Exhibit 623

Kaycee Timken, Christine Harms v. South Denver Cardiology Associates

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

https://covidpenalty.com/wp-content/uploads/2023/11/Doc-1-Complaint.pdf

UNITED STATES DISTRICT COURT

DISTRICT OF COLORADO

KAYCEE TIMKEN and , *et al,* CHRISTINE HARMS *Plaintiffs*,	*	
VERSUS	*	CIVIL ACTION
SOUTH DENVER CARDIOLOGY ASSOCIATES, P.C., TROY STOCKMAN AND JILL HUNSAKER RYAN *Defendants*,	*	

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

COMPLAINT
(JURY TRIAL REQUESTED)

NOW INTO COURT, through undersigned counsel, come Plaintiffs, Kaycee Timken and Christine Harms (hereinafter "Plaintiffs"), who file this Complaint against Defendants, South Denver Cardiology Associates, P.C., its CEO Troy Stockman, and Jill Hunsaker Ryan, the Executive Director of the Colorado Department of Public Health & Environment (hereinafter "Defendants"), presenting allegations and causes of action as follows:

DESCRIPTION OF CAUSE OF ACTION

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

This lawsuit is being brought under 42 U.S.C. §1983 seeking redress for deprivation of rights granted to Plaintiffs by the United States Constitution, 21 U.S.C. §360bbb-3 *et seq* (the EUA statute), 42 USC §247d-6d *et seq* (the PREP Act), 45 CFR Part 46, 18 U.S.C. §242, ICCPR Treaty, and the common laws of the State of Colorado to hold accountable South Denver Cardiology Associates, P.C., and its CEO Troy Stockman, State Actors at all times pertinent herein

(collectively referred to herein as "SDCA"), and Jill Hunsaker Ryan, the Executive Director of the Colorado Department of Public Health & Environment, in her individual and official capacities, for damages arising out of their unconstitutional, unlawful, malicious, unequal and contractually violative COVID-19 investigational drug mandate. Special laws apply to Defendants' vaccine mandates because the FDA defines the drugs at issue as "investigational with no license for any indication." And even though Defendants' mandates were instituted during and in response to a pandemic emergency, as the U.S. Supreme Court noted since the beginning of the pandemic: "**even in a pandemic, the Constitution cannot be put away and forgotten**." *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct. 63, 208 L.Ed.2d 206 (2020).

TABLE OF CONTENTS

I. Introduction

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

2. On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency. The President declared a national emergency on March 13, 2020, of which led to the development of investigational new drugs designed to perform as a vaccine from

the virus, i.e., cause the body to produce antibodies to the virus so that the person is immune from infection when exposed to the true virus.

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

4. The FDA made clear on its website:

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

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

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

6. In August 2021, Troy Stockman, CEO of South Denver Cardiology Associates, P.C. ("SDCA"), usurped the authority of the United States Congress by issuing an official proclamation in defiance of federal law when he subjected Plaintiffs to inject unlicensed investigational drugs into their bodies as a condition to continue employment under his authority.

II. Jurisdiction and Venue

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

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

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

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

11. This court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. 1367.

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

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

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

III. Plaintiffs

15. The following individuals are plaintiffs herein:

16.1. Plaintiff, Kaycee Timken, is an adult individual who all times pertinent resided in the State of Colorado, and was previously an employee of SDC in Colorado.

16.2. Plaintiff, Christine Harms, is an adult individual who all times pertinent resided in the State of Colorado, and was previously an employee of SDC in Colorado.

IV. Defendants

17. The following are named as defendants herein:

17.1. Defendant, South Denver Cardiology Associates, P.C., is a professional corporation formed under the laws of the State of Colorado and domiciled in the State of Colorado.

17.2 Troy Stockman, the CEO of SDCA at all times pertinent, and an individual of the full age of majority and a domiciliary of the State of Colorado.

17.3 Defendant, Jill Hunsaker Ryan, is an individual of the full age of majority and a domiciliary of the State of Colorado who was at all times pertinent the Executive Director of the Colorado Department of Public Health & Environment (CDPHE). Ms. Ryan is named as a defendant in her individual and official capacities.

V. History and Facts

18. Plaintiffs make no assertions regarding whether it is lawful for a public or private entity to mandate a ***licensed*** vaccine. Plaintiffs' allegations herein only relate to Defendants' mandating the use of drugs, biologics, and devices under 21 U.S.C. §360bbb-3 (the EUA statute) and the PREP Act.

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

20. 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, EUA products fall under the investigational or experimental classification by statute.[1]

21. This classification was illustrated in the December 11, 2020, Scope of Authorization letter issued to Pfizer, Inc. wherein the FDA advised Pfizer that its product is "an investigational vaccine not licensed for any indication."[2] The same is true for the Moderna and Jannsen injections.

22. The laws regulating the investigational new drug (IND) industry were largely created after Senator Edward Kennedy held live hearings in 1973 detailing the industry's abuses against the American people.

23. In 1974, Congress enacted the National Research Act[3] in response to those hearings, establishing laws, regulations, and mandatory guidelines to protect Americans from future abuses.

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

25. 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

---

[1] 21 U.S.C. §360bbb-3(a)(2)(A) and (B)
[2] See Exhibit A, FDA EUA Scope of Authorization Letter to Pfizer, December 11, 2020
[3] Public Law 93-348-July 12, 1974 National Research Act
[4] Title II of the National Research Act - https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf

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."

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

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

A. The Belmont Report

28. 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);

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).

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

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

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

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.

30. 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.

31. 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."

32. Congress required the HHS Secretary to act upon the Commission's recommendations as outlined in the Belmont Report by establishing regulations to protect humans involved in biomedical research activities. **Therefore, given the complexity, the intent of Congress was not to draft those laws but to allow the HHS Secretary to promulgate regulations on its behalf** to protect humans involved with investigational drugs. Therefore, these

regulations are unique in that they were expressly requested by Congress to fulfill the intent of Congress via the National Research Act.

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

B. 45 CFR Part 46

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

35. HHS designed a very broad definition of research when, at 45 CFR § 46.102 (Definitions): "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes" [10]

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

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

[9] 45 CFR 46.101(a)

[10] 45 CFR 46.102(l)

(emphasis added). Research under this policy includes medical chart reviews by students or periodic studies of medical products under 21 U.S.C. §360bb-3 authorization.[11]

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

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

> (1) ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research:
>
> > (i) Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or
> >
> > (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
>
> (2) ***Intervention*** includes physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
>
> (3) ***Interaction*** includes communication or interpersonal contact between investigator and subject.
>
> (4) ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
>
> (5) ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the information.

---

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

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

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

[14] " Coded Private Information or Biospecimens Used in Research (2018)." HHS.gov. Published January 19, 2018. https://www.hhs.gov/ohrp/coded-private-information-or-biospecimens-used-research.html#:~:text=Identifiable%20private%20information%20is%20private,is%20associated%20with%20the%20information (Last accessed June 5, 2023)

> (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.)

38. 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"[15] (emphasis added).

39. Therefore, if individuals are administered an investigational medical product and their private identifiable information is collected along with the details about 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," requiring 45 CFR Part 46 compliance when the federal government is involved.

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

---

[15] 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."

[16] 45 CFR § 46.101(c)

[17] 45 CFR § 46.101(i)

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

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

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

44. 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."[18] (45 CFR §46.122)

45. 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."

46. Therefore, pursuant to 45 CFR §46.101, *et seq*., "research" occurs when an individual is administered an investigational drug, the individual's private identifiable information

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

is known, and data collected regarding their interaction with the drug is added to the generalizable knowledge about the drug.

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

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

C. Legally Effective Informed Consent

49. 45 CFR § 46.116 sets forth the Belmont Report's "adequate standards" of informed consent[19], and they include, but are not limited to:

> (a)(1) Before involving a human subject in research covered by this policy, an investigator 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

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

prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research;

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

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

(a)(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled" (Emphasis added).

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

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

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

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

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

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

53. 45 CFR Part 46 applies to all federal agencies, departments, and the military (45 CFR § 46.101(a)). Additionally, twenty federal agencies incorporated 45 CFR Part 46 specifically into their regulatory framework.[20]

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

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

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

57. When Defendants penalized Plaintiffs for refusing to inject a federally funded EUA investigational drug into their bodies, Defendants breached their fiduciary and statutory duties to obtain Plaintiffs' legally effective informed consent. (See, *infra*)

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

D. COVID-19 Research Activities

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

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

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

61. The only COVID-19 drugs made available to Plaintiffs are classified by the FDA as investigational 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.

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

---

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

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

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

63. 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))

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

65. 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*)

66. 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.

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

68. 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).

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

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

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

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

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

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

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

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

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

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

75. 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)."

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

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

78. Under the EUA's "Conditions of Authorization," the Secretary mandates in part:[30]

* * *

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

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome in children and adults; and

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

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

[30] See Exhibit A, FDA EUA Scope of Authorization Letter to Pfizer, December 11, 2020

- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer, Inc.

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

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

* * *

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

* * *

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

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

79. 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.

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

81. 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.

82. 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.

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

84. 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.[31] The use of this information by ACIP demonstrates how the data collected "contributes to generalizable knowledge."

85. The ACIP recommendations[32] referenced in Footnote 1 of the CDC Provider Agreement[33] 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.

[31] 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.

[32] *Id.*, at 1347.

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

G. Inform vaccine recipients about V-Safe, the CDC's vaccine safety monitoring system that the CDC says "helps us monitor the safety of COVID-19 vaccines for everyone."[34]

86. The CDC Provider Agreement further instructs Defendants:

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

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

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

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

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

87. 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."

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

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

E. ICCPR Treaty

89. In 1992, the United States Senate ratified the International Covenant on Civil and Political Rights Treaty (ICCPR).[35] 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)

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

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

92. 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."[36]

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

---

[35] 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

[36] 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

94. 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."

95. 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.[37]

96. 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.

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

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

article 6 (right to life), article 7 (prohibition of torture or cruel, inhuman or degrading punishment, or of medical or scientific experimentation without consent.)"[38] (Emphasis added.)

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

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

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

100. 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.

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

[38]" 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)

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

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

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

105. 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.[39]

[39] 21 U.S.C. 360bbb-3(e)(1)(A)

106. 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.[40]

107. 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 before participating in the product or activity.

108. 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.

109. There are two legal rights conferred upon individuals considering whether to participate in the use of an EUA product, which are (1) the right to **accept** an EUA product, and (2) the right to **refuse** to an EUA product.

110. 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.

111. There are three specific persons upon whom Congress confers a right under the EUA statute, which are:

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

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

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

C. the individual who is authorized to accept or refuse EUA products.

112. 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))

113. 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."

114. These "appropriate conditions" and the "circumstances" are outlined in the EUA letter issued to the manufacturer of the emergency medical countermeasure under the "Scope of Authorization."[41]

115. 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

[41] See Exhibit A, FDA EUA Scope of Authorization Letter to Pfizer, December 11, 2020

duties for the manufacturer and rights of all persons involved in the administrative process of the product.

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

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

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

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

120. The Secretary may not delegate his authority, so by extension, any person participating in an EUA activity is also restricted by Congress from requiring any other person to

participate in "any activity that becomes lawful pursuant to an authorization under" 21 U.S.C. §360bbb-3.

121. **Congress, therefore, prohibits governments (e.g., governors, mayors, school boards) and voluntary participants (e.g., hospitals, manufacturers, doctors, private employers) from having the authority to require any person to participate in any EUA activity at any time, under any statute, regulation, or state policy or custom.**

122. The explicit purpose of this statutory restriction is to ensure that no person is under a "sanction," "coercion," "undue influence," or "unjustifiable pressure"[42] to participate. If individuals are under those pressures, then no federal funds could be expended for the administration of a COVID-19 EUA product, nor could any healthcare provider acting on behalf of the federal government obtain an individual's Legally Effective Informed Consent.

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

124. 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.

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

125. Therefore, if the HHS Secretary is the only person authorized to establish the conditions under which persons can access EUA countermeasures and not even he can mandate participation, **then Defendants had no authority to amend the Scope of Authorization and require that which Congress prohibits**.

126. Therefore, when Defendants established a policy requiring individuals under their authority to become vaccinated against the COVID-19 virus, they were required by federal law to ensure that (1) licensed products existed to meet the legal requirements of the mandate, and (2) Plaintiffs were to be informed that they were under no obligation to inject an unlicensed COVID-19 EUA investigational drug into their body, nor would they incur a penalty or lose a benefit when refusing to do so. Defendants did neither.

G. HHS EUA Precedent

127. On January 28, 2005, HHS issued the first EUA[43] under its new authority provided by 21 USC 360bbb-3 (the EUA statute). The military requested EUA protocols for Anthrax Vaccine Adsorbed (AVA), to be utilized by civilians and service members. HHS stated, "The issuance of this Authorization for the emergency use of AVA is the first time that the EUA authority is being used. FDA intends to explain clearly the reasons for each issuance, termination, or revocation of an EUA. The agency wishes to make its decision-making understandable to help ensure that members of the public, and particularly those individuals who may be eligible to receive a medical product authorized for emergency use, are informed about the basis of an EUA determination."

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

128. 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.[44]

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

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

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

H. Judicial EUA Precedent

131. 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.)

132. 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.

133. 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).

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

I. Federal Wide Assurance (FWA)

135. 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.

136. 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…"[45]

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

137. 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.

138. 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).

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

140. 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.

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

142. 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.

143. The FWA agreement requires Defendants to assure potential participants that they will not incur a penalty or lose a benefit to which they are otherwise entitled when refusing participation.[46]

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

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

A. activated the terms and conditions of the contract,

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

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

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

J. Preemption of State Law – PREP Act and EUA Statute

147. 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

[46]" 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.

immunities for persons volunteering for "covered" activities. In accordance therewith, the HHS Secretary issued a COVID-19 PREP Act declaration in February 2020.[47]

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

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

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

> (8) Preemption of State law
>
> > During the effective period of a declaration under subsection (b)…no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
> >
> > (A) is different from, or is in conflict with, any requirement applicable under this section; and
> >
> > (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.].

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

> (c) Voluntary program
>
> > The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 247d–6d of this title…and that potential participants are educated with respect to contraindications, the

[47] 85 FR 15198

> voluntary nature of the program, and the availability of potential benefits and compensation under this part. [Emphasis added.]

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

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

154. Congress informed the State that if it planned to "administer or use a covered countermeasure," then it may not "establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that…is different from, or is in conflict with…**any matter included in a requirement** applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act."

155. One such **matter included in a requirement applicable to the covered countermeasure** is contained in 21 U.S.C. §360bbb-3 (the EUA statute) whereby Congress, in unambiguous rights-conferring language, conferred upon the individual considering participation in a "covered countermeasure" may choose to "accept" or "refuse" participation.[48]

156. Therefore, by the express language of the PREP Act, and its incorporation of the option to choose contained in the EUA statute, and also based on the Supremacy Clause in the U.S. Constitution, any State laws, ordinances, regulations, or customs that are "different" from or in

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

"conflict" with an individual's authority to freely choose to accept or refuse participation in the medical countermeasure are preempted.

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

158. Similarly, the State and private employers in that State are prohibited from enforcing any at-will employment doctrine when employees refuse participation in a "covered countermeasure" because using the threat of penalty of loss of employment benefits, or even employment itself, "conflict[s]" with the employee's federally secured right to accept or refuse participation in the covered countermeasure (e.g., drugs, biologics, masks, testing articles, etc.) without consequence.[49]

159. The purpose of informing the individual of "the significant known…risks of such use, and of the extent to which such benefits and risks"[50] and of "the alternatives to the product that is available and of their benefits and risks"[51] is because the individual is not only consenting to be *irreparably* injected with an investigational drug but to also participate in a legally binding agreement under the terms and conditions established by Congress.

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

A. forfeiture of civil litigation rights resulting from injuries;[52]

B. allowing their private identifiable information to be collected and used for a variety of purposes by unknown persons;[53]

[49] *Id.*
[50] (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(II))
[51] (21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III))
[52] PREP Act forfeits all civil actions for damages in most situations.
[53] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Agreement requires manufacturers and/or emergency stakeholders to obtain private identifiable information.

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

D. allowing the data collected about their adverse events to be utilized by researchers for unknown purposes and eternity,[54]

E. assuming greater risks to their safety, health, and legal rights.[55]

161. The FDA issued an opinion[56] regarding federal preemption of the State's authority to interfere with 21 U.S.C. §360bbb-3 (aka section 564):

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

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

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

[56] "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

> 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)

162. The Supreme Court has long held that "the test of applicability of state laws [conflicting with the Supremacy Clause] is whether the matter on which the State asserts the right to act is in any way regulated by the Federal Act."[57]

163. 21 U.S.C. §360bbb-3 and the PREP Act can only be executed by the United States HHS Secretary under the prescribed conditions established by Congress.

164. The State and subordinate private parties may only participate in "covered countermeasures" and the use of 21 U.S.C. §360bbb-3 medical products by volunteering to adhere to the conditions established by the HHS Secretary under the respective statutes, which includes the federal statutory requirement to obtain Plaintiffs' legally effective informed consent when considering participation in programs authorized by the above statutes.

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

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

Congress to determine the conditions under which access to unlicensed drugs, biologics, and devices can occur.

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

167. This irrefutable fact is why Congress preempts the State and Defendants (as State Actors) from having any authority to interfere with the right of Plaintiffs to either accept or refuse participation in "medical countermeasures" under the EUA statute and "covered countermeasures" under the PREP Act.

168. In the case at bar, Defendants' use of the state at-will employment doctrine to terminate Plaintiffs' employment as a penalty for refusing administration of an EUA investigational drug conflicts with the federal law's goal of ensuring that only truly willing participants are involved in the use of "covered countermeasures" and EUA products, and as a result of that conflict, the State's at-will employment doctrine is preempted for purposes of the administration of those countermeasures. It is thereby inapplicable as a defense to Defendants' unlawful actions described herein by Plaintiffs.

VI. Statement Of Facts

169. Plaintiffs make no assertions regarding whether it is lawful for a public or private entity to mandate taking a ***licensed*** vaccine. Plaintiffs' allegation herein only relates to Defendants'

mandating the use of drugs, biologics, and devices authorized under the EUA statute and the PREP Act.

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

171. Plaintiffs assert that they have the Constitutional and federal statutory right to refuse the administration of an EUA product and refuse participation in any activity or product covered by the PREP Act.

172. Plaintiffs assert that Defendants are prohibited by Congress from establishing conditions requiring Plaintiffs to surrender their statutory rights and Constitutional protections as a condition to participate in privileges and benefits offered under federal and Colorado State laws, regulations, ordinances, customs, and employment.

173. Plaintiffs assert that Defendants are restricted by Congress from using the state's at-will employment doctrine as the means to terminate Plaintiffs' employment for no other reason than their exercising one of the two legally protected options under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).[58]

174. Plaintiffs were employed as healthcare workers licensed by the State of Colorado, working in healthcare facilities also licensed by the State, which has the authority to deny

[58] 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) (the EUA statute) contains a required condition of the Secretary "to ensure that individuals to whom the product is administered are informed — 'of the option to accept or refuse administration of the product.'"

healthcare facilities and workers the right to conduct commerce by revoking their respective State licenses.

175. Colorado Department of Health and Environment (CDPHE) has lawful authority over the licensed activities of Colorado healthcare facilities and workers.

176. Jill Hunsaker Ryan is the director of CDPHE.

177. South Denver Cardiology Associates, PC is a Colorado corporation doing business at 1000 Southpark Dr., Littleton, Colorado 80120.

178. Troy Stockman is SDCA's CEO and Policymaker.

179. At all times pertinent, Plaintiffs were employed by Defendants.

180. Although Defendants, at other times and in other circumstances, are private parties, they acted under color of law when, as collaborators with the State of Colorado pursuant to Colorado Department of Public Health and Environment (CDPHE) Part 12 rules (see, *infra*), penalized Plaintiffs for refusing to inject one of the mandated unlicensed investigational drugs into their bodies.

181. The Supreme Court and Tenth Circuit Court of Appeals utilize several tests to ascertain when a private party is engaged in state action. Defendants are state actors under the (1) State Compulsion Test,[59] (2) Symbiotic Relationship Test,[60] and (3) Customs Test.[61]

182. Defendants unlawfully required Plaintiffs to inject unlicensed drugs into their bodies as a condition to continue enjoying liberties (e.g., freedom from wearing experimental masks and participating in unwanted experimental medical testing articles) and benefits to which they were otherwise entitled.

183. FWA00010401 is SDCA's agreement number from HHS indicating their assurance to the federal government that they would abide by 45 CFR § 46 and the Belmont Report ANYTIME they involve an individual in a federally funded research program such as the CDC COVID-19 Vaccination Program. The agreement meant that SDCA promised HHS they would never place an individual under a "sanction," "coercion," "undue influence," or "unjustifiable pressure" to participate in federally funded research activities.

---

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

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

[61] 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). Jill Hunsaker Ryan and SDCA developed a state custom whereby a person's 21 U.S.C. §360bbb-3 statutory rights can be ignored "as if" they do not exist.

184. Defendants are legally sophisticated in the laws and regulations pertaining to the administration of investigational new drugs. On its website, SDCA states, "South Denver Cardiology Associates has been participating in clinical research for more than 10 years. We participate in studies that explore new medications and treatments for the patient having a heart attack, so as to limit the size and extent of the damage to the heart muscle. We explore with other centers worldwide, different methods of using medications for other reasons than those originally approved by the Food and Drug Administration (FDA), and we have worked to compare different treatment regimes in the fight against the debilitating and chronic disease of congestive heart failure."[62]

185. The laws governing SDCA's clinical trials are the same laws governing 21 U.S.C. §360bbb-3 authorized investigational new drugs ("INDs").

186. INDs must come under the purview of an Institutional Review Board, having its authority under 45 CFR Part 46, whether the IND is used under FDA marketing trials, educational research, or emergency use authorizations under 21 USC § 360bbb *et. seq.*

187. Irrespective of the expanded access protocol granted, there does not exist lawful authority to mandate participation in an IND by Defendants to Plaintiffs at any time for any reason. A fact with which Defendants were intimately familiar.

188. 21 U.S.C. §355(a) (Chapter 9, Food Drug and Cosmetic Act; Subchapter V, Drugs and Devices; §355, New Drugs) states that "no person shall introduce or deliver for introduction into interstate commerce any new drug unless an approval of an [FDA marketing] application." (Emphasis added).

[62] 1.Research & Clinical Trials | Heart Health | South Denver Cardiology. South Denver Cardiology. Published May 3, 2023. Accessed October 25, 2023. https://southdenver.com/research-clinical-trials/

189. Congress carved out exemptions to that restriction under the EUA statute to allow individuals access to unlicensed drugs, biologics, and devices under compassionate, educational, and emergency conditions.[63]

190. Congress established **a required condition** before expanded access protocols could be issued under the EUA statute, "[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)) (emphasis added)

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

192. However, because for many years prior to 2021, it was clearly established that EUAs drugs, such as the COVID-19 drugs, must comply with 45 CFR 46[64] and the Belmont Report, Defendants should have known that "[n]othing in this section provides the Secretary **any authority to require any person to carry out any activity** that becomes lawful pursuant to an authorization under this section (21 U.S.C. 360bbb-3(l))" (Emphasis added). In other words, not

[63] The EUA statute is also part of Chapter 9 – Federal Food, Drug, and Cosmetic Act.

[64] 45 CFR §46.122: "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." "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes." - 45 CFR §46.102(1) (emphasis added)

even the Secretary of HHS may require any person to manufacture, distribute, administer, or receive an EUA product.

193. The Supremacy Clause Doctrine preempted any lawful state authority upon which Defendants relied to mandate conditions that interfered or conflicted with Plaintiffs' federally secured rights conferred upon them by a valid act of Congress under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).

194. Still, Troy Stockman, legally sophisticated in laws pertaining to investigational new drugs under Institutional Review Board authority, FWA governance, Article VII of the ICCPR Treaty, 45 CFR Part 46, and the Belmont Report, all requiring him to obtain Plaintiffs' "legally effective informed consent" chose to ignore Congress, his duties, and his legal obligations, and mandated that which federal law and his pledge to that law prohibited.

195. On September 8, 2021, SDCA sent an email[65] to Plaintiffs outlining a new company policy stating in part:

> (1) "On August 30th, the Colorado Board of Health implemented new rules requiring licensed health care facilities to mandate all personnel to receive the COVID-19 Vaccine. Effective immediately, all health care facilities in Colorado are required to have their health care workers, support staff and contractors fully vaccinated by October 31st. For employees who have been vaccinated, proof of their vaccination is required to be placed in their confidential personnel file. For employees who are not vaccinated at this time, they are to receive their first COVID-19 dose by September 30th and their second dose no later than October 31, 2021."
>
> (2) "Staff and providers who are not vaccinated must be vaccinated with their first dose by Sept 30th and their second dose by October 31st with proof…"
>
> (3) "Attached is a new policy for South Denver Cardiology that applies to all providers, staff, and contractors in all SDCA facilities. This policy requires that SDCA retains record of every team member of their vaccination record in their HR file and SDCA total vaccination rates be reported to the State of Colorado monthly."

[65] See Exhibit D, September 8, 2021, Email from Troy Stockman

196. The new company COVID-19 drug policy[66] stated in part:

(1) "To protect patients, guests, employees, family members and the community from Sars-Cov-2 (COVID-19) infection, all employees of South Denver Cardiology Associates (the "Company") and contractors must be fully vaccinated against COVID-19."

(2) "This policy is intended to maximize vaccination rates against COVID-19 among Company personnel and is designed to comply with all federal, state, and local laws as of the date of this policy."

(3) "Exemptions to the COVID-19 vaccination will only be granted for medical contraindications or religious beliefs as outlined below."

(4) "South Denver Cardiology Associates requires all employees to be fully vaccinated against COVID-19 as soon as possible. All current employees must receive the first dose or one dose, if applicable, of the COVID-19 vaccine, or be granted an exemption, prior to or by September 30, 2021. In compliance with the Colorado Board of Health Emergency Rule 6 C.C.R. 1101-1, Chapter 2, Part 12, all employees must be fully vaccinated, as defined above, by October 31, 2021, unless an exemption has been granted."

(5) "All current employees are required to provide proof of COVID-19 vaccination or an approved medical or religious exemption no later than September 30, 2021. Failure to comply will result in disciplinary action up to and including termination."

(6) "For those with an approved medical or religious exemption, masking and testing is required. Those failing to comply with masking and testing will be subject to disciplinary action up to and including termination."

(7) "The Company is providing paid time off under its Paid Leave Time (PLT) policy for employees who need time off to receive a COVID-19 vaccine and employees who are unable to work **due to vaccine side effects**." (Emphasis added)

(8) "As a condition of employment, all newly hired employees must receive at least the first shot of the COVID-19 vaccine prior to or during New Employee Orientation (NEO). If a new hire will be requesting a medical or religious exemption, this request must be made prior to NEO such that the Human Resources Department can determine if the exemption request will be granted."

[66] See Exhibit E, SDCA COVID-19 Vaccination Policy

> (9) "Prior to performing any services for the Company, attending any in-person meetings, or visiting one of the Company's office locations, contractors and non-employees must present proof that they are fully vaccinated against COVID-19."
>
> (10) "Employees who are granted an exemption will be required to submit to a COVID-19 test on a weekly basis, starting seven (7) days after their exemption is approved. This testing mandate will remain in effect until the Company notifies employees that they are no longer required to undergo weekly testing."
>
> (11) "Any employee who, in good faith, lawfully and truthfully seeks an exemption from participation in the Company's vaccination program as an accommodation is following this policy. The Company will not tolerate retaliation against that person. The Company takes claims of retaliation seriously. Individuals who engage in retaliatory conduct will be subject to disciplinary action, up to and including termination of employment. If you suspect that you or someone you know has been retaliated against for requesting an accommodation in good faith, you should immediately notify the Company by contacting the Chief Executive Officer."

197. It is indisputable that from the date SDCA issued the mandatory COVID-19 vaccination requirement until they deprived Plaintiffs of their Constitutional and statutory rights, no FDA-licensed COVID-19 vaccine was available to Plaintiffs for compliance with SDCA's policy. Therefore, SDCA exclusively relied on EUA investigational drugs that were also afforded PREP Act immunities for compliance with SDCA's policy.

198. On December 11, 2020, the FDA issued to Pfizer-BioNTech the first COVID-19 EUA for its investigational drug (officially named Pfizer-BioNTech COVID-19 Vaccine[67]), and the FDA confirmed that Pfizer's product "is an investigational vaccine not licensed for any indication."[68]

---

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

[68] 86 Fed.Reg. 5200, Jan. 19, 2021

199. 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."[69]

200. 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."[70]

201. Investigational new drugs[71] (IND) have no FDA-licensed legal indication to treat, cure, or prevent any known disease and are experimental by their very nature.[72]

202. Therefore, it is indisputable that SDCA deprived Plaintiffs of their Constitutional and federal statutory rights to refuse an EUA/EUI[73] or PREP Act product when they required Plaintiffs to inject an unlicensed investigational new drug into their bodies before October 31, 2021, as a condition to continue employment.

203. As a matter of law, Plaintiffs would never have been able to provide proof of full vaccination. Drugs and biologics are regulated according to their classification and not their formulation, and the EUA classification has no legal indication as a "vaccine." That is why the

---

[69] 86 Fed.Reg. 5211, Jan. 19, 2021

[70] 86 Fed.Reg. 28608, May 27, 2021

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

[72] 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

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

FDA stated in its respective EUA letters to the manufacturers that the drugs were "investigational vaccines not licensed for any indication," meaning they were under investigation to receive the vaccine classification potentially.

204. Therefore, since the COVID-19 drugs available to Plaintiffs were only authorized under the EUA statute, Defendants were legally bound to ensure that their mandate complied with their duties under 21 U.S.C. §360bbb-3, 45 CFR Part 46, and the Belmont Report. The primary duty owed to Plaintiffs was for Defendants to respect and defend their chosen option without interference. Moreover, Defendants did not seek to obtain Plaintiffs legally effective informed consent. As previously discussed, this consent is required of Congress anytime a person is involved in a federally funded medical research activity/product, such as Colorado's joint-partnership with the CDC to distribute the federal government's COVID-19 EUA property.

205. Defendants exclusively relied on emergency medical countermeasures for policy compliance, which are also under PREP Act authority. The PREP Act also expressly restricts Defendants from issuing company policies that conflict with or interfere with the statute's provisions.[74]

206. Congress expressly wrote into legislation that Defendants could not establish a "legal requirement" that interfered with "the covered countermeasure, **or to any matter** included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]"

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

(emphasis added). The "any matter" directly links to the authority of Plaintiffs to either accept or refuse the medical countermeasures without consequence under 21 U.S.C. §360bbb-3 (Federal Food, Drug, and Cosmetic Act). Defendants' new COVID-19 policy irrefutably interfered with Plaintiffs' federally secured rights under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).

207. Although the PREP Act does not provide for a private right of action, its restrictions demonstrate that Defendants misrepresented their authority to Plaintiffs. Thus, the mandatory participation in unlicensed COVID-19 drugs was illegal and directly led to Plaintiffs' legal and financial injuries. Therefore, those injuries provide for a private right of action under 42 U.S.C. §1983 and other federal and state laws (see discussion, *infra*). Defendants deceptively used the fact that the COVID-19 EUA drugs were granted expanded access protocols under 21 U.S.C. §360bbb-3 and the PREP Act as the means to push their personal agenda while ignoring the restrictions contained within those same statutes.

208. It is well-established Colorado State common law that Defendants cannot terminate an employee exercising a specific statutory right that is a matter of serious public concern.[75] The forfeiture of legal rights under the PREP Act is a serious public concern.

209. It is well-established Colorado State common law that Defendants cannot use deception to justify terminating Plaintiffs' employment.[76]

210. Defendants utilize investigational drugs on an ongoing basis. They should have known that they were prohibited by their federal assurances, contracts, and institutional review board obligations that they could not mandate participation in drugs undergoing FDA clinical

[75] See, *Martin Marietta Corp. v. Lorenz*, 823 P.2d 100 (Colo. 1992). See, *Crawford Rehab. Servs., Inc. v. Weissman*, 938 P.2d 540 (Colo. 1997), *Rocky Mtn. Hosp. & Med. Serv. v. Mariani*, 916 P.2d 519 (Colo. 1996), *Kearl v. Portage Envtl., Inc*., 205 P.3d 496 (Colo. App. 2008)
[76] *Wisehart v. Meganck*, 66 P.3d 124 (Colo. App. 2002)

review as a condition of employment. Such a mandatory condition violates their well-established lawful obligations.

211. At all times pertinent, Troy Stockman engaged in deception when he concealed material facts from Plaintiffs in his COVID-19 policy and ongoing communications of the terms and conditions Congress established for each person agreeing to participate in a federally funded EUA/EUI/PREP Act product.

212. Congress was explicit that any person receiving a medical countermeasure under EUA protocols/PREP Act authority must agree to the following terms and conditions, including, but not limited to:

A. forfeiture of civil litigation rights resulting from injuries,[77]

B. allow their private identifiable information to be collected and used for a variety of purposes by unknown persons,[78]

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

D. allow the data collected about their adverse events to be utilized by researchers for unknown purposes and eternity,[79]

E. assume greater risks to their safety, health, and legal rights.[80],[81]

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

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

[79] 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.

[80] 21 U.S.C. §360bbb-3 requires potential recipients to be made aware of the risks, alternatives, and the fact that the product is only authorized by the Secretary under emergency conditions. These elements provide potential recipients with the required information to make a quality and legally effective decision to consent. Therefore, consent means the individual agrees to assume more than minimal risk.

[81] 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."

213. Defendants' concealment of material facts was meant to cause Plaintiffs to surrender their Fourteenth Amendment and statutory rights to deceptively compel participation in the investigational drugs under pretense.

214. Moreover, Defendants' COVID-19 Policy lacked information Plaintiffs would want to know when considering participation.[82] For example, COVID-19 mRNA drugs 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."

215. At all times pertinent, Defendants concealed the lawful authority of Plaintiffs to refuse participation in the legally binding agreement as established by a valid act of Congress and the power Plaintiffs held under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). Moreover, Defendants deceptively presented false facts that Plaintiffs were required to seek a medical or religious exemption to have the right to refuse the investigational drugs without consequence.

216. The right to refuse participation in an EUA/EUI/PREP Act product or activity is a right held exclusively by Plaintiffs, which no person can interfere with by penalizing their chosen option or adding additional requirements (e.g., testing, masking, segregation) not established by Congress.

217. Defendants stated that "To protect patients, guests, employees, family members, and the community from Sars-Cov-2 (COVID-19) infection, all employees of South Denver Cardiology Associates (the "Company") and contractors must be fully vaccinated against COVID-

[82] 45 CFR 46.116(a)(4)

19."[83] This statement violates federal law because it promotes investigational new drugs as having a legal indication of safety and effectiveness (21 CFR 312.7(a)).

218. As a matter of material fact, no COVID-19 drug manufacturer has ever claimed that its product would protect all individuals against all COVID-19 variants. The purpose of SDCA's statement was to convey the idea that the drug protected all persons from all COVID-19 variants to justify its unlawful behavior.

219. SDCA stated, "This policy is intended to maximize vaccination rates against COVID-19 among Company personnel and is designed to comply with all federal, state, and local laws as of the date of this policy."[84] The policy was designed to coerce participation among "Company personnel." Additionally, Defendants engaged in constructive fraud when stating the policy was designed to comply with "all federal…laws." The Policy, as applied, violated:

(1) Duties owed to Plaintiffs under SDCA's Federal Wide Assurance agreement.

(2) Duties owed to Plaintiffs under SDCA's Institutional Review Board.

(3) Duties owed to Plaintiffs by SDCA under 45 CFR Part 46, specifically, 45 CFR § 46.116 and 46.122.

(4) Duties owed to Plaintiffs by SDCA under Article VII of the ICCPR Treaty

(5) Plaintiffs legally effective informed consent rights, which require persons offering participation in a federally funded medical research project to ensure individuals are not under outside pressure to participate. Defendants may not be the person administering the injection. Still, they are acting on behalf of the sponsor (federal government) when requiring participation and, therefore, owe the same duties under federal law.

(6) Plaintiffs 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) statutory rights to accept or refuse authorized products without interference.

[83] See Exhibit E, SDCA COVID-19 Vaccination Policy
[84] *Id.*

(7) Plaintiffs' rights under 42 USC 247d-6d(b)(8) requiring Defendants to abstain from interfering with "any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act" which includes the option to accept or refuse.

(8) Plaintiffs rights under 42 USC 247d-6e(c) ensuring only voluntary participation.

(9) Plaintiffs' Equal Protection of Laws rights under the Fourteenth Amendment. The option to accept or refuse are two equal options, but only the option to refuse was penalized by Defendants. Additionally, the requirement for only Plaintiffs to wear PREP Act masks and engage in unwanted experimental testing articles because of their chosen option is a clear violation of the Equal Protection Doctrine.

(10) Plaintiffs' Due Process rights (substantive and procedural) under the Fourteenth Amendment. SDCA and Troy Stockman, at all times pertinent, refused to acknowledge Plaintiffs statutory and Constitutional rights. If persons in authority, such as Todd Stockman and SDCA, refuse to acknowledge laws passed by valid acts of Congress, then Due Process is impossible to secure.

(11) Duties owed to Plaintiffs by SDCA under the Belmont Report. The Belmont Report is a required condition for anyone to comply with when involving individuals in federally funded medical programs such as the CDC COVID-19 Vaccination Program. No COVID-19 EUA drug existed that was not fully funded by the federal government.

220. Therefore, it is plain to see that the policy violated and/or did not comply with federal law.

221. Troy Stockman's moral turpitude is plainly evident in SDCA's COVID-19 medical exemption form, which states in part, "I verify that the information I am submitting in support of my request for an accommodation is complete and accurate to the best of my knowledge, and I understand that any intentional misrepresentation contained in this request may result in disciplinary action, up to and including termination of employment."[85] Upon issuing a new

[85] See Exhibit F, SDCA Medical Exemption Form

COVID-19 company policy filled with "intentional misrepresentation" of facts, SDCA warns Plaintiffs not to engage in the same form of debased conduct as it did.

222. SDCA informed Plaintiffs that "For those with an approved medical or religious exemption, masking and testing is required. Those failing to comply with masking and testing will be subject to disciplinary action up to and including termination."[86] This requirement is a form of coercion the Belmont Report and Congress prohibit. One may not condition refusal of an emergency medical countermeasure upon loss of liberties; such requirement violates the well-established Unconstitutional Conditions Doctrine.

223. SDCA cannot withhold a benefit to which Plaintiffs are otherwise entitled when Plaintiffs choose a federally secured option Defendants disagree with. SDCA's requirement of Plaintiffs to surrender that statutory right as a condition to continue enjoying current or future benefits deprives Plaintiffs of Constitutional and federal statutory rights, a fact that became a reality when Plaintiffs exercised that lawful authority and SDCA terminated their employment because of their federally secured chosen option.

224. The State of Colorado willfully participated in the CDC COVID-19 Vaccination Program Provider Agreement[87] and owed Plaintiffs a Constitutional duty under the Fourteenth Amendment (e.g., Due Process and Equal Protection of Laws) when administering the federal government's property (COVID-19 drugs).

225. On August 30, 2021, CDPHE Director, Jill Hunsaker Ryan, and CDPHE's Director of Health Facilities, D. Randy Kuykendall issued a direct request to the CDPHE Board Members

[86] See Exhibit E, SDCA's COVID-19 Vaccination Policy

[87] "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). – See Exhibit C, Provider Agreement

to vote on amending the State's licensure standards under 6 CCR 1011-1, Chapter 2 pertaining to healthcare facilities. D. Randy Kuykendall requested the new rules on behalf of CDPHE's executive team, stating, "the Department requests the Board adopt the following regulations requiring all licensed healthcare facilities to ensure their eligible employees, direct contractors, and support staff are fully vaccinated against COVID-19."

226. However, Ms. Ryan had full authority and legal duty to prevent that rule request from moving forward. When the Board voted on the new rules, Ms. Ryan had a duty to inform the board members of their legal obligations under CDPHE's FWA, and agreement with the CDC pertaining to its COVID-19 Vaccination Program. Both required only voluntary participation.

227. The Board, accepting the request by Ms. Ryan and Mr. Kuykendall, voted on and approved the new Part 12 rules[88], which interfered with Plaintiffs' right to exercise their 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)[89] option and to enjoy employment in their chosen profession without consequence, thereby violating their Fourteenth Amendment Equal Protection and Due Process rights.

228. The new "Part 12" rules amended the State's licensing requirements for healthcare facilities, stating in part:

> (12.2.1) "Each facility shall develop and implement a policy and procedure to ensure 100% of employees, direct contractors, and support staff have obtained full COVID-19 vaccination status in accordance with the schedule below."
>
> (12.2.1(a)) "All employees, direct contractors, and support staff must have received their first dose of the COVID-19 vaccination no later than September 30, 2021."

[88] See Exhibit G, CDPHE Part 12 Rules

[89] 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.'"

> (12.2.1(b)) "All employees, direct contractors, and support staff must have received their second dose of the COVID-19 vaccination (if applicable) no later than October 31, 2021."
>
> (12.2.1(c)) "All employees, direct contractors, and support staff must obtain a subsequent, or booster, dose of the COVID-19 vaccination should one be recommended by the Advisory Committee on Immunization Practices (ACIP), in accordance with the recommended timelines."
>
> (12.2.1(e)) "On or after October 31, 2021, each facility shall ensure all newly hired employees, direct contractors, or support staff members have obtained full COVID-19 vaccination status, in accordance with this Part 12."
>
> (12.2.4) "Each facility shall maintain the following documentation that may be examined by the Department, at any time, for purposes of verifying compliance with this Part 12. (A) Proof of immunization, as defined at 6 CCR 1011-1, Chapter 2, Part 1.51, or (B) A medical exemption signed by a physician, physician assistant, advanced practice nurse, or certified nurse midwife licensed in the State of Colorado stating that the COVID19 vaccination for the employee, direct contractor, or support staff is medically contraindicated as described in the product labeling approved or authorized by the FDA, or (C) Documentation of a religious exemption, as defined by facility policy."

229. Ms. Ryan should have known that she could not require facilities to "ensure 100% of employees, direct contractors, and support staff have obtained full COVID-19 vaccination" by "October 31, 2021."

230. As previously discussed, no COVID-19 drug had been licensed by the FDA with a legal indication as a "vaccine" that had also been introduced into commerce for general commercial marketing. Therefore, it is an irrefutable fact that Ms. Ryan mandated facilities to require individuals under their authority to have an unlicensed investigational drug injected into their bodies as a condition to continue employment after October 31, 2021.

231. **No person has legal authority to require anyone to inject an unlicensed investigational drug into their body as a condition for anything. This statement is irrefutable by the Constitution, statute, treaty, or regulation. Moreover, no person has legal authority**

to require anyone to participate in a product or activity under PREP Act immunity under threat of penalty.

232. Ms. Ryan should have known the laws and regulations associated with the investigational new drug classification and how those laws restricted CDPHE from enacting mandatory deadlines that relied exclusively on unlicensed investigational drugs for compliance.

233. HHS assigned CDPHE its Federal Wide Assurance number 00003044, indicating that CDPHE pledged never to place an individual under a "sanction" for refusing to participate in an unlicensed investigational medical product. Their assurance includes a pledge (duties) to abide by 45 C.F.R. 46 §101, *et. seq* and the Belmont Report when involving individuals with investigational new drugs (e.g., Pfizer-BioNTech COVID-19 Vaccine).

234. As a matter of law, Ms. Ryan allowed CDPHE to commit fraud when participating in the CDC COVID-19 Vaccination Program through its licensed medical facilities and required Plaintiffs to inject the drugs under threat of penalty. Such a requirement is a fraudulent violation of CDPHE's FWA and CDC COVID-19 Vaccination Provider Agreement.

235. CDPHE also voluntarily agreed to comply with the terms and conditions of the CDC COVID-19 Vaccination Program Provider Agreement and Ms. Ryan should have known that "facilities" that signed the CDC contract could not be required to mandate the use of COVID-19 EUA investigational drugs to Plaintiffs.

236. CDPHE enacted, and Ms. Ryan approved and enforced, a rule that, as applied, required CDC COVID-19 Vaccination Program Providers to commit fraud against the Federal Government.

237. Number 12(a) of 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," which means that Colorado, CDPHE, and facilities are prohibited from amending the conditions that the HHS Secretary established for any EUA, and they must also obtain individuals' legally effective informed consent before administering an EUA product to those individuals.

238. Sanctions for refusing to inject an EUA drug into one's anatomy nullify legally effective informed consent and thus are fraud when healthcare facilities bill the U.S. Government for shots administered to employees under duress.

239. The Provider Agreement warned Ms. Ryan and Colorado licensed facilities 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."

240. The Part 12 rules, as applied, misrepresent CDPHE's authority because it mandates that healthcare facilities must participate in the use of EUA drugs. In turn, the facilities must also mandate individuals under their authority to participate in the use of EUA drugs. The rules, as applied, are illegal[90] and unconstitutional and tempt facilities under CDPHE's authority to commit fraud against the United States Federal Government by ignoring the authority of the HHS Secretary and requiring that which the Secretary and Congress prohibit.

241. SDCA informed Plaintiffs, "On August 30th, the Colorado Board of Health implemented new rules requiring licensed health care facilities to mandate all personnel to receive the COVID-19 Vaccine."[91]

[90] No person may establish conditions for accessing unlicensed drugs other than the HHS Secretary and not even the Secretary has the authority to compel participation.
[91] See Exhibit D, Email from Troy Stockman

242. Therefore, when CDPHE enacted, and Ms. Ryan approved and enforced, a rule requiring facilities to ensure 100% of individuals under their authority receive an injection of an unlicensed investigational COVID-19 drug before October 31, 2021, those rules led to the deprivation of Plaintiffs' Constitutional and federal statutory rights, which caused severe financial and emotional distress injuries.

243. Part 12 Rules violate the well-established Unconstitutional Conditions Doctrine. The Supreme Court held that a person "may not barter away his life or his freedom, or his substantial rights." *Home Ins. Co. of New York v. Morse*, 87 U.S. 455, 451 (1874)

244. The Federal Government owns or funds all COVID-19 drugs and issued explicit requirements to Defendants that persons must be allowed to accept or refuse those products without consequence.

245. The Federal Government entered into an agreement with the State of Colorado whereby the State would utilize its existing immunization program to approve, supervise, and ensure state-authorized healthcare facilities and workers comply with the government's mandate.

246. The CDC enacted a Vaccination Program requiring Colorado Healthcare Facilities and Providers to sign and follow should they participate in the joint action with the Federal and State Governments.

247. That process required all Defendants to ensure persons were under the Equal Protection of Laws, and if not, then Due Process was the reason for that unequal application. Therefore, when all Defendants issued policies demanding Plaintiffs to surrender their 21 U.S.C. §360bbb-3 right to refuse as a condition to continue employment in their chosen profession, that requirement established an Unconstitutional Condition.

248. The Fourteenth Amendment of the U.S. Constitution is a **required** duty of Ms. Ryan; it is not conditional, nor was Ms. Ryan authorized by any law to alter the Amendments by fiat rule. The U.S. Court held in *Frost & Frost Trucking Co. v. Railroad Comm'n, 271 U.S. 583, 593-94 (1926)* that a State "may not impose conditions which require the relinquishment of constitutional rights."

249. The State of Colorado, through Ms. Ryan's actions, and SDCA, a licensed health care provider in the State, unassailably imposed conditions requiring Plaintiffs to relinquish their constitutional rights as a condition to continue employment in their chosen profession.

250. Ms. Ryan did not deny access to living wages when it came to healthcare facilities or their employees who chose the option to ***accept*** administration of an EUA product. Still, they did with respect to those who chose to ***refuse*** administration of an EUA product.

251. The option to choose is a power held by Plaintiffs that the State is **Constitutionally required** to protect equally. Ms. Ryan should have known of the option and that no law allowed them to ignore that federal obligation when they issued Part 12 Rules.

252. CDPHE misrepresented its authority, which Ms. Ryan did not correct, when enacting 12.1.1: "The statutory authority for the promulgation of these rules is set forth in Section 25-1.5-102, 25- 1.5-103, and 25-3-103, C.R.S." CDPHE had no authority to enact, and Ms. Ryan had no authority to enforce, rules amending 21 U.S.C. §360bbb-3, and citing state law as the means to bypass the Supremacy Clause of the U.S. Constitution was nothing more than a fraudulent attempt by Ms. Ryan to deprive Plaintiffs of their legal authority.

253. When the Board voted on the new Part 12 rules, they usurped the authority of the U.S. Congress by amending federal laws and establishing conditions requiring that which Congress prohibits, mainly mandatory participation by healthcare facilities and workers in

"covered countermeasures"[92] and or drugs, biologics, or devices[93] under emergency expanded access protocols.

254. Moreover, Congress preempted, and the Supremacy Clause preempts, the authority of the CDPHE and Ms. Ryan from establishing conditions that conflict with or are different from any requirement under the PREP Act or any matter under 21 U.S.C. §360bbb-3. (42 USC 247d-6d(b)(8))

255. The Part 12 rules deprived Plaintiffs of their 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) option to refuse, which automatically demoted Plaintiffs to second-class citizens because Ms. Ryan refused to protect Plaintiffs' Fourteenth Amendment Equal Protection and Due Process rights. Instead, Ms. Ryan declared who would enjoy Fourteenth Amendment protections, not the United States Constitution, and any person choosing a 21 U.S.C. §360bbb-3 option she disagreed with shall not be treated equally before the law.

256. The Part 12 rules improperly amended Article VII of the ICCPR Treaty by subjecting Plaintiffs to medical experimentation outside their free consent.

257. The Part 12 rules improperly amended the CDC COVID-19 Vaccination Program Provider Agreement the State willfully participated in by not adhering to Section 12(a) of the Provider Agreement requiring 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."[94]

[92] 42 U.S.C. § 247d-6d(a)(1)
[93] 21 U.S.C. §360bbb-3(a)(1)
[94] See Exhibit C, CDC Provider Agreement.

258. The Part 12 rules amend 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) in violation of the U.S. Constitution and demonstrates Ms. Ryan's breach of duty to Plaintiffs under the CDC Covid-19 Vaccination Program Provider Agreement.

259. The Part 12 rules breach Ms. Ryan's duties to Plaintiffs under CDPHE's Federal Wide Assurance agreement.

260. The Part 12 rules breach Ms. Ryan's duties to Plaintiffs under the EUA statute.

261. The Part 12 rules breach Ms. Ryan's duties to Plaintiffs under the PREP Act.

262. The Part 12 rules breach Ms. Ryan's duties to Plaintiffs under the Fourteenth Amendment (Equal Protection and Due Process).

263. The Part 12 rules caused medical facilities to breach their institutional review board duties to Plaintiffs under 45 C.F.R. § 46.101, *et seq.*

264. The Part 12 rules caused medical facilities to breach their duties to Plaintiffs under their Federal Wide Assurance agreements.

265. The Part 12 rules caused medical facilities to breach their duties to Plaintiffs under their signed CDC COVID-19 Vaccination Program Provider Agreement.

266. The wanton disregard for Plaintiffs' health and safety by CDPHE and Ms. Ryan is demonstrated in their Part 12 Rules that they would only accept "A medical exemption signed by the physician…in the State of Colorado stating that the COVID-19 vaccination for the employee…is medically contraindicated as described in the product labeling approved or authorized by the FDA."[95]

267. Investigational new drugs are not labeled for their contraindications because they are investigational, and they have no legal indication to treat, cure, or prevent any known disease,

[95] See Exhibit G, Part 12 Rules, Rule 12.2.4(B).

nor are they labeled safe or effective. Manufacturers of INDs are prohibited from promoting their INDs as being safe or effective (21 CFR 312.7(a)) and have not been licensed to promote their IND drug with a legal indication.

268. There are 19,000 FDA-licensed drugs, and when CDPHE enacted, and Ms. Ryan approved and enforced, its new rules, three mRNA investigational COVID-19 drugs were available to Plaintiffs. Investigational New Drugs' formulations are continually amended from their resulting experiments. Therefore, at a minimum, there were more than one trillion unknown potential contraindications[96] that mere months of research could not have effectively exposed or accounted for. For this reason, the FDA prohibited CDPHE, and anyone else, including Ms. Ryan and SDCA, from requiring anyone to involuntarily participate in one of the three COVID-19 EUA investigational new drugs. An individual's healthcare provider alone has the professional insight and knowledge of that individual's health to ascertain their viable participation in an investigational new drug. Ms. Ryan ignored the standard of care rules and established conditions contrary to ethical medicine and professionalism.

269. Moreover, since no licensed drugs existed with a label containing the required proof of contraindications, no medical exemption could be accepted as valid by any facility. In other words, Ms. Ryan established a requirement that could not be met and that had potentially deadly consequences for individuals, demonstrating the moral turpitude of Ms. Ryan.

---

[96] 19,000 licensed drugs are in the marketplace. The average number of medications Americans take is four (Team S. Prescription drug statistics 2023. The Checkup. Published September 2021. Accessed September 17, 2023. https://www.singlecare.com/blog/news/prescription-drug-statistics/#:~:text=How%20many%20prescriptions%20does%20the,at%20least%20one%20prescription%20medication.). There are 21 major chronic diseases in the U.S. (Chronic Conditions | CMS. Cms.gov. Published 2020. Accessed September 17, 2023. https://www.cms.gov/data-research/statistics-trends-and-reports/chronic-conditions/chronic-conditions). 19,000 drugs interacting with just one mRNA drug contain more than 37,146, followed by 5,715 zeros potential adverse reactions. When taking into account the 21 major chronic diseases that the drug could cause an adverse reaction to, the number is as numerous as the stars. This fact is why it takes a drug years to come to market and years longer to be marketed as a vaccine. This fact is also the reason why Pfizer and Moderna refused to ship their COVID-19 drugs outside of absolute immunity.

270. Ms. Ryan also referred to the available COVID-19 EUA drugs as "vaccines," although the FDA only classified them as INDs. Thus, Ms. Ryan's goal of intentionally misrepresenting facts was to convince Colorado healthcare facilities that these EUA drugs could be mandated as if they were licensed drugs and to give cover for the healthcare facilities to operate illegally and defy the U.S. Congress at the expense of Plaintiffs' Constitutional and statutory rights.

271. At all times pertinent, Ms. Ryan refused even to acknowledge that the EUA statute existed, despite it being the **only** federal statute authorizing healthcare facilities and workers to administer the COVID-19 EUA drugs.

272. Ms. Ryan refused to discuss, inform, train, or educate the medical community about their legal obligation to ensure that healthcare workers administering the drugs must inform recipients of their legal rights to accept or refuse the product without penalty. She intentionally refrained from fulfilling her duties under the EUA statute because the statute proves her actions were illegal, capricious, and violated the rights of medical facilities and healthcare workers[97] licensed by the State of Colorado.

273. The Part 12 Rules mandate that Plaintiffs enter into a legally binding agreement under the terms and conditions established in the EUA statute and the PREP Act outside of their free consent (see, *supra*).

274. At all times pertinent, Ms. Ryan did not inform Plaintiffs that to participate in the use of an EUA COVID-19 drug under PREP Act immunity meant they must voluntarily agree to forfeit their legal rights to judicial relief should they incur a physical injury from the drug's use or its administration.

[97] Healthcare facilities and their employees have the right to administer 21 U.S.C. §360bbb-3 medical products based on their standard of healthcare. The State of Colorado ignored 21 U.S.C. §360bbb-3(l) and unlawfully removed that right by mandating that which Congress prohibits.

275. Moreover, Ms. Ryan did not inform Plaintiffs that they must allow medical researchers to utilize data resulting from their involvement with the drug for unknown purposes for eternity if they chose to participate.

276. Lastly, Ms. Ryan never informed healthcare facilities that their employees had the right to refuse any product under EUA authorization or any covered countermeasure under the PREP Act without incurring a penalty or loss of benefits.

277. By direct extension, this intentional dereliction of duty by Ms. Ryan led to the deprivation of Plaintiffs' Constitutional and statutory rights when SDCA acted on the State policy—that loss of rights led to severe financial damages and traumatic emotional distress.

278. Troy Stockman and SDCA should have been aware that the State policy violated federal laws and its contractual obligations that exceeded Ms. Ryan's authority. However, SDCA was free to, and, in fact, were instructed to, protect Plaintiffs' rights by complying with federal law, their contractual obligations, and HHS's legal obligations unabated, but it intentionally failed to do so.

279. At all times pertinent, Troy Stockman could have notified Mr. Ryan of her unlawful requirement and that such requirement violated federal law.

280. Troy Stockman could have sued CDPHE and Ms. Ryan in court for requiring SDCA to commit fraud under its existing federal government agreements (FWA).

281. Troy Stockman could have sought the federal government's help to compel CDPHE and Ms. Ryan to refrain from violating the authority of Congress to determine the conditions under which emergency medical countermeasures are administered.

282. However, Troy Stockman's personal agenda outweighed his moral conviction to protect the rights, safety, and health of Plaintiffs.

283. Troy Stockman and SDCA, with willful and wanton disregard for the rights, safety, and welfare of the Plaintiffs, intentionally ignored their lawful obligations, contractual duties, and federal agreements for no other reason than enforcing a personal agenda.

284. Worse yet, Defendants used a pandemic to hide their malfeasance and willfully applied as much pressure on Plaintiffs as one in their positions of power could to set them as an example to all others that no one under their authority would ever have the freedom to exercise their Constitutional and statutory rights without severe life-altering consequences.

285. Defendants intentionally inflicted emotional distress upon Plaintiffs by destroying their dreams, careers, goals, housing, education, family life, healthcare, retirement, and feelings of dignity and equal treatment. Defendants subjected Plaintiffs to investigational drug use outside of their free will and voluntary consent. When Plaintiffs held to their Constitutional rights, Defendants deprived Plaintiffs of those Constitutional and federal statutory rights by terminating their employment in violation of federal law and SDCA's contractual agreements with the federal government having intended benefits for Plaintiffs.

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

VII. Legal Claims

287. The facts described above constitute a deprivation of several rights guaranteed to Plaintiffs by the United States Constitution, federal statutes, and treaties. These deprivations are actionable under 42 U.S.C. §1983 because the Defendants acted under color of state law when issuing their COVID-19 vaccination requirements and administrating the CDC COVID-19

Vaccination Program pursuant to the CDC COVID-19 Vaccination Program Provider Agreement and the federal statutes cited therein.

288. Court precedent demonstrates that federal statutes and regulations with rights conferring language are enforceable under 42 U.S.C. §1983.[98]

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

COUNT ONE

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

290. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

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

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

292. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) (a provision in the EUA statute) contains a required condition of the Secretary "to ensure that individuals to whom the product is administered are informed — 'of the option to accept or refuse administration of the product.'"

293. The EUA statute, the CDC COVID-19 Vaccination Program Provider Agreement, and each EUA's Scope of Authorization contains research conditions for COVID-19 medical products meeting 45 CFR 46.102(l)'s definition of research requiring adherence to 45 CFR § 46.101[99] *et seq.*

294. "Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative." 45 CFR 46.116(a)(1)

295. 45 CFR § 46.116 and the Belmont Report contain the only known definition of legally effective informed consent.

296. 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."

297. The Belmont Report, having the force of law,[100] declares, "An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence" and "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to

[99] "This policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency" 45 CFR 46.101(a).
[100] 45 CFR § 46.101(c), 45 CFR 46.101(i), 45 CFR § 46.122

choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."

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

299. 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."

300. The Defendants' actions described above, individually and/or collectively, acting under color of state law, and in deprivation of the Constitutional rights and rights secured by the above federal statutes, regulations, and treaty, unlawfully subjected Plaintiffs to the use of investigational medical products under threat of penalty outside of their legally effective informed consent as described in the above facts, thereby causing them damages described in Paragraphs 384 through 390, *infra*.

COUNT TWO

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

301. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

302. The CDC COVID-19 Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR Part 46, the Belmont Report, 21 U.S.C. §360bbb-3, Article VII of the ICCPR Treaty, Federal Wide Assurance, the EUA Scope of

Authorization letter, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

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

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

305. 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 384 through 390, *infra*.

COUNT THREE

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

306. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

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

308. 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.

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

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

311. Defendants' requirement that Plaintiffs inject unlicensed drugs into their bodies as a condition to sell their labor "is not a legitimate exercise of the police power of the State, but an unreasonable, unnecessary and arbitrary interference with the right and liberty of the individual to contract in relation to labor, and, as such, it is in conflict with, and void under, the Federal Constitution." *Lochner v. New York*, 198 U.S. 45 (1905)

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

313. 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 384 through 390, *infra*.

COUNT FOUR

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

314. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

315. The laws cited in the CDC COVID-19 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.

316. 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, 522, 523, 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)

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

318. The federal government funds any charges associated with the administration of the COVID-19 EUA shots via Medicare.[101]

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

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

320. 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."

321. 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…"

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

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

324. Requirement Number 3 of 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."[102]

325. Provider 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."

[102] See Exhibit C, CDC Provider Agreement

326. These two provisions establish a specific monetary entitlement to the individual (i.e., shots, along with labor and equipment used to administer them, at no charge to the recipient).

327. Provider 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."[103]

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

329. The compliance is found in the EUA Fact Sheet, notating the individual's right to refuse the administration of the product.[104] This express right is the fundamental requirement in obtaining the legally effective informed consent of the individual.

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

331. 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

[103] See Exhibit C, CDC Provider Agreement.
[104] See Exhibit H, Fact Sheet for Healthcare Providers, p.8., "Information to Provide to Vaccine Recipients/Caregivers"

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.

332. 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."[105]

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

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

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

336. The Defendants' actions described above, individually and/or collectively, and in deprivation of the rights and privileges secured by the Constitution and the above statutes and regulations, refused to obtain the legally effective informed consent of the Plaintiffs in violation of spending legislation as described in the above facts, thereby causing them damages described in Paragraphs 384 through 390, *infra*.

[105] See Exhibit C, CDC Provider Agreement

COUNT FIVE

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

337. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

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

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

340. Jill Hunsaker Ryan, Troy Stockman, and SDCA established conditions requiring Plaintiffs to surrender their Constitutional rights under the Fourteenth Amendment as a condition to enjoy privileges of the State, such as the ability to sell their labors in the marketplace freely and or continue to enjoy a benefit to which they were otherwise entitled.

341. 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 384 through 390, *infra*.

COUNT SIX

PREP Act - 42 U.S.C. §1983

342. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

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

344. The PREP Act provides certain immunities to "covered countermeasures" when the HHS Secretary determines there is a public health emergency and makes a declaration of that emergency through the publication in the Federal Register specifying the conditions by which the covered countermeasure and covered persons can participate and the use of such covered countermeasure.[106]

345. Congress preempted the State of Colorado and medical facilities it licenses from establishing laws and continuing in effect with existing ones (at-will employment doctrine) that would otherwise interfere with Plaintiffs' authority with respect to "conduct undertaken" concerning "any matter included in a requirement applicable" to a "covered countermeasure"

[106] 42 USC 247d-6d(b)(1)

under the PREP Act or the EUA staute including the required condition that Plaintiffs be informed of their legal right to either accept or refuse said countermeasure.[107],[108]

346. Congress was explicit that the HHS Secretary must establish conditions ensuring that "potential participants are educated with respect to…the voluntary nature of the program…"[109]

347. The "program" consists of those agreeing to manufacture, distribute, administer ("covered person"), and receive[110] ("covered individual") the product.

348. Congress expressly restricted the HHS Secretary from having any authority to require any person to participate in any activity involving a "drug," "biologic," or "device" under 21 U.S.C. §360bbb-3[111] or any "covered countermeasure" under the PREP Act. By extension, any person authorized to participate in the program is also restricted from mandating participation.

349. Jill Hunsaker Ryan, Troy Stockman, and SDCA established laws and policies that conflicted with the PREP Act and the EUA statute when they required Plaintiffs to participate in the use of a covered countermeasure under threat of penalty. Moreover, Defendants engaged in policy-making and conduct that conflicted with the PREP Act and the Fifth and Fourteenth Amendments of the United States Constitution.

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

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

---

[107] 21 U.S.C. 301 is the Federal Food, Drug and Cosmetic Act, which ranges from §301 to §399, and thus includes 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III).
[108] 42 USC 247d-6d(b)(8)
[109] 42 USC 247d-6e(c)
[110] 42 U.S.C. §247d-6e(e)(2)
[111] 21 U.S.C. §360bbb-3(l) " –Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section…"

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

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

354. Defendants' policies violated Plaintiffs' rights to accept or refuse participation in PREP Act covered countermeasures without pressure or influence being placed upon them.

355. Defendants issued policies requiring participation in investigational drugs, testing articles, masks, and other devices under threat of penalty, violating Plaintiffs' right to voluntary participation and due process rights.

356. Defendants changing the voluntary nature of the program into an involuntary program endangers the immunities of existing covered countermeasures established by the HHS Secretary. Defendants' interference is a direct assault on the Constitutional rights of Plaintiffs, which opens the doors to legal remedies not envisioned by Congress but required of the Constitution for resulting injuries sustained by individuals when under threat of penalty to participate.

357. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, deprived the

Constitutional and federal legal rights of Plaintiffs as described in the above facts, thereby causing them damages described in Paragraphs 384 through 390, *infra*.

COUNT SEVEN

Breach of Contract, Third Party Beneficiary

358. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

359. 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.

360. The primary third-party beneficiary right intended for Plaintiffs is the freedom to consider participation in a federally funded EUA (drug, biologic, or device), PREP Act, or other emergency medical countermeasure products or activities that are free from "sanctions," "coercion," "undue influence," "unjustifiable pressures to participate. The other third-party benefit intended for Plaintiffs is that they must not fear the loss of benefits to which they are otherwise entitled when considering participation. Defendants issued a policy that was an "overt threat of harm"[112] to the financial and emotional well-being of Plaintiffs for the express purpose of coercing them to participate in the CDC COVID-19 Vaccination Program outside of their free will and voluntary consent.

361. The Defendants' actions described above, individually and/or collectively, and in breach of the CDC COVID-19 Vaccination Program Provider Agreement, deprived the Plaintiffs of the benefits intended to be conferred upon them through the terms and conditions of the CDC

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

COVID Vaccination Program Provider Agreement as described in the above facts, thereby causing them damages described in Paragraphs 384 through 390, *infra*.

COUNT EIGHT

Colorado State Common Law Employment Torts

362. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

363. The Supremacy Clause, PREP Act, and the EUA statute preempt State laws conflicting with the United States Government's emergency medical countermeasure objectives, including Colorado State's at-will employment laws.

364. SDCA lacked authority to condition employment upon Plaintiffs participating in an EUA countermeasure or any product or activity under PREP Act authority.

365. SDCA intentionally and unlawfully misrepresented their authority to Plaintiffs to cause them to surrender their constitutional and statutory rights.

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

367. SDCA placed Plaintiffs under moral duress, knowing they exclusively relied on Defendants for access to living wages.

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

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

370. SDCA attempted to coerce Plaintiffs to waive their federally secured right to refuse EUA investigational products and 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.

371. SDCA's actions demonstrate moral turpitude against Plaintiffs' rights, safety, and health.

372. SDCA 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.

373. SDCA used fraud and deception to justify terminating Plaintiffs.[113]

374. SDCA unlawfully terminated Plaintiffs' employment when Plaintiffs exercised their legal right to refuse EUA and PREP Act countermeasures.[114]

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

376. SDCA's actions, individually and/or collectively, and in derogation of Colorado's common laws, deprived the intended benefits conferred upon the Plaintiffs when enjoying employment in the State of Colorado as described in the above facts, thereby causing them damages described in Paragraphs 384 through 390, *infra*.

COUNT NINE

Extreme and Outrageous Conduct

377. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

[113] *Wisehart v. Meganck*, 66 P.3d 124 (Colo. App. 2002)

[114] An employer may not terminate or constructively terminate an employee exercising a specific statutory right that is a matter of serious public concern. The forfeiture of rights under the PREP Act is a serious public concern. — *Martin Marietta Corp. v. Lorenz*, 823 P.2d 100 (Colo. 1992). See, *Crawford Rehab. Servs., Inc. v. Weissman*, 938 P.2d 540 (Colo. 1997), *Rocky Mtn. Hosp. & Med. Serv. v. Mariani*, 916 P.2d 519 (Colo. 1996), *Kearl v. Portage Envtl., Inc*., 205 P.3d 496 (Colo. App. 2008)

378. 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. They 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.

379. Extreme and Outrageous Conduct is proven by (1) demonstrating that Defendants engaged in extreme and outrageous conduct, (2) Defendants' actions caused severe emotional distress, and (3) Defendants intentionally or recklessly caused the emotional distress.[115]

380. The Defendants' conduct committed with gross negligence, reckless, or intent, as described above in the complaint, gives rise to a claim of Extreme and Outrageous Conduct under the common law of the State of Colorado against the Defendants for the damages described in Paragraphs 384 through 390, *infra*.

COUNT TEN

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

381. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 289, as if fully set forth herein.

382. Should the court not agree that SDCA 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).

[115] *Rugg v. McCarty*, 173 Colo. 170, 476 P.2d 753 (1970); *Espinosa v. Sheridan United Tire*, 655 P.2d 424 (Colo. App. 1982); *see also Coors Brewing Co. v. Floyd*, 978 P.2d 663 (Colo. 1999); *Culpepper v. Pearl Street Bldg., Inc.*, 877 P.2d 877 (Colo. 1994); *Reigel v. SavaSeniorCare L.L.C.*, 292 P.3d 977 (Colo. App. 2011); *Green v. Qwest Servs. Corp.*, 155 P.3d 383 (Colo. App. 2006)

383. 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 384 through 390, *infra*.

VIII. Damages Recoverable and Demanded

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

385. 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.

386. 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)

387. 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)

388. 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)

389. 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.

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

IX. Jury Trial Demand

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

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

SCHEXNAYDRE LAW FIRM

BY: /s/ *David J. Schexnaydre*
DAVID J. SCHEXNAYDRE, T.A.
Louisiana Bar Roll #: 21073
2895 Highway 190 • Suite 212
Mandeville, Louisiana 70471
Telephone: (985) 292-2020
Fax: (985) 235-1089
Email: david@schexnaydre.com
Lead Counsel for Plaintiffs