated equally before the law by providing that neither "option" is penalized. Moreover, if a person is not treated equally before the law, then that unequal treatment must be conditioned upon due process.

320. PeaceHealth previously assured the Health and Human Services' Office of Human Research Protections that they would never violate the ethical principles outlined in the Belmont Report or their obligations under 45 CFR 46. In return for that assurance, HHS awarded them the right to participate in federal funding by providing them with the Federal Wide Assurance Agreement compliance number FWA00003906.

321. Washington State Department of Health assured HHS and accordingly received the federal agreement number FWA00000327 signifying a legally binding agreement between Washington and the federal government.

322. Defendants had a Constitutional duty under the Fourteenth Amendment to ensure persons accepting or refusing drugs, biologics, or devices falling under the authority of (1) 21 U.S.C §360bbb-3, (2) Article VII ICCPR Treaty, (3) Washington State Department of Health FWA00000327, (4) 45 CFR 46, (5) Prep Act, and (6) the CDC COVID-19 Vaccination Program

Provider Agreement, were not deprived of their equal protection rights or liberty or property without due process when exercising either option.

323. As the U.S. Supreme Court stated in *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306 (1950):

Many controversies have raged about the cryptic and abstract words of the Due Process Clause, but there can be no doubt that, at a minimum, they require that deprivation of life, liberty or property by adjudication be preceded by notice and opportunity for hearing appropriate to the nature of the case.

* * *

An elementary and fundamental requirement of due process in any proceeding which is to be accorded finality is notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections. *Milliken v. Meyer*, 311 U. S. 457; *Grannis v. Ordean*, 234 U. S. 385; *Priest v. Las Vegas*, 232 U. S. 604; *Roller v. Holly*, 176 U. S. 398. The notice must be of such nature as reasonably to convey the required information, *Grannis v. Ordean*, *supra*, and it must afford a reasonable time for those interested to make their appearance, *Roller v. Holly*, *supra*, and *cf. Goodrich v. Ferris*, 214 U. S. 71.

324. In August 2021, Defendants informed individuals under their authority that they require mandatory COVID-19 investigational drug use of all healthcare workers, contractors, and other employees and set mandatory timelines for compliance.

325. At no point before, during, or after Washington State and PeaceHealth issued their mandatory experimental drug policies were Defendants in possession of COVID-19 drugs licensed by the FDA and also introduced into commerce for general commercial marketing having a legal indication to immunize Plaintiffs from the SARS-CoV-2 (COVID-19) infection. (See discussion *infra*)

326. Defendants informed Plaintiffs of pending action that would deprive them of their liberty (e.g., restrictions of facility use) and property (e.g., wages, insurance, paid-time-off, career) should they exercise their federally secured rights to refuse their illegal demands. Defendants did

not provide Plaintiffs with an opportunity to be heard or the right to defend their federally secured rights when depriving them of their liberties and property. *See Louisville and Nashville R. R. Co. v. Schmidt*, 177 U.S. 230, 236, 20 S.Ct. 620, 44 L.Ed. 747 (1900).

327. Defendants refused to acknowledge federal laws providing Plaintiffs with the explicit authority to refuse COVID-19 investigational drugs without incurring a penalty or losing a benefit to which they were otherwise entitled.

328. If persons in authority, such as Defendants, refuse to acknowledge rights conferred upon Plaintiffs by valid acts of Congress, then due process is legally impossible to secure.

329. Therefore, PeaceHealth, acting under color of law, violated Plaintiffs' substantive and procedural due process rights under the Fourteenth Amendment.

330. The Ninth Circuit reminded us in *Rawson v. Recovery Innovations, Inc.*, No. 19-35520 (9th Cir. 2020) that "The Supreme Court has ... held that private parties may act under color of state law when they perform actions under which the state owes Constitutional obligations to those affected."

331. 21 U.S.C. §360bbb-3 (Section 564) creates an express right for individuals to accept or refuse the administration of products not licensed by the FDA for general commercial marketing during a declared emergency.

332. 45 CFR 46, the Belmont Report, Article VII of the ICCPR Treaty, and the FWA all require the individual's legally effective informed consent before administering an investigational medical product.

333. Congress mandated that should a person refuse to participate in the use of an investigational medical product, no penalty or loss of benefits could be imputed to them.

334. Congress expressly preempts state laws conflicting with the PREP Act.

335. Congress preempts state laws conflicting with 21 U.S.C. §360bbb-3.

336. Therefore, the State is bound by the Supremacy Clause to comply with the obligations above when delegating the COVID-19 immunization program, which relies exclusively on COVID-19 investigational drugs.

337. Therefore, Defendants had a Fourteenth Amendment constitutional obligation and responsibility to ensure all persons were under the equal protection of laws regarding the CDC COVID-19 Vaccination Program, PREP Act, 21 U.S.C. §360bbb-3 protocols, or a medical countermeasure's Scope of Authorization.⁶⁷

338. No person who refuses an EUA medical product under the PREP Act authority can be treated differently before the law than those who accept an EUA medical product under the PREP Act authority.

339. No person choosing the 21 U.S.C. §360bbb-3 option to refuse can be treated differently before the law than those choosing the option to accept.

340. Therefore, the public function of administering the CDC COVID-19 Vaccination program places a duty upon Defendants to protect the due process and equal protection rights of individuals participating in that public function.

341. Given the enormity of federal laws, regulations, and contracts, Defendants effectually deprived Plaintiffs of their Constitutional protections and statutory rights when acting under the color of law.

⁶⁷ The CDC COVID-19 Vaccination Program relied exclusively on investigational medical products that were also under the statutes mentioned above. Therefore, the 14th Amendment violations related to federal statutes and not exclusively to the CDC COVID-19 Vaccination Program.

342. PeaceHealth, among other Washington healthcare facilities, acted under the color of a State custom⁶⁸ and usage to deprive Plaintiffs of their Fourteenth Amendment constitutional protections.

343. The State's custom was to ignore the statutory rights of individuals to refuse the administration of an EUA product without incurring a penalty or losing a benefit to which they were otherwise entitled. The custom of the State was so pervasive that it relegated citizens, who exercised their federal right to refuse, to that of second-class citizens by refusing to protect their equal protection rights.

344. Governor Jay Inslee, correctly stated in his proclamation that “the specific prohibitions in this Proclamation are severable and do not apply to the extent that compliance with a prohibition would violate (1) any U.S. or Washington constitutional provision; (2) federal statutes or regulations; (3) any conditions that apply to the state's receipt of federal funding; (4) state statutes; or (5) applicable orders from any court of competent jurisdiction.”

345. The Governor expressly provided that public or private entities must uphold the Constitutional and statutory rights of individuals if such rights conflicted with any specific prohibitions in his Proclamation.

346. However, the State's custom of not enforcing citizens' 21 U.S.C. § 360bbb-3 rights allowed Jay Inslee to unlawfully displace an estimated 1,900 State employees after issuing his Proclamation without consequence. In other words, the Governor plainly stated that no one was to comply with his Proclamation if any part conflicted with a “constitution,” “statute,” or “regulation.” Yet, the person, Jay Inslee, ignored his own Proclamation and engaged in punitive

⁶⁸ 18 U.S.C. §1983: “Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State...” (Emphasis added).

actions against persons engaging in activities duly authorized by federal law (refusal to take an EUA COVID-19 drug).

347. The Washington State Department of Health refused to issue a public notice that the Plaintiffs had the express right to refuse EUA products without consequence and refused to enforce that right when healthcare facilities and workers abridged that right.

348. Washington State Attorney General Bob Ferguson also refused to protect the rights of Washington's citizens through enforcement when the Governor and PeaceHealth violated the law. The Supremacy Clause dictates that 21 U.S.C. §360bbb-3 is the law of the land within the State of Oregon. Therefore, an abridgment of 21 U.S.C. §360bbb-3 enabled State Executive officers' authority to correct the unlawful behavior due to their FWA, IRBs, and CDC COVID-19 Vaccination agreement.

349. Nearly 100,000 nurses in Washington State were denied their legally effective informed consent rights, and thousands were deprived of their ability to be employed, all without consequence by Attorney General Bob Ferguson to healthcare facilities that engaged in that unlawful activity.

350. The Governor's Proclamation reinforced the unlawful state custom that a person must have a reason such as "disability," "religious belief," or a "medical condition" to refuse existing COVID-19 investigational drugs. The right to refuse the administration of investigational drugs is an unconditional right, except under the Defendants' unlawful customs.

351 To require an individual to request an exemption from investigational drug use is a violation of federal law and the duties of Defendants under the CDC COVID-19 Vaccination Program Provider agreement, FWA agreement, and 45 CFR 46 regulations. Neither PeaceHealth

nor Governor Inslee are empowered to amend federal legislation or require that which Congress prohibits.

352. 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 state-enforced custom...” (emphasis added)

353. Plaintiffs were denied access to living wages and demoted to second-class citizenry because of a State enforced custom that Defendants incorrectly asserted had a force of law overriding the authority of the United States Constitution.

354 The State custom resulted in the Defendants ignoring the authority of Congress by amending 21 U.S.C. § 360bbb-3 as follows:

- A. Congress only authorized the Secretary to grant access to experimental medical products and the conditions under which that access can occur. Defendants illegally established conditions contrary to those established by the Secretary,
- B. Congress only authorized the Secretary to determine who can participate in any activity that becomes lawful to 21 U.S.C. § 360bbb-3. However, the Secretary is prohibited from requiring any person to participate in any such activity. Yet, Defendants usurped the Constitutional authority of Congress and mandated that all healthcare facilities and providers must participate in the EUA program,
- C. Congress expressly preempted all state laws via the PREP Act and 21 U.S.C. § 360bbb-3. Yet, Defendants usurped the authority of Congress, ignored the Constitution's Supremacy Clause, and enforced laws, customs, ordinances, and regulations in defiance of Congress, the Constitution, and the rights of Plaintiffs.

355. Defendants’ actions demonstrate a willful, intentional, and wanton disregard for the United States Constitution, federal law, agency regulations, and the express rights of individuals to determine EUA participation as established by a valid act of Congress.

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

357. Although *Adickes* involved the state custom of racial discrimination, the precise custom is not the relevant point but rather the pervasiveness and persistence of the custom or usage, no matter its name.

358. The *Adickes* Court referenced one of the original Congressional supporters of § 1983, who stated, “[T]he chief complaint is not that the laws of the State are unequal, but that, even where the laws are just and equal on their face, yet, by a systematic maladministration of them, or a neglect or refusal to enforce their provisions, a portion of the people are denied equal protection under them.”

359. The Court commented, “This interpretation of custom recognizes that settled practices of state officials may, by imposing sanctions or withholding benefits, transform private predilections into compulsory rules of behavior no less than legislative pronouncements.”

360. Acting under State custom, Defendants usurped the federal government’s authority, imposed sanctions, and withheld benefits as if that fraudulent authority had legislative pronouncement.

361. After PeaceHealth deprived Plaintiffs of their Fourteenth Amendment rights to due process and altered their employment, Washington State Employment Security Department enforced the custom by denying some Plaintiffs unemployment benefits solely based on Plaintiffs exercising their 21 U.S.C. §360bb-3 legal rights.

362. The State Employment Security Department provided an FAQ of COVID-19-related questions. One Q and A demonstrates the unlawful practice of the State custom:

Question: “If an employer requires vaccinations and an employee refuses to get one, is the employee entitled to unemployment benefits?”

Answer: “When an employee’s separation is the result of failure to comply with an employer’s requirement to become vaccinated, ESD will examine a number of factors. These factors may include when the employer adopted the requirement, whether the employee is otherwise eligible for benefits, the specific terms of the vaccine policy including allowable exemptions, and the reason why the employee did not comply with the vaccine requirement. For example, when the employer offered religious or medical accommodations, but the employee does not qualify for an accommodation and does not comply with the vaccine requirement, a claim would likely be denied. However, some individuals may still qualify based on their own unique circumstances. ESD will evaluate each case on its own merit.” (Emphasis added)

363. The State’s Employment Security Department violated the Unconstitutional Conditions Doctrine by enforcing a custom as though it had the force of law by requiring Plaintiffs to surrender their constitutional and statutory rights as a condition to access public benefits. Moreover, having been approved for unemployment benefits, other Plaintiffs received a letter stating they were to return the money solely based on their refusal to participate in PeaceHealth’s mandatory COVID-19 investigational drug program. The violation of the Unconstitutional Conditions Doctrine is demonstrated by the fact that the Employment Security Department’s laws were “just and equal on their face.” Still, it relied on the use of investigational medical products for determining unemployment benefits, causing a severe violation of Plaintiffs equal protection and due process rights.

364. PeaceHealth and Washington State Employment Security Department defamed the character of Plaintiffs who were denied unemployment benefits by labeling their exercising of a federal right as misconduct.

365. The COVID-19 program did not belong to PeaceHealth. PeaceHealth was only allowed to provide the program as a public function on behalf of the State. PeaceHealth fraudulently usurped the federal government's authority and required that which Congress prohibits because Governor Inslee and the State of Washington developed a custom having more authority than federal law.

366. Washington State Department of Health, having its own FWA agreement and intimate knowledge of the Belmont Report and 45 CFR 46 requirements, refused to enforce the laws on the books and allowed facilities and persons it licenses to subject individuals to investigational drug use under threat of incurring a penalty or losing a benefit to which they were otherwise entitled.

367. Washington State Department of Health, after authorizing numerous entities to enroll in the CDC COVID-19 Vaccination Program and PREP Act activities, refused to enforce the provisions of the CDC Vaccination Program Provider Agreement when those entities violated the terms and conditions of the contract and its supporting statutes (21 U.S.C §360bb-3). The Health Department held the authority to intervene but chose to act on a non-enforcement custom to support Governor Inslee's unlawful edicts.

368. Washington Medical Commission, a State agency mandated with regulating and enforcing the quality standards of medicine, refused to correct the errant behavior of licensed healthcare professionals mandating individuals to participate in the use of 21 U.S.C. §360bbb-3 investigational drugs.

369. Municipalities across the State also required citizens to participate in experimental COVID-19 drugs as a condition to enjoy public employment, access to facilities, and other benefits

in violation of federal law and the citizens' rights, all without consequence by any law enforcement agency within the State or local municipality.

370. The violations of the Constitutional and statutory rights of Washington's citizens are so pervasive in the State that an average person could only conclude that the United States Constitution no longer has the force of law within its boundaries.

371. By and through the above-described facts and law, the Plaintiffs have established that a state-enforced custom abridged their federally secured rights to refuse an investigational drug without penalty. Moreover, PeaceHealth cited the Governor's proclamation in several sources as the reason for their own unlawful COVID-19 policy, demonstrating that they were acting under the color of law at all times pertinent.

XX. The Spending Clause

372. As stated 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)

373. The federal government funds all COVID-19 EUA shots via Medicare.⁶⁹

374. The executive branch of government established the CDC COVID-19 Vaccination Program Provider Agreement to execute the government's objective.

⁶⁹ <https://www.medicare.gov/medicare-coronavirus>

375. Only persons authorized to participate in the CDC Vaccination program can bill the government for administered shots.

376. The Spending Agreement lacks any enforcement scheme that would preclude § 1983 enforcement.

377. 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.”

378. 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.”

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

380. 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.”

381. Agreement Requirement Number Five complies with funding restrictions established by Congress in, 45 CFR §122 and 10 U.S.C. §980.

382. 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.

383. Whether for civilians under 45 CFR § 46.122 or military 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.

384. 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.

385. 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.”

386. 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.

387. Therefore, 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.

XXI. Deprivations of Constitutional and Statutory Rights, Privileges, and Immunities

388. Governor Inslee’s Proclamation (21-14.1) statement that he “prohibits...any operator of a Health Care Setting from permitting a Health Care Provider to engage in work for the operator as an employee, contractor, or volunteer in their capacity as a Health Care Provider after October 18, 2021 if the Health Care Provider has not been fully vaccinated against COVID-19” was no less than a direct attempt to subvert the Constitution of the United States of America.

389. Defendants were well aware that 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) contained a required condition of Congress that they must “ensure that individuals to whom the product is administered are informed — of the option to accept or refuse administration of the product.”

390. Defendants were well aware that 42 USC 247d-6d(b)(8) preempted their authority to establish conditions that would otherwise conflict with the federal government’s voluntary medical countermeasure program and 21 U.S.C. §360bbb-3 expanded access emergency use authorizations.

391. Defendants were well aware that their voluntary agreement to abide by the terms and conditions of the CDC COVID-19 Vaccination Program required them to obtain the legally effective informed consent of Plaintiffs equally and in advance of the product’s administration. That legal requirement meant that, at minimum, Defendants had to establish conditions ensuring potential participants were not under outside pressure to participate in any 21 U.S.C. §360bbb-3 product or 42 USC 247d-6d(b)(8) activity.

392. However, Defendants proceeded as if Plaintiffs’ legal right to accept or refuse participation in activities or products under the above-mentioned statutory authorizations were conditional, not absolute. Such nonsensical behavior by State actors shocks the conscience. Nothing in 21 U.S.C. §360bbb-3 or 42 USC 247d-6d(b)(8) could lead any person to believe that

any State authority has the right to interfere in the decision-making process of an individual considering participation in the use of a 21 U.S.C. §360bbb-3 medical countermeasure. That is why Defendants concealed the Plaintiffs' legal rights under 21 U.S.C. §360bbb-3 in all of their proclamations.

393. Congress expressly preempted Defendants from establishing conditions that would otherwise conflict with the federal government's CDC COVID-19 Vaccination Program under 42 USC 247d-6d(b)(8) and 21 U.S.C. §360bbb-3.

394. Therefore, when Defendants, acting under color of law, enacted laws, regulations, ordinances, and customs requiring Plaintiffs to become "fully vaccinated" before the availability of licensed vaccines, they willfully usurped the authority of the HHS Secretary, ignored the authority of Congress, and intentionally robbed Plaintiffs of their Constitutional protections guaranteed to them under the Fourteenth Amendment.

395. Defendants treated persons exercising the federally secured right to accept a COVID-19 investigational product (drugs, testing articles, masks) differently than persons exercising the federally secured right to refuse the product. A valid Act of Congress enacted both options, and both options must be treated equally before the law. Defendants established punitive conditions only on persons choosing the option to refuse, violating the Fourteenth Amendment's Equal Protection Doctrine.

396. Defendants, at all times pertinent, engaged in moral turpitude by pretending as if Plaintiffs did not have the legal authority to refuse a 21 U.S.C. §360bbb-3 product (drugs, biologics, devices) without consequence. Therefore, irrespective of any established procedures by Defendants to allow Plaintiffs to air their concerns about the COVID-19 vaccination requirements,

Due Process was impossible to secure because Defendants intentionally acted on a custom ignoring Plaintiffs' statutory rights and Congress of its Constitutional authority.

397. Before Defendants could legally access and distribute any COVID-19 investigational drug, they had to agree to comply with the terms and conditions established by the executive branch of the federal government as outlined in the CDC COVID-19 Vaccination Program Provider Agreement. That agreement required Defendants to comply with the Scope of Authorization for each EUA and the laws under 21 U.S.C. §360bbb-3, among others.

398. The CDC COVID-19 Vaccination Program Provider Agreement provides the following statutory and third-party beneficiary rights⁷⁰ to Plaintiffs:

- A. to give legally effective informed consent,
- B. to consider participation without fearing consequences based on the chosen option,
- C. having all associated costs and fees paid for by the federal government irrespective of the chosen option,
- D. to be informed of the risks/benefits/alternatives to the medical countermeasure,
- E. to cease participation at any time without consequences,
- F. to be treated with dignity when discussing the option with a healthcare provider, as discussed in detail in the Belmont Report.

399. Although the State of Washington and PeaceHealth voluntarily agreed to comply with the terms and conditions of the CDC COVID-19 Vaccination Program, they at all times pertinent violated the third-party beneficiary rights outlined in the Contract.

⁷⁰ The CDC COVID-19 Vaccination Program Provider Agreement states in plain language at 12(a) 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." The listed items are associated with the "applicable" laws related to this complaint.

400. 45 CFR § 46.116 contains the only known statutory definition of legally effective informed consent.⁷¹ Therefore, when Congress explicitly or implicitly mandates that a person give their informed consent when involved in the use of an investigational drug, this regulation becomes the only source courts can utilize to ascertain its meaning.

401. 21 U.S.C. §360bbb-3 protocols do not require written informed consent. However, the conditions necessary to establish legally effective informed consent remain the same irrespective of written or oral informed consent requirements, mainly that there can be no outside pressure on Plaintiffs to use a drug not licensed by the FDA for general commercial marketing. Defendants violated the legally effective informed consent doctrine when applying coercion, undue influence, unjustifiable pressures, sanctions, and other punitive acts to Plaintiffs when they did not achieve “fully vaccinated” status by the compliance date. This achievement could only be obtained by relying exclusively on 21 CFR 312.3 investigational new drugs under research conditions.

402. At all times pertinent, Defendants were under strict requirements via the CDC COVID-19 Vaccination Provider Agreement, 21 U.S.C. §360bbb-3, 45 CFR 46.101(c), and 45 CFR 46.101(i) to comply with the ethical principles of the Belmont Report holding third-party beneficiary rights for Plaintiffs.

403. The Belmont Report informed Defendants that:

A. “Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy,”

⁷¹ Congress specifically requested the HHS Secretary to promulgate regulations pertaining to the protection of human subjects via the 1974 National Research Act. Therefore, these regulations represent the express intent of Congress when discussing what is legally effective informed consent.

B. “An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions,”

C. “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.”

404. Defendants failed in their duties to respect the autonomy of Plaintiffs and refused to respect their considered choices, and most certainly obstructed Plaintiffs' actions to make an autonomous choice.

405. The Belmont Report further instructed Defendants that “Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term ‘beneficence’ is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.”

406. 21 U.S.C. §360bbb-3 requires the healthcare professional and the recipient to mutually agree to the product’s administration before the process becomes legal. This legal requirement by Congress is to ensure that proper medical counseling protects individuals from potentially life-altering adverse effects from using a medical countermeasure product.

407. Defendants intentionally withheld factual knowledge that the EUA mRNA products were causing historical harm to recipients. Moreover, there was no historical knowledge or means of ascertaining the more than 6.859 trillion⁷² potential contraindications the products could have

⁷² The FDA has licensed 19,000 marketable drugs, and in 2021, three mRNA drugs were available to Plaintiffs. Therefore, 19,000 to the power of three equals 6,859,000,000,000 potential contraindications that mere months of research could not have exposed.

had with existing medical conditions and other drugs. That is why drugs undergo years of trials and testing before receiving their marketing approval. The lack of quality testing and fear of liability is also why, as of this filing, no COVID-19 drug manufacturer has shipped their licensed products in violation of 21 CFR 312.7(c).

408. The Defendants' actions demonstrate a wanton disregard for Plaintiffs' safety and health. Moreover, Defendants' actions demonstrate violations of the Belmont Report to "minimize possible harms."

409. The Belmont Report was explicit in Defendants' ethical requirement on how to legally and effectively obtain informed consent as follows:

A. "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 (see, supra),"

B. "An agreement to participate in research constitutes a valid consent only if voluntarily given."

410. "Voluntarily given" has no other meaning than the action was free from coercion, unjustifiable pressures, undue influence, and not given out of fearing consequences. Defendants intentionally violated their duties to obtain the Plaintiffs' legally effective informed consent, thus violating the ethical principles of the Belmont Report and its intended benefits for the Plaintiffs.

411. The State of Washington and PeaceHealth provided assurances (FWA agreement) to HHS as a condition to receive federal funds to involve humans in the use and evaluation of investigational medical products. At a minimum, those assurances must comply with 45 CFR 46 protocols and the ethical principles of the Belmont Report.

412. The assurances aim to benefit third parties considering using investigational products offered by Defendants for various research-related purposes. Factually speaking, the only

purpose of the FWA agreement is to benefit non-signatory third parties. Defendants (promisors) assured the federal government (promisee) that they would protect the rights, safety, and health of Plaintiffs (non-signatory party) by promising to abide by the protective protocols under 45 CFR 46 and the Belmont Report; protocols having an unambiguous focus on the third-party beneficiary (Plaintiffs). Defendants' promise to the federal government was by direct nexus also a promise to any third-party participant, such as Plaintiffs.

413. The duties imposed upon Defendants is to obtain legally effective informed consent from Plaintiffs before the product is administered. When Defendants imposed sanctions, such as termination from employment and denial of access to living wages, they violated the intended protective benefits Congress conferred upon Plaintiffs via the Federal Wide Assurance agreement. Defendants voluntarily agreed to comply with their FWA obligations, but Defendants voluntarily violated that agreement harming the intended benefits of Plaintiffs under the FWA agreement.

414. 45 CFR § 46.116 was written by the express consent of Congress as instructed under the National Research Act (1974) (see, *supra*). The entire purpose of this provision of law is to provide individuals involved in federally funded medical research projects with protective legal benefits. The section of the law is unambiguous in its right conferring language, which focuses exclusively on the third-party beneficiary. Some of those intended benefits are:

- A. “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,”
- B. “The information that is given to the subject or the legally authorized representative shall be in language understandable,”
- C. “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,”

D. “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, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence,”

E. “A statement [must be given to the recipient] 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,” and

F. “A statement that the particular treatment or procedure may involve risks to the subject.”

415. Defendants voluntarily participated in COVID-19 federal funding to conduct research activities on its behalf involving humans. Defendants intentionally ignored their duties to third-party beneficiaries (Plaintiffs) under 45 CFR § 46.116 when establishing employment conditions on receiving one of the 21 U.S.C. §360bbb-3 medical countermeasure products in direct violation of federal law and their legal obligations under the FWA and the CDC COVID-19 Vaccination Program Provider Agreement. Defendants, at all times pertinent, were well aware of the rights of Plaintiffs to refuse investigational medical products, irrespective of their authorized expanded access protocol, without consequence but chose to engage in moral turpitude for the express purpose of causing Plaintiffs to surrender their Constitutional protections and statutory rights.

416. Article VII of the ICCPR Treaty binds Defendants, as State Actors, to comply with its principles and legal obligations. In the same legal manner as the Belmont Report, 45 CFR 46, 21 U.S.C. §360bbb-3, FWA, the PREP Act, and the CDC COVID-19 Vaccination Program Provider Agreement, Article VII denies Defendants the legal authority to subject Plaintiffs to

medical experimentation outside of their free will and voluntary consent. Although Defendants were unsuccessful in causing Plaintiffs to surrender their Constitutional and statutory rights, Defendants subjected Plaintiffs to medical experimentation when issuing their respective COVID-19 vaccination requirements and then penalizing them for not complying with those unlawful requirements. Defendants intentionally failed to fulfill their duties under Article VII of the ICCPR Treaty.

417. The PREP Act (42 USC 247d-6d,6e) expressly strips Defendants of all legal authority to amend the voluntary nature of the medical countermeasure program by enacting laws, regulations, and customs that would otherwise allow Defendants to interfere with the objectives of the federal government issuing the declared emergency.

418. Defendants, ignoring Congressional authority, established laws, regulations, and customs that interfered with the PREP Act and 21 U.S.C. §360bbb-3 protocols when they issued their respective COVID-19 vaccination requirements. Moreover, when challenged on the legality of their COVID-19 vaccination policies, Defendants invoked Washington’s at-will employment doctrine and the Washington Department of Public Health and Environment’s emergency COVID-19 rules as adopted by its voting Board Members on August 30, 2021. Laws that specifically conflict and interfere with 42 USC 247d-6d and 21 U.S.C. §360bbb-3 conditions.

419. Governor Inslee cited an erroneous slip opinion by the Department of Justice,⁷³ lacking the force of law, as justification for his fiat dictates. However, he willfully ignored federal

⁷³ “**WHEREAS**, on July 6, 2021, the Office of Legal Counsel of the United State Department of Justice issued a legal opinion stating that federal and state governments were not prohibited by federal law from imposing vaccination mandates, even when the only vaccines available are those authorized under the FDA’s Emergency Use Authorizations.” — Governor Inslee Proclamation 21-14.1 see page 2

law⁷⁴ and contractual obligations⁷⁵ that demonstrated that his actions violated the laws he purported to uphold.

420. Dawn Johnsen, Acting Assistant Attorney General, issued a patently untrue slip opinion⁷⁶ on July 06, 2021 lacking substantial information that would otherwise disprove her assertion that section 564 “does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs.” She does not speak to the fact that only the HHS Secretary is authorized to establish the conditions by which persons can participate in the EUA process. Not even the Secretary can impose “vaccination requirements” utilizing section 564 drugs. Additionally, she does not speak to the legal distinctions between a licensed drug and an investigational medical product authorized only for emergency use. These distinctions have significant legal consequences for the end user. Moreover, her statement, “even when the only vaccines available are those under EUAs,” was a severe mischaracterization of the law. Factually speaking, a vaccine is a classification assigned by the FDA, and as such, that classification can never be under an EUA. All drugs, biologics, and devices under an EUA are classified as investigational for the purpose for which it is being utilized.

421. Governor Inslee cited Dawn Johnsen’s slip opinion, lacking the force of law, because it provided him a semblance of legal cover. However, he willfully ignored laws, contracts, and agreements disproving Dawn Johnsen’s slip opinion and his authority to mandate the use of EUA products.

422. Governor Inslee violated RCW 7.7.060 by unlawfully mandating medical treatment for Plaintiffs, violating the statute’s informed consent protocols.

⁷⁴ 21 U.S.C. §360bbb-3, FWA, Article VII ICCPR Treaty, 45 CFR § 46.(116,122), 10 U.S.C. § 980, each EUA’s Scope of Authorization, and the United States Constitution.

⁷⁵ CDC COVID-19 Vaccination Program Provider Agreement and the State’s FWA agreement.

⁷⁶ <https://www.justice.gov/olc/file/1415446/download>

423. Governor Inslee violated the Plaintiffs' rights under RCW 69.77.050, requiring specific informed consent protocols relating to administering investigational new drugs.

424. PeaceHealth, acting under the color of law, issued its COVID-19 mandate on August 30, 2021 stating in part, (1) "It is the policy of PeaceHealth to require healthcare workers (HCWs) to be fully vaccinated against COVID-19," and (2) "The compliance date for all HCWs to start a COVID-19 vaccination series/dose or submit for an exemption will be August 31, 2021. The compliance date for all HCWs to be fully vaccinated or have an approved medical or religious exemption that can be accommodated is October 15, 2021."

425. PeaceHealth, CEO Liz Dunne, and CPE Doug Koekkoek are legally sophisticated and have a history of conducting joint investigational trials with the National Cancer Institute. Moreover, PeaceHealth's medical professionals have administered investigational drugs under 21 U.S.C. §360bbb protocols to individuals for years before the pandemic. They know of the statute's requirements when administering investigational medical products authorized under the statute's provisions.

426. Therefore, when Governor Inslee issued his proclamation ordering healthcare facilities to subject individuals under their authority to investigational drug use, PeaceHealth knew that the executive Proclamation was a direct violation of federal law and their lawful duties under the CDC Vaccination Program Provider Agreement.

427. The Governor's Proclamation 21-14.1 clearly and unambiguously states that "the specific prohibitions in this Proclamation are severable and do not apply to the extent that compliance with a prohibition would violate (1) any U.S. or Washington constitutional provision; (2) federal statutes or regulations; (3) any conditions that apply to the state's receipt of federal funding; (4) state statutes; or (5) applicable orders from any court of competent jurisdiction."

428. PeaceHealth, like all other healthcare facilities in the State, was free to comply with laws and regulations protecting humans involved in investigational medical products.

429. However, due to the customs of the State of Washington, where certain laws are not enforced by its Attorney General, as demonstrated by the Governor's willful violations of his proclamation⁷⁷, PeaceHealth chose to hide behind the State's mandate and customs to participate in the federal government's COVID-19 cash cow at the expense of Plaintiff's Fourteenth Amendment and statutory rights.

430. PeaceHealth's COVID-19 vaccine policy relied exclusively on investigational new drugs not classified by the FDA as a vaccine.

431. PeaceHealth never informed the Plaintiffs of their right to refuse an investigational new drug without consequence, as required by federal law.

432. PeaceHealth never set a time, date, or place to secure Plaintiff's due process rights.

433. PeaceHealth, CEO Liz Dunne, and CPE Doug Koekkoek violated Plaintiffs' Fourteenth Amendment rights when penalizing them for refusing administration of a COVID-19 investigational drug by October 15, 2021.

434. PeaceHealth only altered the employment of those who refused an EUA product and not those who accepted, severely violating the Fourteenth Amendment's Equal Protection Clause.

435. PeaceHealth only terminated healthcare insurance for Plaintiffs placed on unpaid administrative leave after they refused administration of an EUA drug or refused participation in a PREP Act activity, which is a deprivation of the Plaintiffs' Fourteenth Amendment rights of equal protection.

⁷⁷ An estimated 1,900 Washington State employees were terminated by the governor directly or constructively when refusing to participate in a COVID-19 experimental drug violating the Constitution, federal statutes, and regulations.

436. PeaceHealth only required N95 masks (also under PREP Act authority) for some of the Plaintiffs after they refused administration of an EUA drug or refused participation in a PREP Act activity, which is a deprivation of the Plaintiffs' Fourteenth Amendment rights of equal protection.

437. PeaceHealth only required COVID-19 testing (i.e., utilizing EUA products), for some of the Plaintiffs after they refused administration of an EUA drug or refused participation in a PREP Act activity, which is a deprivation of the Plaintiffs' Fourteenth Amendment rights of equal protection.

438. PeaceHealth did not afford Plaintiffs a date, time, or place to exercise their due process rights. Therefore, PeaceHealth, as State Actor, violated Plaintiffs' substantive and procedural due process rights.

439. PeaceHealth, refused, at all times, to obtain the legally effective informed consent of Plaintiffs, thereby violating Plaintiffs' rights under 45 CFR 46, 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, the Belmont Report, and PeaceHealth duties under its Federal Wide Assurance agreement, Institutional Review Boards, and its signed CDC COVID-19 Vaccination Program Provider Agreement.

440. At all times pertinent herein, Plaintiffs were legally and physically incapable of violating any State or PeaceHealth requirement to receive a licensed COVID-19 vaccine because no such vaccine existed by which they could refuse. This unassailable fact did little to stop the tyrannical dictates of Defendants from punishing Plaintiffs when they exercised their statutory authority.

**XXII. Wanton Disregard for the Safety, Health, and
Rights of Plaintiffs**

441. In August 2021, Governor Inslee issued Proclamations 21-14 and 21-14.1, stating: “COVID-19 vaccines are safe and effective.” The statement was a direct violation of 21 CFR 312.7(a)’s restriction that “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.”

442. Governor Inslee’s statement that available COVID-19 drugs were “vaccines” was patently untrue. The FDA classifies COVID-19 drugs under an EUA as “investigational new drugs,” and the Governor had no authority to promote those drugs outside of their legal indication.

443. Governor Inslee’s statement that “COVID-19 vaccines were evaluated in clinical trials involving tens of thousands of participants and met the U.S. Food & Drug Administration’s (FDA) rigorous scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization; and, to date, more than 346 million doses of COVID-19 vaccines have been given in the United States with 8.2 million of those doses administered in Washington, and serious safety problems and long-term side effects are rare” was a false and misleading statement.

444. The Governor’s statement lacked information people would want to know⁷⁸ when considering participation. 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, he 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

⁷⁸ 45 CFR 46.116(a)(4)

Inslee 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 drug, specifically because they are under PREP Act authority.

445. Governor Inslee’s requirement that “Providers who do not work in a Health Care Setting must provide proof of vaccination to the operator of the facility in which the Provider works, if any, or, if requested, to a lawful authority” was a serious violation of the privacy rights of Plaintiffs.

446. Plaintiffs choosing to be injected with unlicensed medical products is a private matter, and not even the Governor is empowered to force “public disclosure of Plaintiff’s private facts.”⁷⁹ All citizens have the right to accept or refuse investigational (i.e., experimental) products as a private affair, and intrusion into that private matter is “highly offensive”⁸⁰ to Plaintiffs.

447. Governor Inslee stated, “Workers for State Agencies, Workers for operators of Educational Settings, and Health Care Providers are not required to get vaccinated against COVID-19 under this Order if they are unable to do so because of a disability or if the requirement to do so conflicts with their sincerely held religious beliefs, practice, or observance.”

448. The requirement to obtain an exemption from medical experimentation is an unlawful misrepresentation of authority by the Governor. Congress was explicit in that only the HHS Secretary has the authority to establish the conditions under which 21 U.S.C. §360bbb-2 products are administered. Not even the Secretary can require any person to participate in any activity under the section of law. Governor Inslee ignored his constitutional restrictions, legal obligations, and his oath of office to protect the rights, privileges, and immunities of Plaintiffs.

⁷⁹ *Reid v. Pierce County*, 136 Wn. 2d 195, 136 Wash. 2d 195, 961 P.2d 333 (Wash. 1998) and see *Hearst Corp. v. Hoppe*, 90 Wn. 2d 123, 90 Wash. 2d 123, 580 P.2d 246 (Wash. 1978)

⁸⁰ *Adams v. King Cty.*, 164 Wash. 2d 640, 662, 192 P.3d 891, 902 (2008)

With utter disregard for the rule of law, Governor Inslee assumed a power not granted to him for the intentional purpose of causing the Plaintiffs to surrender their constitutional rights resulting from their fears of economic loss.

449. However, the following statement demonstrates Governor Inslee's moral turpitude, "Workers for State Agencies, Workers for operators of Educational Settings, and Health Care Providers are prohibited from claiming an exemption or accommodation on false, misleading, or dishonest grounds, including by providing false, misleading, or dishonest information to a State Agency, operator of an Educational Setting, or operator of a Health Care Setting when seeking an accommodation."

450. Governor Inslee's entire 21-14.1 Proclamation is built upon "false," "misleading," and "dishonest grounds" "by providing false, misleading, or dishonest information" to the general public.

451. Governor Inslee cannot produce a constitution, statute, regulation, treaty, or contract demonstrating his authority to establish conditions contrary to the Plaintiffs' right to refuse 21 U.S.C. §360bbb-3 medical countermeasures without consequence.

452. Governor Inslee attempted to insulate himself from future litigation by stating, "Operators of healthcare settings...must comply with the procedures required under the above-noted laws and any other applicable law when considering and deciding whether to provide accommodations" (emphasis added). However, the entire proclamation was unlawful at the outset because it relied exclusively on investigational drugs for compliance that have no legal indication to treat, cure, or prevent any variant of the SARS-CoV-2 (COVID-19) virus. Moreover, the Governor intentionally withheld any information relating to 21 U.S.C. §360bbb-3, a statute the

entire Proclamation relied upon and which provided an express right of Plaintiffs to refuse administration of an EUA investigational drug without incurring a penalty or losing a benefit.

453. According to the Washington State's Office of Financial Management,⁸¹ 1,900 State employees were directly or constructively terminated by Governor Inslee, demonstrating that not even he would "comply with...any other applicable law" protecting citizens' right to refuse without consequence.

454. Governor Inslee's decision to usurp the authority of Congress and legislate by fiat has created a Constitutional crisis within the State of Washington by establishing two classes of citizens. One class is made up of those who are under the protection of the Constitution and enjoy the liberties it secures for them. The other class comprises those who exercised a statutory right, but a right the Governor disagreed with, resulting in a form of government where Plaintiffs are deprived of liberties and property without due process and are deprived of the equal protection of laws.

455. Governor Inslee mandated that "Workers for State Agencies, Workers for operators of Educational Settings, and Health Care Providers must provide proof of full vaccination against COVID-19 by providing one of the following (1) CDC COVID-19 Vaccination Record Card or photo of the card, (2) documentation of vaccination from a health care provider or electronic health record, (3) State immunization information system record."

456. Being administered a COVID-19 investigational new drug is not legally considered a vaccination. EUA COVID-19 drugs have no legal indication to vaccinate anyone from any known disease. Therefore, no individual who chooses to receive a COVID-19 EUA drug

⁸¹ I.O'Sullivan J. Nearly 1,900 Washington state workers quit or are fired over COVID vaccine mandate. The Seattle Times. Published October 20, 2021. Accessed June 28, 2023. <https://www.seattletimes.com/seattle-news/politics/nearly-1900-washington-state-workers-quit-or-are-fired-over-covid-vaccine-mandate/>

is legally considered vaccinated against the SARS-CoV-2 (COVID-19) infection. Governor Inslee's use of the word "vaccinate" was intentional misinformation designed to confuse the public about its rights, safety, and health when considering whether or not to participate in the CDC's COVID-19 Vaccination program relying exclusively on COVID-19 investigational drugs.

457. Governor Inslee stated, "A person is fully vaccinated against COVID-19 two weeks after they have received the second dose in a two-dose series of a COVID-19 vaccine (e.g., Pfizer-BioNTech or Moderna) or a single-dose COVID-19 vaccine (e.g., Johnson & Johnson (J&J)/Janssen) authorized for emergency use, licensed, or otherwise approved by the FDA or listed for emergency use or otherwise approved by the World Health Organization."

458. Governor Inslee had no lawful authority to assert that if Plaintiffs received a drug still undergoing clinical trials, they would be "fully vaccinated against COVID-19." Neither Pfizer, Moderna, nor Johnson & Johnson (Janssen) stated in any published materials that if a person received one of their investigational drugs, then they would be immunized or protected from COVID-19 variants.

459. Governor Inslee fraudulently utilized his position of authority to place Plaintiffs under moral duress knowing the Plaintiffs relied on their jobs to purchase food, housing, clothing, medical care, educational access, and to otherwise enjoy the pleasures of life in the State of Washington.

460. Governor Inslee refused to ask the 100,000⁸² nurses in Washington State if they:

- A. were willing to forfeit their litigation rights should they become injured from the drug's use,
- B. allowed their private identifiable information to be collected and used for unknown purposes and unknown reasons,

⁸² https://www.wcnursing.org/wp-content/uploads/documents/reports/2022-May_WCN-WA-2021-Nursing-Workforce-Supply-Data-Report-Characteristics-of-LPNs-RNs-and-ARNPs_FINAL.pdf

- C. assumed greater risks to their legal rights, safety, and health when choosing to take an EUA drug under PREP Act authority,
- D. allowed data about their involvement with the drug or testing article to be utilized by medical researchers for unknown reasons and an unknown period of time, before issuing his proclamation.

461. Governor Inslee chose to regulate the United States Government outside of his Constitutional authority, depriving Plaintiffs of their rights as secured by the Constitution. He subjected the entire state to medical experimentation in defiance of Senator Kennedy's 1973 heroic efforts, 45 CFR 46, 21 U.S.C. §360bbb-3, the State's FWA, and the CDC COVID-19 Vaccination Program Provider Agreement, and Article VII of the ICCPR Treaty.

462. When the Plaintiffs refused his fiat dictates, he demoted them to that of a second-class citizenry and stripped them of their Constitutional protections, privileges, and immunities. Governor Inslee demonstrated a willful and wanton disregard for known laws protecting Plaintiffs from medical research abuses which is an outrage in light of our nation's abuse of human rights discussed above.

463. Governor Inslee intentionally refused to allow citizens under his authority to give their legally effective informed consent as if Congress never mandated that legal exercise before the product's administration.

464. Governor Jay Inslee's proclamations and corresponding actions violated Plaintiffs' (1) Fourteenth Amendment rights of equal protection and due process, (2) Article VII of the ICCPR Treaty rights, (3) 21 U.S.C. §360bbb-3 option to accept or refuse without penalty rights, (4) 45 CFR § 45.116 legally effective informed consent rights, (5) protections under the Belmont Report, (6) protections under 45 CFR §122, 10 U.S.C. § 980, (7) protections under the CDC Vaccination Program Provider agreement.

465. PeaceHealth's COVID-19 Vaccine Requirement Policy, issued on August 30, 2021 states, "PeaceHealth recognizes that immunization with a safe and effective vaccine is a proven strategy to reduce COVID-19 related illness for its HCWs, patients, and communities. Only HCWs with a qualified and accepted medical or religious exemption may decline COVID-19 vaccination."⁸³

466. The statement that "immunization with a safe and effective vaccine is a proven strategy to reduce COVID-19 related illness" was an intentionally misleading statement and a violation of federal law (21 CFR 312.7(a)).

467. There does not and did not exist a COVID-19 "vaccine" available to Plaintiffs. No COVID-19 drug manufacturer has ever claimed that their investigational drugs would immunize Plaintiffs from the SARS-CoV-2 (COVID-19) infection. The statement in the preceding paragraph does not claim that there actually existed a "safe and effective vaccine." Still, it misleadingly implies that the statement applies to the drugs under their mandate, making an average person conclude that the COVID-19 EUA drugs were "safe and effective vaccines." The statement demonstrates a wanton disregard for Plaintiffs' rights, autonomous beliefs, and health goals when involving them in using an investigational drug.

468. The policy statement, "Only HCWs with a qualified and accepted medical or religious exemption may decline COVID-19 vaccination, " severely violates federal law and the Plaintiffs' constitutional and statutory rights.

469. Federal law explicitly states that the individual possesses the power to accept or refuse EUA countermeasure participation. The Plaintiffs' statutory authority to refuse is absolute and not conditioned upon them seeking an exemption.

⁸³ See Exhibit B, PeaceHealth's COVID-19 Vaccine Requirement Policy.

470. PeaceHealth is legally sophisticated with laws and regulations involving investigational drugs and knew in advance that the requirement to seek an exemption violated those laws.

471. PeaceHealth and its policymakers knew they were bound by treaty, law, regulation, and contract to create a legally approved environment ensuring no person was sanctioned for not participating in available COVID-19 investigational drugs.⁸⁴⁸⁵

472. PeaceHealth was also well aware that administering an investigational medical product to as little as only one individual requires IRB oversight and compliance with 45 CFR 46, the FWA, and other laws protecting humans involved in medical research activities.⁸⁶

473. PeaceHealth's immunization policy was built upon intentionally fraudulent misrepresentation of facts and illegal statements.

474. No COVID-19 drug manufacturer has claimed to "immunize" any person from any COVID-19 variant.

475. PeaceHealth's policy stated, "Except as set forth below, HCWs are considered fully vaccinated two weeks after they have received Pfizer or Moderna second dose, Johnson & Johnson single dose or other U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA), FDA approved, FDA authorized or World Health Organization (WHO) emergency use/approved COVID-19 vaccine/series."

⁸⁴ "When informed consent is required, it must be sought prospectively, and documented to the extent required under HHS regulations at [45 CFR 46.117](#)." - Informed Consent FAQs. HHS.gov. Published 2018. Accessed June 8, 2023. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

⁸⁵ "Because individuals receiving urgent or emergent medical care frequently may be vulnerable to coercion or undue influence, even if temporarily, additional protections may be required to ensure the subject's consent to participate in research is truly voluntary and sought under circumstances that minimize the possibility of coercion or undue influence ([45 CFR 46.111\(b\)](#), [45 CFR 46.116](#))." - *Id.*

⁸⁶ "This policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel" - 45 CFR 46.101(a) (Basic HHS Policy for Protection of Human Research Subjects)

476. PeaceHealth lacked legal authority to convey that a person would be “fully” protected when and if they were administered experimental drugs undergoing clinical trials having no legal indication to treat, cure, or prevent any known disease. The statement was dangerous because the medical community had not even come close to establishing how many contraindications the EUA drugs had with existing medical conditions or other drugs.

477. PeaceHealth disseminated misinformation when conveying that if Plaintiffs received the recommended doses of one of the unlicensed medical products, they would become “fully vaccinated” against the virus. No COVID-19 drug manufacturer claims to immunize any person from any COVID-19 variant. Moreover, PeaceHealth engaged in a form of medical malpractice by “advertising” the drug outside of its legal indication.

478. RCW 69.04.019 provides: “The term ‘advertisement’ means all representations, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.” (Emphasis added)

479. RCW 69.04.106 provides: “If any article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.”

480. Pfizer was fined more than \$1.2 billion for promoting drugs outside of their legal indication.⁸⁷ The DOJ stated in 2009 about Pfizer’s criminal behavior, “Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – *i.e.*, any use not specified in an application and approved by FDA.” “Illegal conduct and fraud by pharmaceutical companies puts the public health at risk, corrupts medical decisions by health care providers, and costs the government billions of dollars.”

481. CEO Liz Dunne’s COVID-19 policy further stated, “PeaceHealth recognizes that immunization with a safe and effective vaccine is a proven strategy to reduce COVID-19 related illness for its HCWs.” This statement violates 21 CFR 312.7(a) by implying that the investigational new drugs are safe and effective for the purpose under which they are being investigated.

482. Moreover, the implication that the statement applies to the drugs under her mandate violates RCW 69.04.106, RCW 60.04.040, RCW 69.04.710, and RCW 69.04.070.

483. CEO Dunne attempted to shield herself and PeaceHealth from future litigation by creating a document titled “Covid-19 Vaccine Acknowledgment (caregivers).” It includes the following statement to which Plaintiffs were to attest by signing the document: “I am making the choice to get the COVID-19 vaccine on my own and freely. I know I have the option to refuse the vaccine or talk to my physician prior to receiving the vaccine. I ask that the vaccine be given to me.”

484. Dunne holds the proverbial gun to the heads of Plaintiffs, telling them that she will destroy their financial lives if they do not participate in one of the COVID-19 experimental drugs,

⁸⁷ Justice Department Announces Largest Health Care Fraud Settlement in Its History. Justice.gov. Published September 2, 2009. Accessed July 11, 2023. <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history#:~:text=Pfizer%20promoted%20the%20sale%20of,United%20States%20for%20any%20matter.>

and then compels them, under duress, to sign a document before receiving the product, or the product's Fact Sheet, attesting that such action was under their free will and voluntary consent. Dunne's actions are expressly why Congress passed the 1973 National Research Act.

485. PeaceHealth shocks the conscience when mandating, "Fully vaccinated HCWs will be provided a badge sticker by PeaceHealth that indicates vaccination...The badge sticker must be visibly attached to their PeaceHealth name badge or such other name badge used to be on-site at a PeaceHealth location and not cover the HCW's name or other pertinent identifying information."

486. By mandating that the "vaccinated" wear a badge sticker, PeaceHealth not only identified the "vaccinated," but they identified by omission, and thus publicly shamed, the "unvaccinated."

487. Moreover, PeaceHealth is a "covered" entity under HIPAA. It is well aware that it is a criminal violation of law to disclose Private Health Information publicly. The requirement for "vaccinated" employees to wear a badge sticker violated the HIPAA rights, not only the "vaccinated," but the "unvaccinated," including Plaintiffs herein.

488. Moreover, the HHS developed standards for the Privacy of individually identifiable health information. It issued a final rule in 2002⁸⁸ stating in part: "a covered entity must remain cognizant of its dual roles as an employer and as a health care provider, health plan, or health care clearinghouse. Individually identifiable health information created, received, or maintained by a covered entity in its health care capacity is protected health information. It does not matter if the individual is a member of the covered entity's workforce or not. Thus, the medical record of a hospital employee who is receiving treatment at the hospital is protected health information and is covered by the Rule, just as the medical record of any other patient of that hospital is protected

⁸⁸ 67 Fed. Reg. 53191

health information and covered by the Rule. The hospital may use that information only as permitted by the Privacy Rule, and in most cases will need the employee's authorization to access or use the medical information for employment purposes." (Emphasis added)

489. PeaceHealth willfully engaged in criminal violations of HIPAA laws⁸⁹ for the express purpose of subjecting Plaintiffs to public pressures in hopes of causing them to surrender their constitutional protections and receive a COVID-19 experimental drug.

490. As a direct result of PeaceHealth's badge sticker mandate, when Plaintiffs thereafter arrived for their work shifts, PeaceHealth personnel ridiculed Plaintiffs for not having a badge sticker.

491. Even more shocking to the conscience, PeaceHealth patients were all made aware of the badge sticker's meaning. They required Plaintiffs to leave the room, making Plaintiffs feel as if they were a stigma to society, all because Plaintiffs chose to exercise their constitutionally protected rights to refuse administration of a drug that potentially had significant health and legal consequences for their lives.

492. PeaceHealth was disgusted that Plaintiffs chose the option to refuse and engaged in a "scorched earth" policy to make Plaintiffs pay for that choice no matter the laws PeaceHealth had to violate to achieve their unlawful goal.

493. However, what PeaceHealth, CEO Liz Dunne, and CPE Doug Koekkoek allowed to take place within the corridors of PeaceHealth's facilities is truly unimaginable, shocking to the conscience, and demonstrates the moral turpitude of these defendants when PeaceHealth created and publicly displayed, out in the open, actual physical binders containing a list of each employee's

⁸⁹ 42 U.S.C. § 1320d-6(b)(3) "if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both."

full name, facility location where they worked, the Department in which they worked, their employee ID, their job description, their “vaccination” status, and if they were “compliant” or “noncompliant” with PeaceHealth’s COVID-19 policy.

494. These binders were placed at nurses’ stations where employees could view them on demand. Plaintiffs were harassed, ridiculed, mocked, intimidated, and had their privacy continually invaded by staff managers.

495. According to one Plaintiff, “Yes, there were also the occasional ‘check-ins’ from any one of the managers pulling us aside (usually just in the public hallways) to ask if we were planning to get the ‘vaccine’ in the earlier stages and then progressing to multiple instances of being asked as the deadline drew near if we’d changed our minds and were we going to get the ‘vaccine’ and why not if we said ‘no.’ Again, none of their business, and TOTALLY INAPPROPRIATE for them to even ask! Not to be crass or inappropriate, but do they ask HIV-positive people and bipolar people if they’ve been taking their meds on a regular basis? Do they ask staff that have had an STD if they’ve finished the full antibiotic course prescribed? Of course not, because they likely would have never, and should never have, had access to that information to begin with.”

496. PeaceHealth was well aware of RCW 70.02.020(1) (Disclosure By Health Care Provider), “Except as authorized elsewhere in this chapter, a health care provider, an individual who assists a health care provider in the delivery of health care, or an agent and employee of a health care provider may not disclose health care information about a patient to any other person without the patient’s written authorization. A disclosure made under a patient’s written authorization must conform to the authorization.”

497. PeaceHealth knew they were violating both civil and criminal laws by:
- A. requiring employees to wear badges publicly disclosing their and, by omission, Plaintiffs' private health information,
 - B. publicly displaying binders containing Plaintiffs' private health information in unsecured locations, and
 - C. not obtaining the written permission of Plaintiffs for those reckless disclosures.

498. PeaceHealth chose to ignore well-known and practiced laws and regulations to subject Plaintiffs to outrageous conduct to force them to surrender their constitutional protections of being treated equally before the law and being afforded due process.

499. Shockingly, PeaceHealth provided assurance to its employees that "Proof of vaccination shall be maintained by PeaceHealth in a confidential file for the time prescribed by law and will be made available to regulatory bodies upon request to the extent required or allowed by law. PeaceHealth may rely on third parties (e.g., contractors) to assist in maintaining proof of vaccination. In such case, such third party shall sign a declaration outlining its responsibility to help enforce this policy and applicable state law and provide PeaceHealth a copy of said proof of vaccination upon request as allowed by law."

500. It is plain to see that by providing a list of employees who were not "vaccinated," whoever reviewed the list would know who had been injected with an investigational drug, which information should have been kept confidential.

501. PeaceHealth also assured Plaintiffs "Employee Health will track HCW compliance with this policy. PeaceHealth will protect HCW confidential information as required by law."

502. Despite these assurances, PeaceHealth did not comply with its own policy, violated the trust the Plaintiffs placed in them, and allowed Plaintiffs' privacy to be invaded daily. Such actions are unheard of in the nation's other healthcare facilities.

503. CEO Liz Dunne and CPE Doug Koekkoek allowed and encouraged a continual invasion of privacy of Plaintiffs' private health information that was offensive, illegal, and abusive, causing severe emotional distress to Plaintiffs.

504. Defendants' actions subjected Plaintiffs to that of a second-class citizen, causing them to fear for their physical safety, financial security, and loss of believing their rights were as important and equal to other employees.

505. According to another Plaintiff, "Not to mention bad dreams about it. There were a few doctors that I would avoid walking by in the halls, and I really didn't want to manage patients with them because they were so pushy, all-knowing, and obnoxious about it. One of them even badgered one of my coworkers at the nurse's station about the fact that she hadn't gotten the 'vaccine'. She embarrassed her in front of our friends and told her that it was her 'moral obligation' to get 'vaccinated,' and much more."

506. Yet another Plaintiff stated, "The pressure was so extreme, heart poundingly extreme."

507. PeaceHealth staff subjected Plaintiffs to degrading, inhuman, and emotional torture daily without consequence to the abuser. PeaceHealth's executive staff encouraged, enabled, and sustained this form of abuse throughout the pandemic in an effort to subject Plaintiffs to experimental drug use outside of their free will and voluntary consent, leading to life-altering emotional trauma.

508. PeaceHealth's COVID-19 policy states, "HCWs will be subject to COVID-19 vaccination recommendations published by the CDC, including but not limited to a booster dose in the future. HCWs will comply with the requirements issued by PeaceHealth as it relates to any

new COVID-19 vaccination recommendations, subject to the HCWs' right to file a qualifying medical or religious exemption.”

509. PeaceHealth willfully ignored its contractual obligations under the CDC COVID-19 Vaccination Program Provider agreement, its IRB legal obligations, its FWA agreement, and 21 U.S.C §360bbb-3 duties by mandating that which the federal government only recommended. The CDC provided many recommendations that may not come under any mandate because such requirements would violate well-established laws.

510. When PeaceHealth declared that it would subject employees “to a booster dose in the future,” it demonstrated an intentional disregard for the law because it chose to amend laws enacted by a valid act of Congress governing the administration of investigational drugs. No Constitution, statute, regulation, contract, or ordinance affording PeaceHealth authority to subject any person to an investigational drug at any time. As demonstrated in this Complaint, such actions are not only restricted, they are illegal.

511. PeaceHealth continued by stating, “HCWs that have received the vaccine but have not achieved a fully vaccinated status; are fully vaccinated but refuse to wear a vaccine badge sticker; or who are granted an exemption and a reasonable accommodation; or who are granted an exception as allowed below will be subject to the Universal Masking Policy, Physical Distancing Policy and other PeaceHealth PPE, infection control, and safety policies applicable to COVID-19, which include the requirement of routine PCR testing for COVID-19 infection.” (Emphasis added).

512. Even employees who were “fully vaccinated but refuse[d] to wear a vaccine badge sticker” would be denied their Constitutional rights of equal protection and privacy rights under Washington State’s common law. They, too, would be subjected to “the Universal Masking Policy,

Physical Distancing Policy and other PeaceHealth PPE, infection control, and safety policies applicable to COVID-19, which include the requirement of routine PCR testing for COVID-19 infection.” Such tyrannical disregard for the rule of law is outrageous in modern America.

513. According to one Plaintiff, “I had a lot of anxiety and dreaded coming to work. Nausea and pounding heart, tears at one point. Had to sit in my car and talk myself down. This was out of character for me.”

514. PeaceHealth violated the Fourteenth Amendment rights of Plaintiffs when stating they would be subjected to a “Universal Masking Policy, Physical Distancing Policy and other PeaceHealth PPE, infection control, and safety policies applicable to COVID-19, which include the requirement of routine PCR testing for COVID-19 infection” should they choose one of the two federally protected options under 21 U.S.C. 360bbb-3 because the option to refuse is as equal as the option to accept. Moreover, the COVID-19 testing articles were also under EUA status, prohibiting PeaceHealth from including them under a mandate.

515. PeaceHealth placed employees under undue influence, illegal sanctions, and moral duress when stating, “Employed HCWs who fail to comply with the requirements of this policy will be placed on unpaid leave until compliant. Failure to comply may result in corrective action up to and including termination of employment.”

516. The moral duress is evident in the fact that Plaintiffs built careers, lives, and dreams around working at PeaceHealth. CEO Liz Dunne and CPE Doug Koekkoek knew the reliance the Plaintiffs had on PeaceHealth for employment. With callous disregard for the general welfare of Plaintiffs’ lives, CEO Dunne and CPE Koekkoek demoted Plaintiffs to second-class citizen status. They deprived them of their rights to continue earning a living at PeaceHealth, all because CEO Dunne and CPE Koekkoek disagreed with Plaintiffs’ chosen option under 21 U.S.C. 360bbb-3.

CEO Dunne and CPE Koekkoek disregarded the rule of law as established by Congress, and under fiat authority, wrote their COVID-19 vaccination policy with the backing of Washington's Governor as cover, knowing that Attorney General Bob Ferguson would not enforce the laws on the books.

517. PeaceHealth engaged in additional discriminatory acts when declaring, "Non-employed HCWs who fail to comply with the requirements of this policy will be excluded from engaging in work for Health Care Settings operated, owned, leased, or controlled by PeaceHealth." The statement violates the legal conditions PeaceHealth voluntarily agreed to under 21 U.S.C. 360bbb-3, FWA, IRB, 45 CFR 46, and the CDC COVID-19 Vaccination Program Providers Agreement.

518. 21 U.S.C. §360bbb-3 required Defendants to provide Plaintiffs with information about a medical countermeasure regarding the risks, benefits, alternatives, and risks and benefits to those alternatives when they were offered participation in a medical countermeasure authorized by the Secretary. Defendants refused to inform Plaintiffs of this information in any company policy requiring EUA drug participation.

519. The law also requires Defendants to inform Plaintiffs of their right to refuse, which is a legal right. Defendants intentionally withheld this information to increase acceptance of an EUA drug, to which 15,000 other employees agreed.

520. Moreover, when an individual agrees to participate in a PREP Act activity or to use a 21 U.S.C. §360bbb-3 medical countermeasure, they agree to

- A. forfeit litigation rights in courts when sustaining an injury,
- B. assume greater risks to their health, safety, and legal rights,
- C. allow their private identifiable information to be known by unknown persons and for unknown reasons,

- D. allow the data collected about their involvement with the product or activity to be utilized by researchers for unknown purposes and for eternity.

521. Defendants intentionally refrained from informing employees of the consequence of accepting an investigational drug only authorized for emergency use under PREP Act authority.

522. Refusing to inform Plaintiffs of this information was a violation of 21 U.S.C. §360bbb-3 and done to induce participation outside of Plaintiffs' free will and voluntary consent.

523. PeaceHealth, CEO Liz Dunne, and CPE Koekkoek all knew that their actions violated every known law relating to private health information, investigational drug administration, emergency use of investigational drugs, their duties under the CDC COVID-19 Vaccination Program Provider Agreement, FWA, and their personal Institutional Review Boards.

524. Instead of continuing in the lawful application of their duties which they practiced for decades, they decided to implement a personal agenda of cashing in on the government's COVID-19 gold mine at the expense of Plaintiffs' rights as protected by the Constitution.

525. Moreover, Defendants chose to ignore the Constitution and federal law by denying the authority of Congress. They chose to establish their own mandates, conditions, and laws in defiance of contractual obligations made to the CDC, HHS, and those under the authority of those entities.

526. One Plaintiff best sums up the illicit behavior when stating, "Being pregnant and forced to wear an N95 was horrible. I already had a hard time breathing because of the baby, and then add an N95 to it, and it wasn't bearable. I would go hide in the break room or med room to take my mask off and breathe. I became anemic and had iron infusions towards the end, so I truly was having a hard time getting oxygenated as it was. The N95 was so restrictive. There were many times when I felt dizzy and lightheaded, tingling of extremities because of constantly inhaling my own CO2. Managers would walk by and be like make sure you mask up. Can I breathe for a

moment? Or would you rather me, a pregnant woman, pass out? I was extremely anxious because we had no idea if I would have enough PTO to get me through October to keep my insurance so I can deliver and not worry about the financial burden. By the grace of God, I had a few hours left to cover me. My anxiety was through the roof when COBRA quoted me \$1,000 to keep my insurance. When I get anxious, I don't eat, and my stomach turns on itself. That's the last thing I needed to feel prior to birth. I would have doctors belittle me in conversation about not thinking about 'my baby's safety.' Coming into work sucked the life and happiness out of me. I was anxious and bitter. You walk in, and everyone stares at you and reminds you of your deadline before you get booted. To top it off, my husband, who is a truck driver, had his car truck completely broken down. Which meant two incomes LOST. The tears I shed for weeks could fill a lake. The tears left me exhausted, with pounding headaches, and heart palpitations. And it worsened as I would get closer and closer to the day I'd be placed on leave and have zero assurance."

527. The absolute callous disregard for the rule of law and the health, safety, and welfare of the Plaintiffs is aptly demonstrated by the recollection of one plaintiff stating, "I was placed on leave August 31 2021, and my delivery date was October 20 2021. I was seen by Dr. Coleen Fox, an obstetrician employed by PH, and remained with her from the beginning and end of my pregnancy. When it was announced that all employees needed to be vaxxed, I immediately called the PH OB office, where the front desk told me, she was unable to receive any requests from patients requesting their OB sign a medical exemption due to pregnancy and lack of studies. The reason cited was that they were 'following instructions.' After being denied my request to obtain a medical exemption, at my next appointment, my OB offered the vaccine, I respectfully and firmly declined and cited concerns that there were zero studies on the vaccine and its effects on pregnancy and the baby. Dr. Fox assured me some women had taken it with no side effects, and 'these

anecdotal stories’ have been reassuring. She also reiterated that the ‘board’ made a decision for the office to deny medical exemptions as the benefits outweighed the risk for those pregnant, and it would go against the advice of medical associations. She explained she could only provide a medical exemption in cases of suspected or confirmed allergy to the ingredients.”

528. PeaceHealth has routinely administered investigational drugs under 21 U.S.C. §360bbb protocols for decades and knows that a pregnant woman cannot be under threat of penalty to participate in an investigational drug program. Moreover, if the drug involves more than minimal risk to the mother or the fetus,⁹⁰ then the mother is prohibited from participating.

529. 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.”

530. At all times pertinent, PeaceHealth knew that myocarditis and pericarditis were risks of taking the Pfizer BioNTech COVID-19 EUA investigational drug.⁹¹

531. PeaceHealth was aware that Pfizer itself published data stating that its COVID-19 EUA drug caused adverse events including but not limited to syncope, diminished immune response, lymphadenopathy, anaphylaxis, pruritus, urticaria, angioedema, vomiting, dizziness, all of which could pose serious medical trauma to the mother and death to the embryo or fetus.

532. PeaceHealth’s callous disregard for the safety and well-being of expectant mothers is unheard of by healthcare professionals. Its arrogant position that pregnant mothers who are also employees may not be granted a medical exemption from experimental drug use is illegal and medical malpractice.

⁹⁰ 45 CFR 46.204(b)

⁹¹ See Exhibit C, Fact Sheet for Recipients and Caregivers

533. Moreover, PeaceHealth knew that no expectant mothers could provide “medical documentation” to support an exemption solely based on pregnancy because no COVID-19 drug manufacturer conducted, much less concluded, studies of the product’s safety for pregnant women, with Pfizer’s non-interventional study on the effects of its BioNTech COVID-19 Vaccine Exposure during pregnancy not being complete until June 30, 2025.⁹²

534. PeaceHealth used its positions of power to compel the participation of pregnant women in the use of potentially dangerous investigational drugs and medical products with willful, wanton, and shocking disregard for their safety, health, and rights.

535. PeaceHealth and its policymaker, Liz Dunne’s moral turpitude⁹³ are evidenced by willful acts of disregarding federal and state laws, fraudulent misrepresentations of facts, publishing lies, and intentionally misleading employees about the legal distinctions between a licensed vaccine and a drug undergoing clinical investigation having no legal indication to treat, cure, or prevent any known disease.

536. At no time before, during, or after PeaceHealth’s immunization policy was issued did any defendant attempt to educate Plaintiffs of their rights to refuse the administration of an investigational new drug without incurring a penalty or losing a benefit to which they were otherwise entitled. The lack of such communication is an act of intentional fraud.

537. The continual unlawful promotion that the products were safe and effective and that it was the “duty” of healthcare workers to be injected with those products implied that the Plaintiffs did not care about the welfare of patients or their community. PeaceHealth affirmed this position when it informed Washington State Employment Security Department that Plaintiffs engaged in

⁹² GmbH B. Our STN: BL 125742/0 BLA APPROVAL.; 2021. <https://www.fda.gov/media/151710/download>

⁹³ “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.

misconduct (i.e., exercising a federal right to refuse the EUA product) and, thus, must not be allowed to receive unemployment benefits.

538. Not only did PeaceHealth's actions result in lost economic benefits, but the actions resulted in defamation of character of Plaintiffs who worked for decades without a blemish on their employment records, the same Plaintiffs who continually were called upon to give up their weekends, holidays, and other pleasures of life to sweat, toll, and labor for the express purpose of providing life-saving medical care to the community. The assault on Plaintiffs' character was designed to place fear into other employees and in the hopes of causing Plaintiffs to surrender their rights conferred upon them by Congress.

539. It shocks the conscience to think that in modern-day America, Liz Dunne, Chief Executive Officer of the State's largest hospital network, employing more than 16,000 healthcare heroes, would lie to the State about the conduct of her employees all to avoid paying higher unemployment insurance when it was her actions acting under color of law that led to the State having a higher financial burden resulting from needless loss of wages by Plaintiffs.

540. Liz Dunne willfully and intentionally deprived employees of their rights and then lied to the State about her misconduct in an effort to soften the financial blow to PeaceHealth's bottom line. Such actions are outrageous.

541. The abusive action shocks the conscience when one realizes that Plaintiffs have spent hundreds of combined years laboring in love to wipe the tears of pain from injured patients, reassuring little ones, and comforting those who lost the love of their lives only moments ago.

542. Plaintiffs were targeted for abuse by PeaceHealth to set them as an example for the express purpose of placing fear into the hearts of other PeaceHealth employees resulting in them surrendering their Constitutional protections and statutory rights.

543. The actions of Governor Inslee, PeaceHealth, CEO Liz Dunne, and CPE Doug Koekkoek were atrocious, intolerable, and so extreme and outrageous as to exceed the bounds of decency.

XXIII. Recap of the Essentials

544. Due to the volume of information in this Complaint resulting from its novelty and substantial impact on the nation, it is prudent to recapitulate the essential points of the Complaint into one section.

545. To protect the safety and health of the public, Congress mandates that “no person shall introduce or deliver for introduction into interstate commerce any new drug unless an approval of an application” by the FDA is issued. (21 U.S.C. §355(a))

546. However, congress recognized the potential benefits of providing access to unlicensed drugs, biologics, and devices to persons under emergency conditions and enacted legislation to provide “expanded access to unapproved therapies and diagnostics.”⁹⁴ (21 U.S.C. § 360bbb *et seq.*)

547. In 2005, Congress passed Project Bioshield to provide emergency broad access (large population) to unlicensed uses of drugs, biologics, and devices during a declared emergency. Congress declared

- A. that only the Secretary “may authorize the introduction into interstate commerce, during the effective period of a declaration...,

⁹⁴ “The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.” 21 U.S.C. § 360bbb(a)

a drug, device, or biological product intended for use in an actual or potential emergency.

- B. that the Secretary “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...”
- C. the Secretary has no “authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section...”

548. In 2005 Congress passed the PREP Act⁹⁵ which provided the following regarding preemption of state law:

- (8) 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.].

549. Therefore, via the PREP Act and 21 U.S.C. §360bbb-3, Congress expressly prohibits Defendants from:

- A. interfering with the authority of the Secretary,
- B. establishing a condition not authorized by the Secretary,
- C. establish conditions contrary to the Secretary and the congressional statute under 21 U.S.C. §360bbb-3,
- D. mandate participation in any 21 U.S.C. §360bbb-3 product or PREP Act activity,
- E. interfere with an individual considering participation in a 21 U.S.C. §360bbb-3 product or PREP Act activity,

⁹⁵ 42 USC 247d-6d and 42 USC 247d-6e

- F. penalize a person refusing to participate in a PREP Act product or activity or 21 U.S.C. §360bbb-3 product.

550. The executive branch of the United States Government purchased all COVID-19 licensed and EUA drugs using federal funds. Congress expressly prohibits the federal government and any person acting on behalf of the federal government from applying outside pressures on individuals to participate in 21 U.S.C. §360bbb-3 products.

551. Therefore, Defendants not only lacked statutory authority to alter the employment of Plaintiffs choosing one of the two federally funded COVID-19 options to accept or refuse, but the government prohibited them from interfering with that choice. That prohibition is under the PREP Act, 21 U.S.C. §360bbb-3, and the CDC COVID-19 Vaccination Program Provider Agreement.

552. Congress expressly provided the individual with two equal choices; accept or refuse.

553. The 14th Amendment guarantees that all persons shall enjoy the equal protection of the laws. Defendants violated the equal protection of Plaintiffs when only penalizing persons exercising the option to refuse. The 14th Amendment guarantees the right to due process of law before infringing a citizen's interest in life, liberty, or property. The defendants' unwillingness to respect the authority of Congress by recognizing the statutory right of Plaintiffs to refuse 21 U.S.C. §360bbb-3 products and PREP Act activities without consequence nullifies the substantive and procedural due process rights of Plaintiffs.

554. Defendants committed arrestable offenses under 18 U.S.C. § 241&245 by interfering with Plaintiffs' Constitutional and statutory rights and Plaintiffs' involvement with a federally funded program.

555. Defendants' actions demonstrate a willful and wanton disregard for the rights of the Plaintiffs, Congress, the Constitution, and their assurances under the CDC COVID-19 Vaccination Program Provider and FWA agreements not to subject Plaintiffs to medical experimentation outside of their free will and voluntary consent.

XXIV. Legal Claims

556. The facts described above constitute violations of several of the rights guaranteed to Plaintiffs by the United States Constitution, federal statutes, and treaties. These violations 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 administering the CDC COVID-19 Vaccination Program Provider Agreement

COUNT ONE

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

557. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

558. The CDC COVID 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.

559. 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."

560. The Belmont Report 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.”

561. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) 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.”

562. 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.”

563. The Defendants’ actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, unlawfully subjected Plaintiffs to the use of investigational medical products under threat of penalty outside of their free will and voluntary consent as described in the above facts, thereby causing them damages described in Paragraphs 621 through 626, *infra*.

COUNT TWO

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

564. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

565. The CDC COVID 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.

566. The courts have long held that an individual “may not barter away his life or his freedom, or his substantial rights.” *Insurance Company v. Morse*, 87 U.S. 445 (1874)

567. “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)”. *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593-94 (1926)

568. 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 621 through 626, *infra*.

COUNT THREE

Equal Protection - 42 U.S.C. § 1983

569. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

570. The CDC COVID 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.

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

572. 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 621 through 626, *infra*.

COUNT FOUR

Due Process - 42 U.S.C. § 1983

573. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

574. The CDC COVID 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.

575. 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.

576. 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 621 through 626, *infra*.

COUNT FIVE

Deprivation of Rights Under Color of Law - 42 U.S.C. § 1983

Spending Clause Doctrine

577. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

578. The CDC COVID Vaccination Program Provider Agreement, 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.

579. 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."

580. 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..."

581. The United States Government fully funds the CDC COVID-19 Vaccination Program's research activities involving human subjects. Additionally, the United States Government fully funds the required research activities assigned by the HHS Secretary for Pfizer-BioNTech COVID-19 Vaccine, Moderna, Janssen, and Novavax. Those specific research

protocols are outlined in the Secretary's Scope of Authorization contained in the Emergency Use Authorization for each COVID-19 drug.

582. The Defendants' actions described above, individually and/or collectively, and in derogation of 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 621 through 626, *infra*.

COUNT SIX

Breach of Contract, Third Party Beneficiary

583. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

584. 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.

585. The Defendants' actions described above, individually and/or collectively, and in derogation of the CDC COVID-19 Vaccination Program Provider Agreement, violated the intended benefits conferred upon the Plaintiffs 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 621 through 626, *infra*.

COUNT SEVEN

Washington State Common Law Employment Torts

586. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

587. The Supremacy Clause, PREP Act, and 21 U.S.C. §360bbb-3 preempt State laws conflicting with the United States Government's emergency medical countermeasure objectives, including Washington State's at-will employment laws.

588. Defendants lacked authority to condition employment upon Plaintiffs participating in a 21 U.S.C. §360bbb-3 medical countermeasure or any product or activity under PREP Act authority.

589. Defendants intentionally and unlawfully misrepresented their authority to Plaintiffs to cause them to surrender their constitutional and statutory rights.

590. Defendants engaged in acts of coercion, undue influence, and retaliation, creating a hostile work environment.

591. Defendants placed Plaintiffs under moral duress⁹⁶ knowing they exclusively relied on Defendants for access to living wages.

592. Defendants segregated Plaintiffs under discriminatory acts upon Plaintiffs exercising their absolute right to refuse investigational new drugs.

593. Defendants unlawfully altered Plaintiffs' employment schedules under coercive acts to punish them for exercising their absolute right to refuse investigational new drugs.

594. Defendants attempted to coerce Plaintiffs to engage in a legally binding agreement under the terms and conditions (21 U.S.C. §360bbb-3 and PREP Act) established by the United States Congress outside their free will and voluntary consent.

595. Defendants' actions demonstrate moral turpitude against Plaintiffs' rights, safety, and health.

⁹⁶ 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.

596. Defendants willfully and intentionally placed Plaintiffs under historic public and private pressure to enter into a legally binding agreement outside of their free will and voluntary consent.

597. Defendants unlawfully terminated Plaintiffs' employment when Plaintiffs exercised a legal right or privilege.⁹⁷

598. Defendants have, willfully and with the intent to deprive, failed to pay wages to Plaintiffs since the date Defendants unlawfully placed Plaintiffs on administrative leave.

599. The plaintiffs did not knowingly submit to the deprivation of labor, wages, or employment.

600. In addition to other damages listed below, Plaintiffs are entitled to double damages, costs of suit, and reasonable attorney's fees pursuant to Washington Rev. Code § 49.520.070

601. PeaceHealth engaged in retaliatory acts when reporting to Washington State Security Department that some of the Plaintiffs engaged in misconduct when exercising a legal right.⁹⁸

602. The Defendants' actions, individually and/or collectively, and in derogation of Washington State's common laws, violated the intended benefits conferred upon the Plaintiffs when enjoying employment in the State of Washington as described in the above facts, thereby causing them damages described in Paragraphs 621 through 626, *infra*.

⁹⁷ *Becker v. Community Health Systems*, 184 Wn.2d 252, 359 P.3d 746 (2015); *Rose v. Anderson Hay & Grain Co.*, 184 Wn.2d 268, 358 P.3d 1159 (2015), and *Rickman v. Premera Blue Cross*, 184 Wn.2d 300, 358 P.3d 1153 (2015)

⁹⁸ *Id.*

COUNT EIGHT

Outrage

603. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

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

605. Outrage⁹⁹ is proven by (1) demonstrating that Defendants engaged in extreme and outrageous conduct, (2) Defendants' actions caused severe emotional distress, (3) Defendants intentionally or recklessly caused the emotional distress, (4) that Plaintiffs are the direct recipients of the conduct.¹⁰⁰

606. The facts and the Defendants' conduct committed with gross negligence, reckless, or intent, as described above in the complaint, give rise to a claim of Outrage under the common law of the State of Washington against the Defendants for the damages described in Paragraphs 621 through 626, *infra*.

⁹⁹ "Outrage" and "intentional infliction of emotional distress" are synonyms for the same tort. See *Snyder v. Med. Serv. Corp.*, 145 Wn.2d 233, 250, 35 P.3d 1158 (2001); *Kloepfel v. Bokor*, 149 Wn. 2d 192, 194 n.1 (Wash. 2003)

¹⁰⁰ *Kloepfel v. Bokor*, 149 Wn.2d 192, 195, 66 P.3d 630 (2003); *Robel v. Roundup Corp.*, 148 Wn.2d 35, 64, 59 P.3d 611 (2002); *Reid v. Pierce County*, 136 Wn.2d 195, 202, 961 P.2d 333 (1998) (citing *Dicomes v. State*, 113 Wn.2d 612, 630, 782 P.2d 1002 (1989)); *Kirby v. City of Tacoma*, 124 Wn.App. 454, 473, 98 P.3d 827 (2004).

COUNT NINE

Invasion of Privacy and Defamation of Character

607. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

608. In *Reid v. Pierce County*, 136 Wn. 2d 195, 136 Wash. 2d 195, 961 P.2d 333 (Wash. 1998), the court held:

- (1) The RESTATEMENT (SECOND) OF TORTS § 652D (1977) provides the general rule for invasion of privacy. It states:

RESTATEMENT (SECOND) OF TORTS § 652H (1977) provides for damages available to one who establishes a cause of action for invasion of privacy: “One who has established a cause of action for invasion of his privacy is entitled to recover damages for (a) the harm to his interest in privacy resulting from the invasion; (b) his mental distress proved to have been suffered if it is of a kind that normally results from such an invasion; and (c) special damage of which the invasion is a legal cause.”

- (2) “In *Hearst Corp. v. Hoppe*, 90 Wn.2d 123, 580 P.2d 246 (1978), we indicated that a tort action for invasion of the right of privacy exists in Washington.”
- (3) “the tort right is the most widely recognized and established definition of the legal right of privacy”
- (4) “So that no further confusion exists, we explicitly hold the common law right of privacy exists in this state and that individuals may bring a cause of action for invasion of that right.”

609. PeaceHealth established an identification system (badges) denoting employees’ private health information (use of investigational drugs) and forced employees to wear or not to wear the badge under threat of penalty.

610. PeaceHealth painted in a false light employees who were not wearing a badge.

611. PeaceHealth staff informed the public that the badge, or absence of one, disclosed the private health information about each staff member, including Plaintiffs.

612. The public disclosure of the private health information painted Plaintiffs in a false light leading to malicious harassment by staff and patients.

613. PeaceHealth implied that a person wearing a badge was immunized from the COVID-19 virus and thus unable to transmit it to other persons, which was, and still is, unlawful to convey to the public as well as being factually incorrect.

614. PeaceHealth defamed the character of Plaintiffs when fraudulently informing Washington State Employment Security Department that Plaintiffs engaged in misconduct and, therefore, should be denied unemployment benefits leading to economic damages.

615. PeaceHealth openly disclosed and publicly displayed private health information, employment records, and other private information about Plaintiffs throughout its facilities with malicious intent to punish Plaintiffs for exercising a right secured for them by a valid act of Congress.

616. Defendants intentionally violated the privacy rights of Plaintiffs to inflict severe emotional stress, publicly humiliate them under a false light, and rob them of their peace and feelings of being treated equally before the law for the express purpose of causing them to surrender their constitutional and statutory rights to refuse investigational drugs without consequence.

617. The facts and the Defendants' conduct committed with gross negligence, reckless, or intent, described above give rise to a claim of Invasion of Privacy under the common law of the State of Washington against the Defendants for the damages described in Paragraphs 621 through 626, *infra*.

COUNT TEN

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

618. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 30 and 36 through 556, as if fully set forth herein.

619. Should the court not agree that PeaceHealth 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).

620. 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 621 through 626, *infra*.

X. Damages Recoverable and Demanded

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

622. 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.

623. 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)

624. 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)

625. 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)

626. 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.

627. 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.

XI. Jury Trial Demand

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

WHEREFORE, Plaintiffs pray that Defendants be served with a copy of this Complaint and be 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.

Respectfully submitted,

SCHEXNAYDRE LAW FIRM

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