UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

HOUSTON DIVISION

JENNIFER BRIDGES, *et al,*	*	
	*	
Plaintiffs,	*	
	*	
VERSUS	*	CIVIL ACTION 4:23-cv-1699
	*	
THE METHODIST HOSPITAL d/b/a THE METHODIST HOSPITAL SYSTEM and HOUSTON METHODIST THE WOODLANDS HOSPITAL,	*	
	*	
Defendants,	*	

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

AMENDED COMPLAINT
(JURY TRIAL REQUESTED)

NOW INTO COURT, through undersigned counsel, come Plaintiffs, Jennifer Bridges, *et al*, (hereinafter "Plaintiffs"), who respectfully file this Amended Complaint against Defendants, The Methodist Hospital d/b/a Houston Methodist Hospital and Houston Methodist The Woodlands Hospital, and adding new defendants, Marc Boom, in his individual and representative capacities, Robert A. Phillips, in his individual and representative capacities, the Houston Methodist voting Board of Directors in their individual and representative capacities, the Texas Workforce Commission, the Texas Department of Health and Human Services, and the Texas Medical Board, (hereinafter "Defendants"), presenting allegations and causes of action as follows:

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PRELIMINARY STATEMENT

This is an action brought under the United States Constitution, 42 U.S.C. § 1983, 21 U.S.C. §360bbb-3, 42 USC 247d-6d, 45 CFR 46, 18 U.S.C. §242, ICCPR Treaty, and the laws of the State of Texas to hold accountable The Methodist Hospital, a State Actor at all times pertinent herein, via its policymakers, the CEO, CMO, and Voting Board Members, for damages arising out of their unconstitutional, unlawful, malicious, unequal and contractually violative mandatory employee "immunization" program. Special laws apply to this "immunization" program because the FDA defines the drugs at issue as investigational with no licensed indication to treat, cure, or prevent any known disease. And even though this "immunization" program was instituted during, and in response to a

pandemic emergency, as the U.S. Supreme Court noted since the beginning of the pandemic: **"even in a pandemic, the Constitution cannot be put away and forgotten."** *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct. 63, 208 L.Ed.2d 206 (2020)

I. Introduction

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

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

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

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

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

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

7. Some of those research abuses included:

A. the US Navy sprayed the entire city of San Francisco with a bacterial agent to study biological warfare (Operation Sea-Spray), injuring many unsuspecting residents;

B. Chester M. Southam of Sloan-Kettering Institute injected live cancer cells into 300 healthy female prisoners without informing them or asking permission;

C. In the early 1960s, Saul Krugman of Willowbrook State School in Staten Island, New York, deliberately infected children with viral hepatitis by feeding them extracts made from infected feces;

D. In 1966, the U.S. Army injected gas infused with bacteria throughout the New York City Subway system to study the impact of biological warfare;

E. In the 1950s, the Atomic Energy Commission (AEC) and Nebraska College of Medicine subjected healthy infants to radioactive iodine to test its effects on the thyroid gland;

F. Throughout the 1960s, Inuit natives in Alaska were treated with radioactive iodine without being informed of the potential dangers, nor did the AEC conduct any long-term follow-up.

G. The Department of Defense, in the late 1960s, funded non-consensual whole body radiation experiments on African-American, poor, and terminally ill persons, without informing them of the life-altering dangers.

H. Other illegal research activities numbering in the thousands included irradiating thousands of male testicles, removing skull parts of babies still in the womb, sterilizing black females, chemical baths, irradiating entire towns with nuclear material, and injection of live cancer cells into prisoners and terminally ill patients.

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

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

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

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

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

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

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

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

16. The FDA made clear on their website:

> FDA believes that terms and conditions of an EUA issued under Section 564 preempt state or local law, both legislative requirement and common-law duties, that impose different or additional

> requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564…In an emergency, it is critical that the conditions that are part of the EUA or an order or waiver issued pursuant to section 564A – those that FDA has determined to be necessary or appropriate to protect public health – be strictly followed, and no additional conditions be imposed.

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

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

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

19. In April 2021, Houston Methodist, the Board of Directors, Robert A. Phillips, MD, PhD, and CEO Marc L. Boom, as Houston Methodist's policymaker, decided that the suffering of the few was justified by the windfall such suffering had on Houston Methodist's financial bottom line. Thus, Houston Methodist prescribed its own "required conditions" in defiance of Senator Edward Kennedy, Congress, and the rights of individuals under their authority as secured by the Constitution.

20. On April 01, 2021, CEO Boom issued a despicable illegal mandate that shocked the conscience. During the height of the pandemic, when hospitalization rates soared, and SARS-Cov-2 variants abounded, he subjected 29,000 employees to investigational drug use under threat of penalty outside of their free will and voluntary consent. Should the employee refuse his tyrannical rule, they were to be terminated from employment, thus causing harm to the ability of the hospital to provide a quality standard of healthcare to communities within the state of Texas.

21. Hiding behind the PREP Act as a liability cover, Houston Methodist, its policymaker, CEO Marc Boom, and the Board of Directors chose to engage in violations of federal law willfully. Their wanton conduct mirrors the abuses of power perpetrated against humanity that led Senator Kennedy and Congress to act in the early 1970s. Yet, half a century later, humanity in the United States still suffers due to the willingness of persons and entities such as Defendants to violate the lawful Constitutional ideal of treating all persons equally before the law.

II. Jurisdiction and Venue

22. This Court has original jurisdiction under 28 U.S.C. §§ 1331 and s1343.

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

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

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

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

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

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

III. Plaintiffs

29. Plaintiff, Jennifer Bridges, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

30. Plaintiff, Ceranise Alcindor, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 4, 2021.

31. Plaintiff, Rosemarie Aldaya, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

32. Plaintiff, Sandra Altamirano, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

33. Plaintiff, Dina Amaya, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

34. Plaintiff, Scott Anderson, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA

entities. He was terminated on June 21, 2021.

35. Plaintiff, Judith Andriko, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

36. Plaintiff, Mary Apacway, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

37. Plaintiff, Dajuana Armstrong, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 7, 2021.

38. Plaintiff, Kim Bane, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

39. Plaintiff, Edna Barrera, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

40. Plaintiff, Debra Baugh, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

41. Plaintiff, Latricia Blank, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

42. Plaintiff, James Borje, is an adult individual who all times pertinent resided in the

State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

43. Plaintiff, Laura Bowden, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

44. Plaintiff, Savannah Brazil, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

45. Plaintiff, John Brockus, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 21, 2021.

46. Plaintiff, Katherine Brol, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on April 20, 2021.

47. Plaintiff, Monika Bury, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on December 28, 2022.

48. Plaintiff, Amanda Castro, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

49. Plaintiff, Patrick Charles, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

50. Plaintiff, Tameka Clark, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

51. Plaintiff, Brian Clegg, is an adult individual who all times pertinent resided in the State of Texas, and was a vendor to The Methodist Hospital or one of its DBA entities. He was coerced to receive an EUA drug and has fear of long term adverse health consequences and was forced to resign in September 2021 when he refused to receive a booster.

52. Plaintiff, Sherry Colbert, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

53. Plaintiff, De'Anna Conway, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

54. Plaintiff, Brett Cook, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 5, 2021.

55. Plaintiff, JoAnn Crump-Creamer, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on November 3, 2022.s

56. Plaintiff, Zoretta Curry, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

57. Plaintiff, Julie DeTorre, is an adult individual who all times pertinent resided in

the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on March 31, 2021.

58. Plaintiff, Sierra Dockray, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on May 25, 2021.

59. Plaintiff, Stephanie Dunlap, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on June 25, 2021.

60. Plaintiff, Manuel Elizondo, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on November 3, 2022.

61. Plaintiff, Celina Elvir, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on May 13, 2021.

62. Plaintiff, Breann Emshoff, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 6, 2021.

63. Plaintiff, Brian Felgere, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on May 28, 2021.

64. Plaintiff, Elizabeth Flores, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on April 27, 2022.

65. Plaintiff, Rebekah Fontenot, is an adult individual who all times pertinent resided in the State of Texas, and was previously a physician with privileges at The Methodist Hospital or one of its DBA entities, and on July 16, 2021 was forced to resign her staff privileges due to her refusal to accept an EUA investigational drug.

66. Plaintiff, Michelle Fuentes, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on May 21, 2021.

67. Plaintiff, Gerardo Garza, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 7, 2021.

68. Plaintiff, Aquarius Grady, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

69. Plaintiff, Cedrick Green, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

70. Plaintiff, Ashton Hanley, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was constructively terminated on May 21, 2021.

71. Plaintiff, Tara Hansen, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on July 23, 2021.

72. Plaintiff, Stacey Hanzelka, is an adult individual who all times pertinent resided

in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on December 30, 2021.

73. Plaintiff, Tanisha Hatchet, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 7, 2021.

74. Plaintiff, Starla Haugenater, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on July 9, 2021.

75. Plaintiff, Philip Herin, is an adult individual who all times pertinent resided in the State of Texas, and is an employee of The Methodist Hospital or one of its DBA entities. He was coerced to receive an EUA drug and has fear of long term adverse health consequences.

76. Plaintiff, Shauna Herin, is an adult individual who all times pertinent resided in the State of Texas, and is an employee of The Methodist Hospital or one of its DBA entities. She was coerced to receive an EUA drug and has fear of long term adverse health consequences.

77. Plaintiff, Jade Hernandez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

78. Plaintiff, Luz Hernandez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 8, 2021.

79. Plaintiff, Sharon Hollier, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on July 14, 2021.

80. Plaintiff, Walter Infantes, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

81. Plaintiff, Dana Janoch, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

82. Plaintiff, Jason Jimenez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

83. Plaintiff, John Lasseigne, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

84. Plaintiff, Ashlee Leon-Lewis, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on September 11, 2021.

85. Plaintiff, Shayna Lincoln, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on May 9, 2021.

86. Plaintiff, Amanda Lofton, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

87. Plaintiff, Bennie Lopez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA

entities. He was terminated on June 22, 2021.

88. Plaintiff, Stacey Martinez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on August 3, 2022.

89. Plaintiff, Stefanie Martinez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on May 30, 2021

90. Plaintiff, Brian Matthews, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

91. Plaintiff, James McCann, is an adult individual who all times pertinent resided in the State of Texas, and was previously a vendor to The Methodist Hospital or one of its DBA entities. His vendor privileges were terminated on June 21, 2021.

92. Plaintiff, Becky Melcer, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

93. Plaintiff, Rogelio Mendez, Jr., is an adult individual who all times pertinent resided in the State of Texas, and is an employee of The Methodist Hospital or one of its DBA entities. He was coerced to receive an EUA drug and has fear of long term adverse health consequences.

94. Plaintiff, Kimberly Mikeska, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on July 7, 2021.

95. Plaintiff, Norma Miller, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on April 14, 2022.

96. Plaintiff, Yolunda Milton, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

97. Plaintiff, Ahmed Montgomery, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

98. Plaintiff, Robert Morin, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 6, 2021.

99. Plaintiff, Thomas Mulkey, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 20, 2021.

100. Plaintiff, Bob Nevens, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on April 29, 2021.

101. Plaintiff, Linda Pickard, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

102. Plaintiff, McKenli Pinkney, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its

DBA entities. She was terminated on June 22, 2021.

103. Plaintiff, Jonae Powell, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on November 19, 2021.

104. Plaintiff, Juan Ramirez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 22, 2021.

105. Plaintiff, Averi Reed, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

106. Plaintiff, Kimberly Rensi, is an adult individual who all times pertinent resided in the State of Texas, and was a vendor to The Methodist Hospital or one of its DBA entities. She was coerced to receive an EUA drug and has fear of long term adverse health consequences. Her vendor privileges were terminated on June 21, 2021.

107. Plaintiff, Amanda Rivera, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

108. Plaintiff, Peejayé Robins, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

109. Plaintiff, Maria Rodriguez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

110. Plaintiff, Betty Samuel, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on August 12, 2022.

111. Plaintiff, Diana Sanchez, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on March 18, 2022.

112. Plaintiff, Giovanni Savans, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on May 29, 2021.

113. Plaintiff, Leevetra Seals, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. Plaintiff was terminated on June 22, 2021.

114. Plaintiff, Maria Serrano, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

115. Plaintiff, Kara Shepherd, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

116. Plaintiff, Mandy Sisto, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

117. Plaintiff, Nicole Smith, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA

entities. She was terminated on June 22, 2021.

118. Plaintiff, Talisha Smith, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

119. Plaintiff, Anna Luz Soberano-Hathorn, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 7, 2021.

120. Plaintiff, Mary Louise Stephens, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 6, 2021.

121. Plaintiff, Freenea Stewart, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 27, 2021.

122. Plaintiff, Karene Tanner, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 8, 2021.

123. Plaintiff, Kelly Tate, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on March 21, 2023.

124. Plaintiff, Shelby Thimons, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

125. Plaintiff, Paige Thomas, is an adult individual who all times pertinent resided in

the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on June 4, 2021.

126. Plaintiff, Kaylan Timmons, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

127. Plaintiff, Kathy Tofte, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on June 4, 2021.

128. Plaintiff, Derek Trevathan, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was constructively terminated on July 16, 2021.

129. Plaintiff, Maria Trevino, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

130. Plaintiff, Terah Trevino, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

131. Plaintiff, Charles Varghese, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on November 24, 2021.

132. Plaintiff, Brandi Vincent, is an adult individual who all times pertinent resided in the State of Texas, and is an employee of The Methodist Hospital or one of its DBA entities. She was forced to receive the J&J injection and suffered cardiac issues and has fear of long term

adverse health consequences.

133. Plaintiff, Mathea Volesky, is an adult individual who all times pertinent resided in the State of Texas, and is an employee of The Methodist Hospital or one of its DBA entities. She was coerced to receive an EUA drug and has fear of long term adverse health consequences.

134. Plaintiff, Jennifer Warren, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on November 3, 2022.

135. Plaintiff, Alexandra Williams, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

136. Plaintiff, Karen Witt, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 22, 2021.

137. Plaintiff, Kidist Woldergabriel, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. Plaintiff was terminated on November 11, 2021.

138. Plaintiff, Latasha Woods, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was constructively terminated on April 24, 2021.

139. Plaintiff, Katie Yarber, is an adult individual who all times pertinent resided in the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. She was terminated on June 21, 2021.

140. Plaintiff, Ricardo Zelante, is an adult individual who all times pertinent resided in

the State of Texas, and was previously an employee of The Methodist Hospital or one of its DBA entities. He was terminated on June 21, 2021.

IV. Defendants

141. Defendant, The Methodist Hospital, doing business as The Methodist Hospital System ("Houston Methodist"), is a corporation duly authorized to conduct business within the State of Texas. Defendant may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136.

142. Defendant, Methodist Health Centers, doing business as Houston Methodist The Woodlands Hospital, doing business as Houston Methodist Willowbrook Hospital, doing business as Houston Methodist Sugarland Hospital, and doing business as Houston Methodist Baytown Hospital, among others, is a corporation duly authorized to conduct business within the State of Texas located at 17201 Interstate 45, The Woodlands, Montgomery County, Texas, 77385. Defendant may be served through its registered agent: CT Corporation System, 1999 Bryan St., Ste. 900, Dallas, Texas 75201-3136.

143. Defendant, Marc L. Boom, M.D. is the President and Chief Executive Officer of Houston Methodist. Marc L. Boom, M.D. is named as a defendant in his official and individual capacities.

144. Defendant, Robert A. Phillips, MD, PhD, FACC, is Houston Methodist's Executive Vice President & Chief Physician Executive, and President & CEO of Houston Methodist Physician Organization. The Chief Physician Executive is a required signatory to the CDC COVID-19 Vaccination Program Provider Agreement. Robert A. Phillips,

MD, PhD, FACC, is named as a defendant in his official and individual capacities.

145. The Houston Methodist voting Board of Directors is vested with the authority and responsibility of managing the affairs, control, direction, and disposition of the property and funds of the Corporation.

146. Voting Board Members Carlton E. Baucum, John F. Bookout, Emily A. Crosswell, Mary A. Daffin, Martha S. DeBusk, Gary W. Edwards, Juliet S. Ellis, Mark A. Houser, Bishop Scott Jones, Rev. Kenneth R. Levingston, Vidal G. Martinez, Constance M. Mobley, M.D., Ph.D., W. Benjamin Moreland, Gregory V. Nelson, Dr. Thomas J. Pace, III, Joe Bob Perkins, Dr. Edmund W. Robb, III, Stuart L. Solomon, M.D., Douglas E. Swanson, Jr., Spencer A. Tillman, David M. Underwood, Jr., Joseph C. "Rusty" Walter, III, Elizabeth Blanton Wareing, Ewing Werline, Jr., were all listed by the State of Texas as active board members at all times pertinent herein. Defendants are named in their official and individual capacities. Defendants are listed at the address 6565 Fannin St., Ste. D200 Houston, Texas 77030.

147. Defendant, Texas Workforce Commission, is a state agency that administers unemployment benefit services for the general public.

148. Defendant, Texas Health and Human Services, is a state agency that administers several state programs, including the CDC COVID-19 Vaccination Program.

149. Defendant, Texas Medical Board, is a state agency mandated to regulate the practice of medicine by licensed healthcare professionals. The Board is comprised of 12 physician members and seven public members appointed by the Governor and confirmed by the Senate.

V. History and Facts

150. Plaintiffs make no assertions regarding (1) whether a private employer mandating participation in a licensed vaccine is lawful or not, (2) the safety or efficacy of any drug, biologic, or medical device, or (3) natural immunity versus drug-induced immunization.

151. Plaintiffs adamantly assert, however, that an individual has the federally secured right to refuse the administration of an Emergency Use Authorization (EUA) drug (e.g., Pfizer BioNTech COVID-19 Vaccine), biologic, or device without incurring a penalty or losing a benefit to which they are otherwise entitled.

152. Because the EUA statute was created to allow the Secretary of HHS to authorize the use of a product for a purpose it is not already licensed for, medical countermeasure products fall under the investigational or experimental classification by statute.[1]

153. Because EUA products are, by definition, used only during times of emergency, the laws regulating these products are not litigated as much as more commonly used statutes, so a brief recitation of the origin and history of these laws should prove to be helpful.

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

154. The above-mentioned 1974 National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research[2] (hereinafter referred to as the "Commission").

155. Congress required the Commission to:

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

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

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

156. Congress further required the Commission to consider "the nature and definition of informed consent in various research settings."

157. On April 18, 1979, the Commission published its findings in the Federal Register in a report titled, "The Belmont Report."[3]

VI. The Belmont Report

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

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

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

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).

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

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

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

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

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

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

160. 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."

161. 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.

162. 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. The statutory authority for the HHS regulations derives from 5 U.S.C. 330v-(b); and 42 U.S.C. 289."[4]

[4] 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

VII. 45 CFR 46

163. 45 CFR 46 is entitled, "Protection of Human Subjects." Subpart A is entitled, "Basic HHS Policy for Protection of Human Research Subjects" and establishes that (a) the policy (for protection of human research subjects) "applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency..." (emphasis added).[5]

164. The nationwide COVID-19 vaccination program was 100% fully funded by the federal government, so it was "supported" by a "Federal department or agency."

165. HHS scripted 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."[6] (emphasis added). Research under this policy could include clinical trials, medical chart reviews by students, or periodic studies of medical products under 21 U.S.C. §360bb-3 authorization.

[5] 45 CFR 46.101(a)
[6] 45 CFR 46.102(l)

166. The CDC Provider Agreement, EUA authorizations, and CDC's Advisory Committee on Immunization Practices (ACIP) recommendations demonstrate how systematic of an investigation the nationwide COVID-19 vaccination program is.

167. The CDC Provider Agreement provides that Defendants "must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP)."

168. 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 postauthorization vaccine safety monitoring," which 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.[7] The use of this information by ACIP demonstrates how the data collected "contributes to generalizable knowledge."

169. The ACIP recommendations[8] referenced in Footnote 1 of the CDC Provider Agreement[9] instruct Defendants to:

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[7] 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.

[8] *Id*., at 1347.

[9] 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.

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

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

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

G. Inform vaccine recipients about V-Safe, the CDC's vaccine safety monitoring system that the CDC says "helps us monitor the safety of COVID-19 vaccines for everyone."[10]

170. 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

Organization must monitor such identified guidance for updates. Organization must comply with such updates."

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

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.

171. Based on the detailed, organized, and methodical way 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."

172. A "human subject" is broadly defined as (1) a living individual, (2) from whom data is obtained and used,[11] and (3) from whom identifiable private information is known.[12]

173. HHS regulations define[13] 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:

[11] 45 CFR 46.102(e)(1)(i)
[12] 45 CFR 46.102(e)(1)(ii)
[13] "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)

> (i) Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or
>
> (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
>
> (2) ***Intervention*** includes physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
>
> (3) ***Interaction*** includes communication or interpersonal contact between investigator and subject.
>
> (4) ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
>
> (5) ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the information.
>
> (6) ***An identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the biospecimen. (Emphasis in original.)

174. Drugs, biologics, and devices authorized under 21 U.S.C. §360bbb-3 are classified by the FDA as medical research products according to their labeling. They have no legal indication to treat, cure, or prevent any disease according to their labeling. Moreover, if a product is licensed by the FDA for its intended use under the declared emergency, that license prohibits the FDA from issuing an EUA. (21 U.S.C. §360bbb-3(c)(3))

175. 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."

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

177. On January 19, 2021[14] the Secretary established mandatory conditions that Pfizer and emergency stakeholders (distributors, manufacturers, etc.) must follow involving research activities meeting the definition under 45 CFR 46 in the Emergency Use Authorization letter.

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

* * *

> F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
>
> - Serious adverse events
> - Cases of Multisystem Inflammatory Syndrome in children and adults
> - Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer, Inc.

[14] 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

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

179. 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 historic entries for a drug and the sheer involvement of the medical community to add to the generalizable knowledge of the product.

180. 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.

181. As of April 01, 2021, when Defendants issued their mandate, all COVID-19 drugs were undergoing clinical trials and were already under an Institutional Review Board, which must comply with 45 CFR 46 and the FWA (see discussion *infra*).

182. 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.

183. 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).

[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."

184. HHS ensured that all research activities would comply with Belmont Report's ethical requirements: (1) "Department or agency heads retain final judgment as to whether a particular activity is covered by this policy, and this judgment shall be exercised consistent with the ethical principles of the Belmont Report"[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]

185. Therefore, Congress effectually ensured that anytime the federal government participates in a research activity involving a human with an investigational drug, biologic, or medical device, it will comply with the ethical principles of the Belmont Report.

186. Therefore, the intent of Congress was to give the Belmont Report the force of law through 45 CFR 46 and the Federal Wide Assurance agreement (see discussion, *infra*).

VIII. Legally Effective Informed Consent

187. 45 CFR § 46.116 sets forth the Belmont Report's "adequate standards" of informed consent[18], 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

[16] 45 CFR § 46.101(c)
[17] 45 CFR § 46.101(i)
[18] The Belmont Report and 45 CFR §46.116 contain the only definition for what Congress deems to be legally effective informed consent. Therefore, when statutes explicitly or implicitly mandate a person to give their legally effective informed consent then these definitions must be understood as the intent of Congress.

informed consent of the subject or the subject's legally authorized representative; (emphasis added)

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

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

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

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

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

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

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

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

189. "Sanctions" that result in a penalty or loss of benefits for refusing to take an investigational drug (e.g., Pfizer-BioNTech COVID-19 Vaccine) nullify legally effective informed consent.

190. Congress preempted state laws when products are authorized under 21 U.S.C. §360bbb-3 and under PREP Act immunities (see *infra*) to ensure that no authority would have the right to apply a sanction for non-participation.

191. Only when authorities comply with 45 CFR 46 and the ethical principles of the Belmont Report can an opportunity exist for an individual to give their legally effective informed consent according to 45 CFR § 46.116(a)(1).

192. 45 CFR 46 applies to all federal agencies, departments, and the military (45 CFR § 46.101(a)). Additionally, twenty federal agencies incorporated 45 CFR 46 specifically into their regulatory framework.[19]

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

193. Through the Federal Wide Assurance (FWA) agreement (see *infra*), all U.S. States and Territories (i.e., state health agencies have FWA agreements) have agreed to comply with 45 CFR 46 and the Belmont Report's ethical guidelines.

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

IX. ICCPR Treaty

195. In 1992, the United States Senate ratified the International Covenant on Civil and Political Rights Treaty (ICCPR).[20] 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).

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

[20] 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

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

198. 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."[21]

199. 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."

200. 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.[22]

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[21] 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

[22] "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

201. 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.

202. 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: article 6 (right to life), article 7 (prohibition of torture or cruel, inhuman or degrading punishment, or of medical or scientific experimentation without consent)[23] (emphasis added)."

203. Article 4.2 of the ICCPR Treaty established the restriction of derogation of informed consent rights as a peremptory norm, potentially opening Defendants up to criminal liability for issuing and executing mandates involving non-consensual medical experimentation.[24]

204. It cannot be reasonably disputed that Defendants subjected individuals under their authority to medical experimentation outside of their free will and voluntary consent.

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[23] "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)

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

When Plaintiffs refused to participate, Defendants intentionally inflicted "cruel," "inhumane," and "degrading" treatment in violation of federal law and the International Covenant on Civil and Political Rights Treaty.

205. Specific examples of the cruel, inhumane, and degrading treatment that Houston Methodist inflicted upon the Plaintiffs herein include employment termination, unpaid leave, mandatory testing (even for teleworkers), public humiliation, segregation, isolation, gaslighting, and weekly emails from executives praising those who accepted the drugs and demeaning those who did not.

206. The only COVID-19 drugs made available to the American public are now, and always have been classified by the FDA as investigational drugs. No FDA-licensed COVID-19 Vaccines have been introduced into commerce for general commercial marketing since the pandemic's beginning through the filing of this Amended Complaint.

207. On December 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine was granted an Emergency Use Authorization.[25]

208. 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

[25] 86 Fed.Reg. 5200, Jan. 19, 2021

Vaccine[26]), and the FDA confirmed that Pfizer's product "is an investigational vaccine not licensed for any indication."

209. 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]

210. 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]

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

212. 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

[26] *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."
[27] 86 Fed.Reg. 5211, Jan. 19, 2021
[28] 86 Fed.Reg. 28608, May 27, 2021

drug in the course of medical practice." (21 CFR 312.3 "Clinical investigation") (emphasis added).

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

214. 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 EUA medical countermeasure products must not be via federal statute. (See 21 USC 355a, et seq, 21 USC 360bbb-3(a)(2)(a,b))

215. Therefore, consensual medical experimentation involving COVID-19 investigational drugs can only exist under conditions that ensure individuals are free from outside pressures to participate.

216. Houston Methodist's COVID-19 immunization mandate, relying exclusively on experimental medical products, violated each plaintiff's Constitutional rights under the 14th Amendment, federal statutes under Section 564 and 45 CFR 46, Article VII of the ICCPR Treaty, and the Belmont Report.

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

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

218. 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 the legal obligations of the United States government are met.

219. 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

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

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

222. Making it patently clear of their intent to protect Americans from medical research abuses, Congress drafted 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).

223. Section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C §360bbb-3[29] authorizes the HHS Secretary to grant emergency expanded access protocols to (1) FDA-licensed products that are utilized for unlicensed uses or (2) products the FDA has not licensed for general commercial marketing.

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

> (i)(II) the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown;"
>
> (i)(III) the option to accept or refuse administration of the product;"
>
> (i)(III) the consequences, if any, of refusing administration of the product" and
>
> (i)(III) the alternatives to the product that are available and of their benefits and risks."[30]

225. Informing the individual of the risks, alternatives, benefits, and health consequences of the product provides that individual with the quality information required to give legally effective informed consent.[31]

226. Congress requires healthcare professionals to inform the individual of "the option to accept or refuse administration of the product," meaning the healthcare

[29] Because it is commonly referred to by its FDCA section number, and for the sake of simplicity, reference is hereinafter made to Section 564, rather than by its United States Code citation.
[30] 21 U.S.C. 360bbb-3(e)(1)(A)
[31] 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.

professional is required by Congress to inform the individual of his or her legal rights under Section 564.

227. 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.

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

229. The right to decide 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, and thus their rights have been infringed upon.

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

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

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

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

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

232. 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))

233. 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."

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

235. 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,

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

236. To ensure individuals are protected when they are offered EUA medical products, Congress was explicit in that "[n]othing in this section [564] provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section (42 U.S.C. 360bbb-3(l))." (emphasis added)

237. Congress, therefore, prohibits governments and volunteering participants from having the authority to require any person to participate in any Section 564 activity, at any time, under any statute, regulation, or state policy or custom.

238. The explicit purpose of this statutory restriction is to ensure that no person is under a "sanction," "coercion," "undue influence," or "unjustifiable pressure"[32] to participate. If individuals are under those pressures, then no federal funds could be expended for the administration of an EUA product, nor could any healthcare provider acting on behalf of the federal government obtain any individual's Legally Effective Informed Consent.

239. The individual has the right to accept the product, and the healthcare professional has the authority to administer the product. Still, neither person is required to act on the demands of the other. Congress established a guideline requiring both the

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

healthcare professional and the individual to mutually agree to the process to meet the legal requirements of Section 564.

240. 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 product.

241. Therefore, if the HHS Secretary is the only person authorized to establish the conditions under which persons can take or use EUA medical products, then Houston Methodist had no authority to amend the Scope of Authorization requiring that which Congress prohibits.

242. Therefore, when Houston Methodist, Marc L. Boom, Robert A. Phillips, and the Board of Directors established a policy requiring individuals under their authority to take a mandated, COVID-19 EUA investigational drug, they were required by federal law to ensure that (1) licensed products existed to meet the legal requirements of the mandate, and (2) individuals were to be informed that they were under no obligation to take unlicensed COVID-19 EUA drugs, and that they would not incur a penalty nor lose any benefit to which they were otherwise entitled if they chose not to take existing COVID-19 EUA investigational drugs. They did neither.

243. Houston Methodist decided to violate federal law, contractual duties, and the 14th Amendment rights of individuals under their authority when they issued a mandate before the availability of a truly licensed COVID-19 vaccine.

XI. HHS EUA Precedent

244. On January 28, 2005, HHS issued the first EUA[33] under its new Section 564 authority. The military requested EUA protocols for Anthrax Vaccine Adsorbed (AVA), to be utilized by civilians and service members. HHS stated, "The issuance of this Authorization for the emergency use of AVA is the first time that the EUA authority is being used. FDA intends to explain 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."

245. 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

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

> 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.[34]

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

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

XII. Judicial EUA Precedent

248. 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

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

> 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.)

249. 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 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.

250. 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)

251. *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.

XIII. Federal Wide Assurance (FWA)

252. 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.

253. 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…"[35]

254. 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.

255. 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

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

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).

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

257. 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.

258. 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 Houston Methodist penalized them for refusing to take EUA products (i.e., investigational drugs).

259. 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.

260. The FWA agreement requires Houston Methodist to assure potential participants that they will not incur a penalty or lose a benefit to which they are otherwise entitled for refusing participation.[36]

261. The benefits to which potential and participating individuals are otherwise entitled include, but are not limited to:

A. continued employment,

B. 4th Amendment rights,

C. 5th Amendment rights,

D. paid time off,

E. bonuses,

F. raises,

G. health insurance,

H. 401k contributions,

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

263. Therefore, when Houston Methodist punished third-party beneficiaries for refusing the administration of an investigational drug, Houston Methodist:

A. activated the terms and conditions of the contract,

[36] "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.

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

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

264. The 14th 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.

265. Houston Methodist and other Defendants violated the Equal Protection Clause when they coordinated with the Texas Workforce Commission to deny unemployment benefits to Plaintiffs solely on the basis of them exercising a federally secured option of refusing administration of an investigational drug, thus violating the Unconstitutional Conditions Doctrine (see *infra*).

266. The Unconstitutional Conditions Doctrine reflects the U.S. Supreme Court's repeated pronouncements that the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests."[37]

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

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

interest in freedom of speech. For if the government could deny a benefit to a person because of his constitutionally protected speech or associations, his exercise of those freedoms would in effect be penalized and inhibited. This would allow the government to 'produce a result which (it) could not command directly.'"[38] "Such interference with constitutional rights is impermissible."[39]

268. Based on longstanding Supreme Court precedent, the government is prohibited from denying individuals the right to receive unemployment benefits because the individual exercised his or her constitutionally protected right to bodily autonomy by refusing investigational drug administration.

269. The State denying employment benefits to Plaintiffs on the sole basis of refusing Section 564 countermeasure products demonstrates State policy and custom (see *infra*) under which Houston Methodist acted when retaliating against Plaintiffs exercising their Section 564 option to refuse.

XIV. PREP Act & Section 564 Preemption of State Law

270. In 2005, Congress passed the Public Readiness and Emergency Preparedness Act, hereafter referred to as the PREP Act (42 USC 247d-6d and 42 USC 247d-6e), to provide immunities for persons volunteering for "covered" activities. Accordingly, the HHS Secretary has issued a COVID-19 PREP Act declaration at 85 FR 15198.

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

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

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

273. Congress expressly crafted language preempting state law (42 USC 247d-6d(b)(8)), which provides, in pertinent part:

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

274. Congress also expressly established that the plan to administer a covered countermeasure (i.e., any of the EUA COVID-19 investigational drugs) shall be voluntary. Specifically, Congress stated the following at 42 USC 247d-6e(c), in pertinent part:

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

275. The purpose of Section 564 informing the individual of "the significant known…risks of such use, and of the extent to which such benefits and risks" and of "the alternatives to the product that is available and of their benefits and risks" is because the individual is not only consenting to be injected with an investigational drug, but they must also consent to participate in a legally binding agreement under the terms and conditions established by Congress.

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

A. forfeiture of civil litigation rights resulting from injuries;[40]

B. allowing their private identifiable information to be collected and used for a variety of purposes by unknown persons;[41]

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

D. allow the data collected about their adverse events to be utilized by researchers for unknown purposes and for eternity,[42]

E. agree to assume greater risks to their safety, health, and legal rights.[43]

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

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

[42] 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.

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

277. Houston Methodist cannot coerce individuals under a threat of penalty to enter into a legally binding agreement outside of their free will and voluntary consent. In fact, Congress expressly preempted all state and local laws, regulations, and rules to ensure no individual would be coerced into participating in Defendants' legally binding agreement.

278. Congress was explicit when it pronounced that "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that…is different from, or is in conflict with, any requirement applicable under this section; and…or to any matter included in a requirement applicable to…the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]" (42 USC 247d-6d(b)(8),(A),(B)).

279. 21 U.S.C. §360bbb-3 is under 21 U.S.C. 301. Therefore, the PREP Act preemption extends to "the option to accept or refuse," which must only be under voluntary conditions.

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

281. Under § 247d-6d(b)(8)(A), "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any

provision of law or legal requirement that is different from, or is in conflict with, any requirement applicable under this section."

282. The FDA issued an opinion[44] regarding federal preemption of 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.'

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

> FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564. Similarly, an order or waiver issued under section 564A and pre-positioning under section 564B preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements related to the activity authorized under sections 564A or 564B. To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular medical product within the scope of the declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and 'conflicts with the exercise of Federal authority under [§ 564].' The same rationale applies to an order or waiver issued under section 564A and pre-positioning of an MCM under section 564B (emphasis added.)"

283. However, although no express preemption language exists within Section 564 statutes, the field preemption doctrine demonstrates that Congress created a pervasive regulatory scheme designed only to be regulated by the federal government. Moreover,

state laws in conflict with Section 564's regulatory scheme pose an obstacle to the goals of the federal government's medical countermeasure program.

284. State laws affording private employers legal authority to interfere with the federal statutory requirements of Section 564 and the PREP Act (e.g., at-will employment doctrine) violate the Supremacy Clause of the United States Government.

285. Houston Methodist's mandate of involuntary participation and corresponding actions to coerce, threaten, and unduly pressure Plaintiffs into taking a COVID-19 investigational drug changes the "voluntary nature of the program" into an obligatory condition, depriving Plaintiffs of their federally protected authority "to accept or refuse" without consequence. Houston Methodist's actions demonstrate that it attempted to unlawfully usurp the regulatory power of the United States government instead of properly implementing the emergency medical countermeasure protocols with which it voluntarily agreed to comply.

286. Therefore, Congress expressly claimed preemption for the PREP Act and thereby Section 564, and thus Houston Methodist is expressly prohibited from acting in a fiat manner to establish conditions regarding participation in the use of a covered countermeasure product contrary to federal statutes, agency regulations, and the Scope of Authorization outlined in the FDA-issued EUA letter to the manufacturer covering all EUA activities.

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

A. coercing employees to surrender their federally secured right "of the option to accept or refuse administration of the [PREP Act] product,"

B. usurping the HHS Secretary's authority to "[a]ppropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use, (emphasis added),"

C. requiring that which Congress explicitly prohibits: "Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section,"

D. interfering with the explicit requirement of Congress that "[t]he Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure (e.g., Pfizer BioNTech COVID-19 Vaccine)…are educated with respect to contraindications, the voluntary nature of the program…"(emphasis added) (42 U.S. Code §247d-6e(c)).

288. The immunities granted to volunteering participants require the legally effective informed consent of any person acting in any activity specifically because they are denied relief for resulting damages from the program's involvement.

XV. CDC COVID-19 Vaccination Program Provider Agreement

289. The Centers for Disease Control (CDC) states that "[a]t this time, all COVID-19 vaccine in the United States has been purchased by the U.S. government (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remains U.S. government property until administered to the recipient. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other

possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law." [See Exhibit A.]

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

291. Before the CDC accepts a person or entity as a Provider in the CDC Vaccination Program, that person or entity is required to sign the CDC COVID-19 Vaccination Program Provider Agreement (hereinafter referred to as the "Provider Agreement").

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

293. The Provider Agreement requires the organization to assign a person or persons who will be under a legal obligation to ensure the program is carried out effectively, declaring, "For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions

specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements."

294. "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).

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

296. The executive branch of the government is not exempted from Section 564 requirements nor laws and regulations protecting humans involved in investigational medical products under emergency access protocols.

297. Therefore, when the executive branch of the government chose to purchase all COVID-19 vaccines (i.e., licensed and unlicensed COVID-19 drugs), they were required to ensure all applicable laws associated with each drug's classification were adhered to by all volunteering participants.

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

299. Therefore, the Provider Agreement does not replace the laws and regulations governing any EUA drug classification. Rather, it is, in addition to those laws, added as an extra layer of legal obligations required of volunteer participants.

300. Houston Methodist, Mark L. Boom, and Robert A. Phillips signed the Provider Agreement agreeing to comply with all "applicable laws" regarding EUA products and PREP Act activities.

301. Houston Methodist agreed to inform individuals under their authority of their legal rights to accept or refuse EUA medical products.

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

303. Houston Methodist, by signing the Provider Agreement, agreed to waive applicability of all state and local laws that are "in conflict" with the terms and conditions of the Provider Agreement or requirements applicable to the PREP Act and Section 564 protocols.

304. Houston Methodist agreed to directly benefit individual potential vaccine recipients under their authority by signing the Provider Agreement.

305. The Provider Agreement requires that all volunteer participants:

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

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

C. "Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine,"

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

306. The EUA fact sheet is required because the Executive Branch of the government is the sole sponsor of EUA products[45], and federal law requires them to obtain the legally effective informed consent of each individual prospectively. Moreover, the HHS Secretary requires each recipient to be given the fact sheet for each EUA COVID-19 investigational drug from which the federal branch of government cannot exempt itself from. The fact sheet is required to act as the informed consent process for persons ascertaining whether or not they will participate in the EUA product.

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

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

A. "This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe)

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

that may otherwise be applicable and that provide additional protections for human subjects" (45 CFR 46.101(g));

B. Additionally, federal law declares, "The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective" (45 CFR 46.116(i));

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

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

XVI. Nature of Case

310. This is a case for damages against Houston Methodist, Policymaker CEO Marc Boom, Chief Physician Executive Robert Phillips, and the Board of Directors, who at all times pertinent herein served as State Actors, and the Texas Workforce Commission, the Texas Department of Health and Human Services, and the Texas Medical Board, for illegally and unconstitutionally penalizing individuals exercising their statutory right to refuse an investigational drug without incurring a penalty or losing a benefit to which they are otherwise entitled. The State of Texas had outsourced its Centers for Disease Control (CDC) emergency COVID-19 immunization program to Houston Methodist, among

others, in what they believed was an effort to combat the spread of the SARS-CoV-2 virus. As a result, Houston Methodist acted under color of state law at all times pertinent and abridged Plaintiffs' constitutional rights of equal protection and due process when Plaintiffs refused to participate in the use of those products.

XVII. Statement Of Facts

311. Houston Methodist is a licensed "general hospital" provider under Texas Health and Safety Code Chapter 241.

312. Houston Methodist is owned by the Texas Annual Conference of the United Methodist Church under the leadership of Bishop Cynthia Harvey.

313. Houston Methodist employees include healthcare professionals licensed by the State of Texas under Title 26 §554.101 of the Texas Administrative Code.

314. The State of Texas licenses, regulates, and oversees the operations of Houston Methodist.

315. Houston Methodist operates facilities throughout Texas and is a participating immunization provider for the Texas Department of State Health Services immunization program.

316. Immunization program administration constitutes a public function of the State of Texas.

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

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

319. The CDC works through existing state immunization programs whereby the State contracts with licensed medical facilities and healthcare professionals to administrate and administer the federal government's COVID-19 program and property.

320. Houston Methodist is a voluntary participant in the CDC COVID-19 Vaccination Provider Program. The program authorizes licensed medical facilities and healthcare professionals to administer licensed and unlicensed COVID-19 drugs under the PREP Act (42 USC 247d-6d) and 21 U.S.C. §360bbb-3 emergency authorization.

321. The CDC COVID-19 Vaccination Program constitutes an exclusive public function of the State.[46]

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

323. On April 01, 2021 Houston Methodist, Marc L. Boom, Robert A. Phillips, and the Board of Directors, acting under the color of law, illegally subjected Plaintiffs to investigational drug use under threat of penalty outside of Plaintiffs' free will and voluntary consent.

[46] "The first step to becoming a COVID-19 vaccine provider is registering through EnrollTexasIZ.dshs.texas.gov. Only providers registered through this site can receive and administer COVID-19 vaccine in Texas." — Vaccination Provider Enrollment, Texas DSHS. Texas.gov. Published 2019. Accessed June 2, 2023. https://www.dshs.texas.gov/immunization-unit/covid-19/vaccination-provider-enrollment

324. Houston Methodist mandated all employees to inject a COVID-19 investigational drug into their body or face imminent illegal punitive actions.

325. Houston Methodist's actions led to (1) a deprivation of both substantive and procedural due process rights under the 14th Amendment, (2) a deprivation of equal protection rights under the 14th Amendment, and (3) a deprivation of rights guaranteed under the Spending Clause.

XVIII. State Action Doctrine

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

327. The State's COVID-19 immunization program relies exclusively on investigational new drugs under federal statutes governing their administration.

328. In *Maine v. Thiboutot*, 448 U.S. 1 (1980), the court held that "Even were the language ambiguous, however, any doubt as to its meaning has been resolved by our several cases suggesting, explicitly or implicitly, that the § 1983 remedy broadly encompasses violations of federal statutory as well as constitutional law."

329. Additionally, in a decision dated June 8, 2023, just 13 days before the filing of this Amended Complaint, the United States Supreme Court in *Health and Hospital Corporation of Marion Cty. V. Talevski*, 599 U.S. ___ (2023)[47], stated, "Although federal

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

statutes have the potential to create §1983-enforceable rights, they do so under this Court's precedents only when the statute unambiguously confers those rights."

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

331. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) contains a required condition of the Secretary "to ensure that individuals to whom the product is administered are informed—"of the option to accept or refuse administration of the product."

332. Therefore, the intended beneficiary class is those considering whether or not to participate in the EUA medical countermeasure. The "option to accept or refuse" is unambiguous conferral of power upon the individual considering participation.

333. 45 CFR 46 was developed by the express request of Congress to confer protective benefits for persons participating in medical research activities (see note #160).

334. The CDC COVID-19 Vaccination Program Provider Agreement is medical research activity requiring 45 CFR 46 compliance (see note #164).

335. 45 CFR 46 §116 provision "use clear rights creating language, and speaks in terms of the persons benefited," and has an "unmistakable focus on the benefited class." (See note #186)

336. Article VII of the ICCPR Treaty states in clear rights conferring language that no person may be subjected to medical experimentation without their consent. (See note #194)

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

338. 45 CFR 46 §122 states, "Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied." By direct nexus, this restriction is rights conferring language for any spending legislation enacted by Congress involving this section.

339. 10 U.S.C. § 980 states, "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless - the informed consent of the subject is obtained in advance."

340. Although there are many rights conferring items contained in the above provisions of law, the most notable is that no person can incur a penalty or lose a benefit

to which they are otherwise entitled when refusing to accept an investigational medical product, irrespective of its authorized expanded access protocol.

341. The purpose of these provisions directly relates to the Belmont Report's ethical principles of (1) "Respect for Person," (2) "Beneficence", and (3) "Justice," for persons involved in any research element. The Belmont Report is required compliance for every federal agency, department, and military. Moreover, not a single penny of federal funding can be expended on research activities if Belmont Report's ethical principles are not clearly established prospectively.[48] (see note #157)

342. The U.S. Supreme Court has held that "to act 'under color of' state law for § 1983 purposes does not require that the defendant be an officer of the State. It is enough that he is a willful participant in joint action with the State or its agents. Private persons, jointly engaged with state officials in the challenged action, are acting "under color" of law for purposes of § 1983 actions."[49]

343. Texas required Houston Methodist to be authorized by them before they were allowed to participate in the State's COVID-19 emergency medical countermeasure program.

344. The State required Houston Methodist to sign the CDC COVID-19 Vaccination Program Provider Agreement.

[48] Houston Methodist and Texas HHS's FWA agreement are their promise to comply with the Belmont Report's ethical principles and adherence to 45 CFR 46.
[49] *Dennis v. Sparks*, 449 U.S. 24 (1980)

345. The State provided Houston Methodist with rights and duties "with an unmistakable focus on the benefitted class."[50]

346. Houston Methodist chose to act on behalf of the State out of their free will and voluntary consent.

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

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

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

350. The State only authorizes healthcare professionals they license to administer the medical countermeasure products.

351. The State only authorizes medical facilities and pharmacies they license to administrate the COVID-19 immunization program.

352. The federal government owns all doses of COVID-19 investigational drugs. (See note #289)

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

[50] The CDC Vaccination Program Provider Agreement, 45 CFR 46, 21 U.S.C. §360bbb-3, FWA, among others.

354. The State is required to obtain the legally effective informed consent of those considering participating in the use of federally owned investigational drugs.

355. Houston Methodist and the State are in a symbiotic relationship to obtain the legally effective informed consent of potential recipients for the success of the State's COVID-19 immunization program.[51]

356. The State did not provide for an alternative to comply with federal statutory obligations of obtaining legally effective informed consent apart from authorized private parties engaging in that state action on its behalf.

357. Houston Methodist is required to update the vaccination status of individuals on behalf of the State.

358. Houston Methodist exclusively relies on the State for full reimbursement of COVID-19 vaccination patients.

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

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

360. 100% of all private parties participating in the State's COVID-19 immunization program are "clothed with the authority of state law" to access investigational medical products, administer those medical products, and bill the State for those activities on behalf of State authority.[52]

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

362. The State's COVID-19 emergency medical countermeasure program is so intimately regulated, licensed, and funded that "The State has so far insinuated itself into a position of interdependence…that it must be recognized as a joint participant in the challenged activity" *Burton v. Wilmington Pkg. Auth*, 365 U.S. 715, 81 S. Ct. 856 (1961).

363. The State of Texas received an estimated $321 billion in COVID-19 related federal funding.[53]

364. "If a private actor is functioning as the government, that private actor becomes the state for purposes of state action."[54]

365. The State required Houston Methodist to accept any person as a COVID-19 immunization patient as a public function, irrespective of the individual's ability to pay.

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

[53] https://www.pgpf.org/understanding-the-coronavirus-crisis/coronavirus-funding-state-by-state#state-budget-tool

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

366. The State restricted Houston Methodist from conditioning access to the COVID-19 emergency immunization program upon an individual obtaining additional medical services.

367. Houston Methodist administered more than 1 million doses of COVID-19 investigational drugs to the public.[55]

368. The government exclusively funds the CDC COVID-19 Vaccination Program.

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

> "we must inquire 'whether there is a sufficiently close nexus between the State and the challenged action of the regulated entity that the action of the latter may fairly be treated as that of the State itself." *Jackson v. Metropolitan Edison Co.,* 419 U.S. 345, 351, 95 S.Ct. 449, 453, 42 L.Ed.2d 477 (1974); *accord, Flagg Brothers, Inc. v. Brooks,* 436 U.S. 149, 157, 98 S.Ct. 1729, 1733, 56 L.Ed.2d 185 (1978). In holding that a privately-owned utility's termination of service is not "state action", the Court in *Jackson* makes it clear that state involvement without state responsibility cannot establish this nexus. *See* 419 U.S. 358, 95 S.Ct. 457. A state becomes responsible for a private party's act if the private party acts (1) in an exclusively state capacity, (2) for the state's direct benefit, or (3) at the state's specific behest. It acts in an exclusively state capacity when it "exercises powers traditionally exclusively reserved to the state[,]" 419 U.S. 352, 95 S.Ct. 454; for the state's direct benefit when it shares the rewards and responsibilities of a private venture with the state, *see id.,* 357-58, 95 S.Ct. 456-57, *Burton v. Wilmington Parking Authority,* 365 U.S. 715, 723-24, 81 S.Ct. 856, 860-61, 6 L.Ed.2d 45 (1961); and at the state's specific behest when it does a particular act which the state has directed or encouraged."

370. The State of Texas determines:

[55] https://catalyst.nejm.org/doi/full/10.1056/CAT.22.0017

A. who can participate in the program,

B. the conditions under which the person can participate,

C. who can administer emergency countermeasure products,

D. who can receive emergency countermeasure products, and

E. the rules and regulations governing the administration of the emergency countermeasure program,

F. who will obtain the legally effective informed consent on their behalf.

371. Houston Methodist is under express COVID-19 vaccination protocols by the State and the CDC to include[56]:

A. Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP),

B. Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority,

C. Organization must submit Vaccine-Administration Data through either [a] the immunization information system (IIS) of the state and local or territorial jurisdiction or [b] another system designated by CDC according to CDC documentation and data requirements,

D. Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law,

E. Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other

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

constituent products and ancillary supplies that the federal government provides without cost to Organization,

F. Organization **must** administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees, (emphasis added)

G. Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative,

H. Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines,"

I. Organization must comply with CDC requirements for COVID-19 Vaccine management,

J. Organization must report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction,

K. Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses,

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

M. Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards,

N. Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine (emphasis added) and

O. Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws. (emphasis added).

372. The State of Texas, via the CDC COVID-19 Vaccination Program Provider Agreement, must also ensure authorized agents of the State comply with 21 U.S.C. §360bbb-3 statuary requirements: ensure the healthcare professional prospectively informs the recipient of (a) the significant known and potential benefits and risks of the use of the product, (b) the option to accept or refuse administration of the product (c) the health consequences of refusing the product, (e) the alternatives, risks, and potential benefits.

373. The State of Texas must comply with the HHS Secretary's regulatory framework outlined in each EUA's Scope of Authorization[57], adding additional entanglement between Defendants and the State. See Brentwood Academy v. Tennessee Secondary School Athletic Assn., 531 U.S. 288 (2001)

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

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

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

376. The CDC Provider Agreement states, "Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine" (emphasis added)"

377. 21 U.S.C. §360bb-3 (a/k/a Section 564 of the FDCA, which authorizes EUA products under "applicable requirements" of the FDA) contains rights conferring language to accept or refuse EUA medical products without incurring a penalty or losing a benefit to which they are otherwise entitled.

378. Legally effective informed consent required Houston Methodist to ensure that they did not place individuals under a "sanction," "coercion," "undue influence," or "unjustifiable pressures" to participate. (See note #157)

379. The COVID-19 investigational drugs are federal property and may not be administered to persons without first obtaining their legally effective informed consent.

380. The CDC required Defendants to obtain the legally effective informed consent of individuals on its behalf when offering COVID-19 investigational new drugs via its Vaccination Program Provider Agreement.[58]

381. The CDC informed Defendants that "before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.[59]"

382. Therefore, the federal government choosing to purchase all COVID-19 drugs under 21 U.S.C. §360bb-3 authority is Constitutionally obligated to obtain the legally effective informed consent of individuals prospectively. The State, by extension, is also required to comply with the federal requirement and may not delegate this function to a private party without also delegating the Constitutional obligation.

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

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[58] Number 12(a) of the Agreement states "Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine." This section requires adherence to 21 U.S.C. §360bbb-3 (Section 564) protocols.

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

384. Therefore, the constitutional duty placed upon the State is to ensure that all persons choosing to accept or refuse are treated equally before the law. Moreover, if a person is not treated equally before the law, then that unequal treatment must be conditioned upon due process.

385. Houston Methodist previously assured the Health and Human Services' Office of Human Research Protections that they would never violate the ethical principles outlined in the Belmont Report or their obligations under 45 CFR 46. In return for that assurance, HHS awarded them the right to participate in federal funding by providing them with the Federal Wide Assurance Agreement compliance number FWA00000438.

386. Houston Methodist gave similar assurances to HHS via their Institutional Review Boards (IRB) under the assigned numbers IRB00010841, IRB00006784, and IRB00005005.

387. IRBs are governed by 45 CFR 46 and must govern research activities under their authority accordingly.

388. Texas Health and Human Services provided their assurance to HHS and accordingly received the federal agreement number FWA00008616 signifying a legally binding agreement between Texas and the federal government.

389. Houston Methodist oversees (1) $264 million in research projects, (2) 2,270 credentialed researchers, (3) 1,430 clinical protocols, and (4) 530 active clinical trials and is one of the top 10 medical research institutions in the nation.[60]

[60] Houston Methodist Statistics | Houston Methodist. Houstonmethodist.org. Published 2019. Accessed June 2, 2023. https://www.houstonmethodist.org/research/about-us/facts-stats/

390. Houston Methodist was well aware of their legal, ethical, and contractual obligations to ensure that no person was under outside pressure to participate in the use of an investigational product, irrespective of the expanded access protocols the product was under.

391. Houston Methodist was well aware of the statutory rights of individuals under their authority to refuse EUA medical products without penalty or losing a benefit to which they were otherwise entitled, thus restricting Houston Methodist from issuing a mandate to participate.

392. Houston Methodist had a constitutional duty under the 14th Amendment to ensure persons refusing drugs, biologics, or devices falling under the authority of (1) 21 U.S.C §360bbb-3, (2) Article VII ICCPR Treaty, (3) Texas Health and Human Services FWA00008616, (4) 45 CFR 46, (5) Prep Act, and (6) the CDC COVID-19 Vaccination Program Provider Agreement, were not deprived of their equal protection rights or liberty or property without due process when refusing their administration.

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

> Many controversies have raged about the cryptic and abstract words of the Due Process Clause, but there can be no doubt that, at a minimum, they require that deprivation of life, liberty or property by adjudication be preceded by notice and opportunity for hearing appropriate to the nature of the case.
>
> * * *
>
> An elementary and fundamental requirement of due process in any proceeding which is to be accorded finality is notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections. *Milliken v. Meyer,* 311 U. S. 457; *Grannis v. Ordean,*

> 234 U. S. 385; *Priest v. Las Vegas,* 232 U. S. 604; *Roller v. Holly,* 176 U. S. 398. The notice must be of such nature as reasonably to convey the required information, *Grannis v. Ordean, supra,* and it must afford a reasonable time for those interested to make their appearance, *Roller v. Holly, supra, and cf. Goodrich v. Ferris,* 214 U. S. 71.

394. On April 01, 2021 Houston Methodist informed individuals under their authority that "Houston Methodist is requiring mandatory immunization of all covered Houston Methodist (HM) employees" and set mandatory timelines for compliance.

395. At no point before, during, or after Houston Methodist issued the mandatory immunization policy were they in possession of COVID-19 drugs licensed by the FDA for general commercial marketing having a legal indication to immunize persons from the SARS-CoV-2 (COVID-19) infection. (See discussion *infra*)

396. Houston Methodist informed Plaintiffs of pending action that would deprive them of their liberty (e.g., restrictions of facility uses) and property (e.g., wages, insurance, paid-time-off, career) should they exercise their federally secured rights to refuse its illegal demands. Still, it did not provide Plaintiffs with an opportunity to be heard or the right to defend their federally secured rights. *See Louisville and Nashville R. R. Co. v. Schmidt*, 177 U.S. 230, 236, 20 S.Ct. 620, 44 L.Ed. 747 (1900).

397. Houston Methodist acted with wanton indifference to the constitutional and statutory rights of the Plaintiffs. When Plaintiffs exercised their federally secured right to refuse Covid-19 investigational drugs (e.g., Pfizer-BioNTech COVID-19 Vaccine), biologics, and or medical devices (e.g., masks, testing articles, etc.), Houston Methodist engaged in a scorched earth policy of applying maximum financial and emotional punitive actions in hopes of causing Plaintiffs to surrender their Constitutional protections.

398. The penalties included segregation, isolation, gaslighting, termination from living wages, public humiliation, discriminatory acts, and loss of back pay, health insurance, retirement funds, and other financial instruments.

399. Plaintiffs were not allowed to access fitness facilities unless they participated in a COVID-19 investigational drug, a deprivation of the Plaintiffs' 14th Amendment rights of equal protection.

400. Plaintiffs were not allowed to stand in the presence of employees who accepted the investigational product but were segregated to the other side of the room, which is a deprivation of the Plaintiffs' 14th Amendment rights of equal protection.

401. If they chose to exercise their federally secured right to refuse investigational drug use, Houston Methodist required Plaintiffs to test for the COVID-19 virus using EUA testing articles, which is a deprivation of the Plaintiffs' 14th Amendment rights of equal protection.

402. Houston Methodist paid to certain Plaintiffs matching 403B bonuses for working during the pandemic, but then, without permission, advance notice, or a hearing of any sort, it took those funds out of Plaintiffs' 403B accounts when they exercised their federally secured right to refuse an investigational COVID-19 drug, which is a deprivation of the Plaintiffs' 14th Amendment rights of equal protection.

403. Houston Methodist terminated access to living wages and careers only for Plaintiffs choosing the 21 U.S.C. 360bbb-3 option of refusing the medical countermeasure because Plaintiffs did not believe the products would help them to achieve their

autonomous health goals, which is a deprivation of the Plaintiffs' 14th Amendment rights to due process and equal protection of laws.

404. Houston Methodist did not provide a notice of date, time, or location for Plaintiffs to understand exactly what law they violated nor the ability to be heard before it deprived Plaintiffs of their liberty and property.

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

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

407. Therefore, Houston Methodist violated Plaintiffs' substantive and procedural due process rights under the 14th Amendment.

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

409. 21 U.S.C. §360bbb-3 (Section 564) creates an express right for individuals to accept or refuse the administration of products not licensed by the FDA for general commercial marketing during a declared emergency.

410. 45 CFR 46, the Belmont Report, Article VII of the ICCPR Treaty, and the FWA all require the individual's legally informed consent before administering an investigational medical product.

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

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

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

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

415. Therefore, Houston Methodist had a 14th Amendment constitutional obligation and responsibility to ensure all persons were under the equal protection of laws regarding the CDC COVID-19 Vaccination Program[61].

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

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

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

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

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

420. Houston Methodist acted under color of a State custom[62] and usage to deprive Plaintiffs of their 14th Amendment constitutional protections.

421. The State's custom was to ignore the statutory rights of individuals to refuse the administration of an EUA product without incurring a penalty or losing a benefit to which they were otherwise entitled. The custom of the State was so pervasive that it demoted citizens exercising their federal right to refuse to that of a second-class citizen.

422. Governor Abbott, responding to public pressure, issued Executive Order GA 40[63] stating, "No entity in Texas can compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19. I hereby suspend all relevant statutes to the extent necessary to enforce this prohibition."

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[62] 18 U.S.C. §1983: "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State…" (emphasis added).

[63] Executive Order GA 40, Gov. Greg Abbott, October 11, 2021, https://gov.texas.gov/uploads/files/press/EO-GA-40_prohibiting_vaccine_mandates_legislative_action_IMAGE_10-11-2021.pdf

423. The only "COVID-19 vaccines" available were investigational drugs authorized under 21 U.S.C. §360bbb-3, which already provided an absolute statutory right of refusal by any person without the need to seek out an exemption to exercise that right. Moreover, "all relevant statutes to the extent necessary to enforce this prohibition" were already suspended by Congress under the PREP Act and 21 U.S.C. §360bb-3's preemptory language.

424. The Governor's Executive Order reinforced the state custom that a person must have a reason such as "conscience," "religious belief," or a "medical" condition in order to refuse existing COVID-19 investigational drugs. The right to refuse medical experimentation is an unconditional right except under Defendant's customs.

425. 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)

426. Plaintiffs were refused access to living wages and demoted to second-class citizenry because a State custom had a force of law overriding the authority of the United States Constitution.

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

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

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

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

431. Houston Methodist, acting under State custom, usurped the federal government's authority, imposed sanctions, and withheld benefits as if that fraudulent authority had legislative pronouncement.

432. After Houston Methodist deprived Plaintiffs of their 14th Amendment rights to due process and terminated their employment, the Texas Workforce Commission enforced the custom by denying some Plaintiffs unemployment benefits solely based on Plaintiffs exercising their 21 U.S.C. §360bb-3 legal rights. The Texas Workforce Commission violated the Unconstitutional Conditions Doctrine by enforcing a custom as though it had the force of law by requiring Plaintiffs to surrender their constitutional rights to access public benefits. Moreover, having been approved for unemployment benefits,

other Plaintiffs received a letter stating they were to return the money solely based on their refusal to participate in Houston Methodist's mandatory COVID-19 investigational drug program.

433. Houston Methodist told individuals under their authority that their actions were labeled misconduct. Therefore, Houston Methodist believes exercising a federally secured right protected by the 14th Amendment is misconduct when refusing to participate in the State's COVID-19 experimental drug program.

434. The COVID-19 program did not belong to Houston Methodist. Houston Methodist was only allowed to provide the program as a public function on behalf of the State. Houston Methodist fraudulently usurped the federal government's authority and required that which Congress prohibits.

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

436. Texas Health and Human Services, after authorizing numerous entities to enroll in the CDC COVID-19 Vaccination Program, refused to enforce the provisions of the CDC Vaccination Program Provider Agreement when those entities violated the terms and conditions of the contract and its supporting statutes (21 U.S.C §360bb-3).

437. The Texas Medical Board, a State agency mandated with regulating the practice of medicine, refused to correct the errant behavior of licensed healthcare

professionals mandating individuals to participate in the use of 21 CFR 312.3 investigational drugs.

438. Houston Mayor Sylvester Turner issued an executive order illegally subjecting 21,000 city employees to investigational drug use under threat of penalty. The State's Attorney General refused to protect the rights of city employees due to the state's custom and allowed Mayor Turner to engage in violations of federal law freely, depriving the public of its 14th Amendment Equal Protections.

439. Texas Health Resources' CEO, Barclay Berdan, issued a mandatory policy subjecting 22,000 plus individuals to investigational drug use without the ability to refuse unconditionally.

440. By the above-described actions, the State established a custom or usage of non-enforcement of the right to refuse an investigational drug without penalty, violating the Plaintiff's statutory rights, regulatory privileges, and constitutional protections.

441. By and through the above-described facts and law, the Plaintiffs have established that a state-enforced custom abridged their federally secured rights to refuse an investigational drug without penalty and their constitutional rights of equal protection when Houston Methodist fired them, denied them the use of its facilities, opposed their unemployment claims, confiscated their already earned and paid bonus for working during the pandemic, and other benefits to which they were otherwise entitled, along with general, special, and punitive damages.

XIX. The Spending Clause

442. In *Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002), the court states, "the Court has found that spending legislation gave rise to rights enforceable under § 1983 only in *Wright* v. *Roanoke Redevelopment and Housing Authority,* 479 U. S. 418, 426, 432, and *Wilder* v. *Virginia Hospital Assn.,* 496 U. S. 498, 522523, where statutory provisions explicitly conferred specific monetary entitlements upon the plaintiffs, and there was no sufficient administrative means of enforcing the requirements against defendants that failed to comply." See also, *Health and Hospital Corporation of Marion County v. Talevski*, *supra*, 599 U.S. ____ (2023)

443. The federal government funds all COVID-19 EUA shots via Medicare.[64]

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

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

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

447. Agreement Requirement Number 3 on the CDC Provider Agreement states, "Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization."

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

448. 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."

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

450. 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."

451. Agreement Requirement Number 5 complies with funding restrictions established by Congress in,45 CFR §122 and 10 U.S.C. §980.

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

453. Therefore, whether for civilians under 45 CFR 46 or military personnel under 10 U.S.C. §980, Congress created a specific monetary entitlement for individuals considering whether or not to participate in a federally funded research activity. That entitlement means they have an 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.

454. This monetary entitlement is most apparent in the CDC COVID-19 Vaccination Program Provider Agreement. An individual can seek out a participating

COVID-19 Program healthcare professional, obtain medical counseling, ask questions, and read literature. If they choose not to participate, they will not incur a fee from the professional for the administrative time spent considering whether or not to participate since the healthcare professional must inform them of their legal right to refuse under 21 U.S.C. §360bbb-3.

455. 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."

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

457. Therefore, 21 U.S.C. §360bbb-3, 45 CFR § 46.122, and 10 U.S.C. §980 clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983 when federal funds are expended under those provisions of law.

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

458. On April 02, 2021 Houston Methodist issued the following policy:

> "To create a safe environment, free of infection/transmission of disease and to protect our patients, employees, and the community

from SARS-CoV-2 (COVID-19) infection, Houston Methodist is requiring mandatory immunization of all covered Houston Methodist (HM) employees."[65]

459. The immunization policy outlined a two-phase process for implementation:

(1) "**HM Phase 1 employees** are defined as all HM management (emphasis added)."

(a) "Apply for and submit all required documentation for an exemption based on a medical condition (including pregnancy deferment) or sincerely held religious belief **on or before April 7, 2021**, in accordance with the procedure described in this policy (emphasis added)."

(b) "Any HM Phase 1 employee (i) who is not vaccinated with a first or second dose of the two-dose COVID-19 vaccine by April 15, 2021, or (ii) does not have an approved exemption as provided in this policy by April 15, 2021 **will be** placed on a two-week, unpaid suspension (emphasis added)."

(c) "If the vaccine regimen (including a second dose) **is not** completed before the expiration of the suspension period on **April 29, 2021**, HM will immediately initiate the **employment termination** process as described in this policy (emphasis added)."

(d) "Any HM Phase 1 employee who does not get a second dose at the appointed time will, absent exceptional circumstances, be placed on an immediate two-week, **unpaid suspension**. If the second dose is not administered before the expiration of the suspension period, HM will immediately initiate the **employment termination** process as described in this policy." (emphasis added)

(2) "**HM Phase 2 employees** are defined as all HM employees not covered in Phase 1 (emphasis added)."

(a) "Apply for and submit all required documentation for an exemption based on a medical condition (including pregnancy deferment) or sincerely held religious belief on or before May

[65] See Exhibit B, Houston Methodist's Mandatory COVID-19 Vaccine Procedure.

3, 2021, in accordance with the procedure described in this policy."

(b) "Any HM Phase 2 employee who does not meet the vaccine program requirements as outlined in section F.1 **will be** placed on a two-week, **unpaid suspension** starting June 8, 2021" (emphasis added)

(c) "If the vaccine program requirements are not completed before the expiration of the suspension period on June 21, 2021 or as otherwise stated for those receiving vaccinations after exemption denials, HM **will immediately initiate the employment termination process** as described in this policy." (emphasis added)

460. When Houston Methodist issued the policy, they knew that such an action was an illegal act. Houston Methodist oversees (1) $264 million in research projects, (2) 2,270 credentialed researchers, (3) 1,430 clinical protocols, and (4) 530 active clinical trials and is one of the top 10 medical research institutions in the nation.[66]

461. Houston Methodist established the "Houston Methodist Academic Institute Board of Directors," which in turn established and oversaw its "Compliance Committee." The Compliance Committee is wholly dedicated to ensuring compliance with laws providing for the Protection of Human Subjects involved in biomedical and or behavioral research.

462. Moreover, Houston Methodist established the "Office of Research Protections" to ensure compliance with their Institutional Review Board legal obligations, but its actions reflect that they do not engage in such compliance.

[66] Houston Methodist Statistics | Houston Methodist. Houstonmethodist.org. Published 2019. Accessed June 2, 2023. https://www.houstonmethodist.org/research/about-us/facts-stats/

463. Therefore, Houston Methodist has a long history of conducting clinical trials, research projects, and administering investigational drugs to individuals under their authority and, thus, has boards, offices, and personnel dedicated to ensuring that the rights of employees, vendors, patients, and others are protected anytime they are involved in an investigational drug, biologic, or device.

464. Houston Methodist knew they were bound by treaty, law, regulation, and contract to create a legally approved environment ensuring no person was sanctioned for not participating in available COVID-19 investigational drugs.[67][68]

465. Houston Methodist was also well aware that administering an investigational medical product to as little as only one individual requires IRB oversight and compliance with 45 CFR 46, the FWA, and other laws protecting humans involved in medical research activities.[69]

466. Houston Methodist immunization policy was built upon intentionally fraudulent misrepresentation of facts and illegal statements.

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

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

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

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

468. Only COVID-19 investigational new drugs undergoing clinical trials existed when Houston Methodist issued its mandate, none of which had a legal indication to prevent, treat, or cure any disease.

469. Houston Methodist knew that a "sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." (21 CFR 312.7(a)).

470. Houston Methodist acted on behalf of the sponsor (the Federal and State government and manufacturers of EUA products) when administrating the CDC COVID-19 Vaccination Provider Program.

471. Houston Methodist violated federal law when it implied that should an individual participate in the use of one of the COVID-19 drugs undergoing clinical trials, they would become "safe" and "free of infection/transmission" from any SARS-CoV-2 (COVID-19) variant.

472. Houston Methodist dangerously conveyed medical information under fraudulent pretense to coerce participation in the use of investigational drugs outside the free will and voluntary consent of Plaintiffs.

473. On May 28, 2021 Houston Methodist's policymaker, CEO Marc Boom, sent out an email to all employees of Houston Methodist stating in part, "Over the next few days, you may see media coverage on a lawsuit pending on behalf of 117 current and

former Houston Methodist employees regarding our COVID-19 immunization mandate, and I wanted you to hear about this from me first. It is unfortunate that the few remaining employees who refuse to get vaccinated and put our patients first are responding in this way."

474. The statement that "it is unfortunate that the few remaining employees…are responding this way" was meant to publicly humiliate the Plaintiffs as a form of coercion to other employees.

475. CEO Marc L. Boom continued, "As we told the media, it is legal for health care institutions to mandate vaccines, as we have done with the flu vaccine since 2009. The COVID-19 vaccines have proven through rigorous trials to be very safe and effective and are not experimental."

476. The statement "it is legal for health care institutions to mandate vaccines" was intentional misdirection because licensed vaccines are not what Marc L. Boom mandated.

477. The statement that the COVID-19 drugs were "vaccines" was patently untrue. The FDA classified all drugs available at the time as investigational new drugs.

478. The statement that the "COVID-19 vaccines" were "not experimental" was patently untrue. The word "investigational" is synonymous with experimental.

479. The statement that the "COVID-19 vaccines" went through "rigorous trials" was patently untrue. (See *infra*.)

480. Houston Methodist and Marc L. Boom illegally misbranded the drugs when "advertising" the COVID-19 "vaccines" as if they were licensed products violating Chapter 431 of the Texas Food, Drug, and Cosmetic Act stating in part:

481. "Advertising" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics (emphasis added)." Section 431.002

482. "If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or any combination of these, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof, or under such conditions of use as are customary or usual (emphasis added)." Section 431.003

483. A person reading Marc L. Boom's statement that these drugs were not experimental could only conclude that they were not. This a simple fact for certain, but one demonstrating that Marc Boom's statement was "misleading," and that he failed to "reveal facts material" to the legal issue at hand, resulting in the false belief that he had the authority to mandate these drugs because they were not "experimental."

484. In 2009, the FDA charged Pfizer with a felony for promoting four drugs outside of their legal indication and fined them over $1.19 billion. The Department of Justice noted,[70] "Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – i.e., any use not specified in an application and approved by FDA."

485. Marc L. Boom, may not promote an investigational new drug for an indication and usage not licensed nor approved of by the FDA in an effort to induce participation. These actions can be construed as medical malpractice.

486. Houston Methodist's mandate of a COVID-19 "mandatory immunization" was legally and physically impossible to fulfill. No drug has ever existed that was licensed by the FDA and introduced into commerce for general commercial marketing, which had a legal indication to prevent the SARS-CoV-2 (COVID-19) infection.

487. Houston Methodist knew that no COVID-19 drug manufacturer claimed to "immunize" persons from SARS-CoV-2 (COVID-19) infection.

488. Houston Methodist fraudulently and fictitiously presented to Plaintiff's facts as if they were scientific and legal in order to coerce entire communities into participating

[70] Justice Department Announces Largest Health Care Fraud Settlement in Its History. Justice.gov. Published September 2, 2009. Accessed June 6, 2023. https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history#:~:text=Pfizer%20promoted%20the%20sale%20of,United%20States%20for%20any%20matter.

in the use of investigational drugs and medical products outside their free will and voluntary consent.

489. Houston Methodist chose to use its position of influence to coerce and apply undue influence on Plaintiffs to fraudulently bill the government for those COVID-19 injections.[71],[72]

490. Houston Methodist subjected individuals under its authority to "undue influence" (see note #158(c)) when they offered an unlawful "Hope Bonus" of $500 to anyone who participates in the "mandatory immunization" program by receiving COVID-19 investigational drugs.

491. Houston Methodist placed Plaintiffs under moral duress when illegally "requiring mandatory immunization" because Plaintiffs relied on it for employment, and Plaintiffs adamantly did not want to participate in the use of investigational drugs that were still undergoing clinical trials[73] and having no legal indication to treat, cure, or prevent any known disease.

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[71] CMS paid Houston Methodist an average of $40 per dose. Medicare COVID-19 Vaccine Shot Payment | CMS. Cms.gov. Published 2023. Accessed June 2, 2023. https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment

[72] Houston Methodist has received in excess of $580 million in Covid funding - Top U.S. Non-Profit Hospitals & CEOs Racked Up Huge Pandemic Profits. Open The Books . Published 2023. Accessed June 8, 2023. https://www.openthebooks.com/substack-top-us-non-profit-hospitals--ceos-racked-up-huge-pandemic-profits/

[73] At the time of the mandate, all COVID-19 drugs were undergoing clinical trials to study their safety and efficacy. The Houston Methodist employees were not subjects involved in the manufacturer's clinical trials. Instead, they were required to participate in Houston Methodist's "mandatory immunization" program involuntarily without the benefits of being a clinical trial subject. Ironically, had an employee been a clinical trial subject, he or she could have withdrawn without consequence but would have immediately come under a mandate to participate in the "mandatory immunization" program, which utilizes the same EUA COVID-19 investigational drugs, with consequence. This irony demonstrates the illegality of the mandate.

492. Houston Methodist published a FAQ to support the new COVID-19 "mandatory immunization" policy.

493. The FAQ contained legally inadequate answers and a mischaracterization of facts written to coerce participation under false pretenses.

494. FAQ #1 - "Why is Houston Methodist mandating this [use of investigational drugs] before it is FDA approved?" Answer: "This is a much-misunderstood fact. The vaccines all have Emergency Use Authorization, which is a form of FDA approval that allows for the manufacturing and approval of vaccines to be streamlined in a public health emergency. This designation does not mean shortcuts were taken in the research and clinical studies that were conducted. In fact, these went through the same trials that other drugs use in a more traditional approval process just on a different track that is commonly used by the FDA."

495. FAQ #1 is an intentional mischaracterization of the facts for the following reasons:

A. EUA drugs are not required to comply with the same quality manufacturing processes as licensed drugs.

B. The EUA drugs that Houston Methodist mandated were all undergoing clinical trials, and the data from those trials would not be concluded for years to come.

C. Pfizer's clinical trial had a 93% failure rate before it completed even six months of its 24-month timetable.

D. Houston Methodist had no scientific basis for implying that shortcuts were not taken when factually speaking, due to the speed with which EUA approval was granted, such shortcuts were taken regarding the Pfizer-BioNTech COVID-19 Vaccine. Specifically, Operation Warp Speed (a special program initiated in 2020 to accelerate the

> development of COVID-19 drugs) was novel and not similar to a traditional track used by the FDA for approving vaccines.

496. FAQ #2 - "Is it legal to make employees get a COVID-19 vaccine?" Answer: "Yes it is. State and federal employment laws allow private companies to mandate vaccinations. We did the same thing in 2009 with the flu vaccine, and a few years later the state mandated it for health care workers."

497. With this answer, Houston Methodist intentionally attempt to mislead Plaintiffs into believing that the COVID-19 investigational drug can be treated the same as an FDA-licensed vaccine. As demonstrated above, it cannot reasonably be disputed that Houston Methodist knew the COVID-19 injections were investigational and that federal law referenced in the CDC Provider Agreement requires the potential vaccine recipient to have the right to accept or refuse without any penalty or loss of benefit. Therefore, the Houston Methodist fraudulently concealed from the Plaintiffs that they cannot mandate the EUA COVID-19 investigational drugs without respecting and allowing the right to accept or refuse without penalty or loss of benefit.

498. FAQ #3 - "Are there exemptions?" Answer: "The deadline to request a religious or medical vaccine exemption has passed."

499. Constitutional rights do not have deadlines, nor do the rights secured by 21 USC 360bbb-3 (Section 564), 45 CFR 46, the FWA, the IRB, or the ICCPR Treaty, nor did Congress authorize Houston Methodist to amend the Scope of Authorization for any EUA drug or medical product and require employees to request an exemption as a condition to exercising the right to refuse.

500. An exemption process itself is an infringement of the right to refuse investigational medical countermeasures without penalty or loss of benefit.

501. The following statement by Houston Methodist shocks the conscience, given the volume of research projects they conduct annually: "Exemption from vaccination **may be granted** for medical contraindications (including pregnancy if properly supported by medical documentation)."[74] (emphasis added)

502. Houston Methodist engages in hundreds of annualized research activities involving investigational drugs and knows that a pregnant woman cannot be under threat of penalty to participate in an investigational drug program. Moreover, no pregnant woman can participate in the use of an investigational drug if the associated research activity involves more than minimal risk to the mother or the fetus[75].

503. 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."

504. At all times pertinent, Houston Methodist knew that myocarditis and pericarditis were risks of taking the Pfizer BioNTech COVID-19 EUA investigational drug.[76]

[74] See Exhibit B, Houston Methodist's Mandatory COVID-19 Vaccine Procedure.
[75] 45 CFR 46.204(b)
[76] See Exhibit C, Fact Sheet for Recipients and Caregivers

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

506. Houston Methodist's callous disregard for the safety and well-being of expectant mothers is unheard of by healthcare professionals. Its arrogant statement that mothers "may be granted" exemption if their request is supported by medical documentation is a gross betrayal of its duties under the CDC COVID-19 Provider Agreement, the FWA agreement, 45 CFR 46, Belmont Report, and Houston Methodist's IRBs.

507. Moreover, Houston Methodist knew that no expectant mothers could provide "medical documentation" to support an exemption solely based on pregnancy because no COVID-19 drug manufacturer conducted, much less concluded, studies of the product's safety for pregnant women, with Pfizer's non-interventional study on the effects of its BioNTech COVID-19 Vaccine Exposure during pregnancy not being complete until June 30, 2025.[77]

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

[77] Gmbh B. Our STN: BL 125742/0 BLA APPROVAL.; 2021. https://www.fda.gov/media/151710/download

509. Houston Methodist and its policymaker, Marc L. Boom's moral turpitude[78] are evidenced by wilful acts of disregarding federal and state laws, fraudulent misrepresentations of facts, publishing lies, and intentionally misleading employees about the legal distinctions between a licensed vaccine and a drug undergoing clinical investigation having no legal indication to treat, cure, or prevent any known disease.

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

511. Houston Methodist, Marc L. Boom, and the Board of Directors decided they would regulate Congress and usurp constitutional authorities to pursue personal goals of **profiting from** the COVID-19 funding windfall.

512. Some Plaintiffs state that on the last day to comply with Houston Methodist's mandate to participate in experimental COVID-19 drugs, a manager would serve them with a suspension letter in person informing them that they were being suspended for the reason of misconduct. The manager would then issue a verbal mandate, using an authoritative tone, that they had to sign the confession right then or quit.

513. The abusive action shocks the conscience, when one realizes that these healthcare heroes have spent hundreds of combined years, laboring in love, to wipe the

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

tears of pain from injured patients, reassuring little ones, and comforting those who lost the love of their lives only moments ago.

514. Plaintiffs were targeted for abuse by Houston Methodist to set them as an example for the express purpose of placing fear into the hearts of other Houston Methodist employees.

515. Persons participating in a COVID-19 investigational new drug must agree to the terms and conditions of a contractual relationship between the recipient, manufacturer, and the federal government as it relates only to the CDC COVID-19 Vaccination Provider Program. Additionally, these terms were enacted by a valid act of Congress.

516. When Houston Methodist engaged in coercion, undue influence, fraud, constructive termination, retaliation, sanctions, segregation, humiliation, and other unlawful activities, they were acting to coerce Plaintiffs into participating in a legally binding agreement outside of their free will and voluntary consent.

517. The legally binding agreement could have led to serious legal, financial, health, and other consequences of which there could be no legal recourse for remedy.

518. Instead, plaintiffs exercised their liberty rights as secured for them by Congress and lost careers, businesses, dreams, retirement funds, health insurance, childcare, and housing. Some Plaintiffs lost access to medical care leading to life-altering consequences.

519. Plaintiffs suffered significant emotional trauma, and now, others are having to work multiple jobs to earn only a portion of their former income.

520. The actions of Houston Methodist, CEO Marc L. Boom, Chief Physician Executive Robert Phillips, and the voting Board of Directors were atrocious, intolerable, and so extreme and outrageous as to exceed the bounds of decency.

XXI. Legal Claims

521. The facts described above constitute violations of several of the rights guaranteed to Plaintiffs by the United States Constitution, federal statutes, and treaty. These violations are actionable under 42 U.S.C. § 1983 because the Defendants, Houston Methodist, and the individual defendants, acted under color of state law when administrating the CDC COVID-19 Vaccination Program Provider Agreement.

COUNT I

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

522. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 21 and 150 through 521, as if fully set forth herein.

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

524. 45 CFR 46.116(b)(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."

525. The Belmont Report declares, "An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence."

526. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) contains a required condition of the Secretary "to ensure that individuals to whom the product is administered are informed—"of the option to accept or refuse administration of the product."

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

528. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes, regulations, and treaty, unlawfully subjected Plaintiffs to the use of investigational drugs under threat of penalty outside of their free will and voluntary consent as described in the above facts, thereby causing them damages described in Paragraphs 557 through 562, *infra*.

COUNT II

Equal Protection - 42 U.S.C. § 1983

529. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 21 and 150 through 521, as if fully set forth herein.

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

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

532. 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 557 through 562, *infra*.

COUNT III

Due Process - 42 U.S.C. § 1983

533. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 21 and 150 through 521, as if fully set forth herein.

534. The CDC COVID Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR 46, the Belmont Report, 21 U.S.C.

§360bbb-3, Article VII of the ICCPR Treaty, Federal Wide Assurance, the EUA Scope of Authorization letter, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

535. 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

536. 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 557 through 562, *infra*.

Count IV

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

Spending Clause Doctrine

537. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 21 and 150 through 521, as if fully set forth herein.

538. The CDC COVID Vaccination Program Provider Agreement, 45 CFR §46.122, 10 U.S.C. §980, and the Fourteenth Amendment clearly and unambiguously create rights enforceable pursuant to 42 U.S.C. § 1983.

539. 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."

540. 10 U.S.C. §980: "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless--the informed consent of the subject is obtained in advance…"

541. The Defendants' actions described above, individually and/or collectively, and in derogation of the Constitution and the above statutes and regulations, refused to obtain the legally effective informed consent of the Plaintiffs in violation of spending legislation as described in the above facts, thereby causing them damages described in Paragraphs 557 through 562, *infra*.

COUNT V

Breach of Contract, Third Party Beneficiary

542. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 21 and 150 through 521, as if fully set forth herein.

543. 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.

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

conditions of the CDC COVID Vaccination Program Provider Agreement as described in the above facts, thereby causing them damages described in Paragraphs 557 through 562, *infra*.

COUNT VI

State Common Law Employment Torts

545. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 21 and 150 through 521, as if fully set forth herein.

546. The PREP Act and 21 U.S.C. §360bbb-3 preempt State laws conflicting with the United States Government's COVID-19 objectives to include employment laws.

547. Houston Methodist engaged in acts of coercion, undue influence, and retaliation, creating a hostile work environment.

548. Houston Methodist placed Plaintiffs under moral duress[79] knowing they exclusively relied on Defendants for access to living wages.

549. Houston Methodist's actions demonstrate moral turpitude against the Plaintiff's rights, safety, and health.

550. Houston Methodist 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.

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

551. The Defendants' actions, individually and/or collectively, and in derogation of Texas common law, violated the intended benefits conferred upon the Plaintiffs when enjoying employment in the State of Texas as described in the above facts, thereby causing them damages described in Paragraphs 557 through 562, *infra*.

COUNT VII

Outrage

552. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 21 and 150 through 521, as if fully set forth herein.

553. The facts and the Defendants' conduct committed with gross negligence, reckless, or intent, described above give rise to a claim of Outrage under the common law of the State of Texas against the Defendants for the damages described in Paragraphs 557 through 562, *infra*.

COUNT VIII

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

554. Plaintiffs hereby incorporate by reference the allegations contained in Paragraphs 1 through 21 and 150 through 521, as if fully set forth herein.

555. Should the court not agree that Houston Methodist 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).

556. 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 557 through 562, *infra*.

XXII. Damages Recoverable and Demanded

557. The following paragraphs are hereby incorporated by reference into Counts I through VIII, as if set forth there *in extenso*.

558. 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.

560. In addition, as to Plaintiff Fontenot, loss of her medical practice, and loss of earnings from that business and from her hospital privileges.

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

560. 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)

561. Because Defendant's 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)

562. Because Defendant's 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)

XXIII. Jury Trial Demand

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

WHEREFORE, Plaintiffs pray that Defendants be served with a copy of this Amended Complaint and be duly cited to appear and answer same, and after due proceedings are had, including but not limited to a trial by jury, there be judgment herein against the Defendants awarding Plaintiffs all damages claimed herein, plus legal interest,

taxable costs, expert fees, and attorney's fees, and all other relief determined to be just and equitable by this Court.

Respectfully submitted,

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of June, 2023, I presented the foregoing pleading to the Clerk of Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ David J. Schexnaydre
DAVID J. SCHEXNAYDRE

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