No. 24-20483

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Jennifer Bridges; Breann Emshoff; Amanda Lofton; Brett Cook; Stefanie Martinez; Et al,

Plaintiffs-Appellants,

v.

The Methodist Hospital, doing business as The Methodist Hospital System; Houston Methodist The Woodland Hospital; Methodist Health Centers, doing business as Houston Methodist Baytown Hospital, doing business as Houston Methodist Sugar Land Hospital, doing business as Houston Methodist The Woodlands Hospital, doing business as Houston Methodist Willowbrook Hospital; Marc L. Boom; Robert A. Phillips; Et al,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of Texas
No. 4:23-cv-1699
Hon. George C. Hanks, Jr.

APPELLANTS' OPENING BRIEF

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CERTIFICATE OF INTERESTED PERSONS

No. 24-20483; *Jennifer Bridges, et al v. Methodist Hospital, et al*. For the judges to evaluate possible disqualification or recusal, undersigned certifies the following persons/entities as described in the fourth sentence of 5th CIR Rule 28.2.1 have an interest in the outcome of this case:

Appellees:	**Counsel for Appellee:**
The Methodist Hospital, doing business as The Methodist Hospital System; Houston Methodist The Woodland Hospital; Methodist Health Centers, doing business as Houston Methodist Baytown Hospital, doing business as Houston Methodist The Woodlands Hospital, doing business as Houston Methodist Willowbrook Hospital; Mark L. Boom; Robert A. Phillips	Daniel Patton and Michael Burke, of Scott Patton PC, Houston, TX; Constance H. Pfeiffer and Andrew Ingram of Yetter Coleman, LLP, Houston, TX
Appellee:	**Counsel for Appellee:**
Cecile Erwin Young and Brian Daniel	Joseph Keeney of Office of the Attorney General, Austin, TX

Appellants:	**Counsel for Appellant:**
Plaintiffs-Appellants, Jennifer Bridges, et al	David J. Schexnaydre of Schexnaydre Law Firm, Mandeville, LA

Other Interested Parties:	**Counsel for Interested Parties:**
Honorable George C. Hanks, Jr., U.S. District Court for the Southern District of Texas.	**District Court Judge Rendering Decision Below**

/s/David J. Schexnaydre
Attorney of record for Appellants

STATEMENT REGARDING ORAL ARGUMENT

As required by 5th CIR. R. 28.2.3 and FED. R. APP. P. 34(a)(1), Appellants attest that Oral Argument would be helpful in this matter and requests same because issues raised by Appellant are not only novel, but also involve a multitude of federal Constitutional issues and complex federal statutory provisions. Further, decisions on these issues and provisions vary across the country such that an opportunity to discuss and be questioned would be beneficial to the court.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Regulations

I. JURISDICTIONAL STATEMENT

The United States District Court for the Southern District of Texas, Judge George C. Hanks, Jr., granted in part and denied as moot in part Defendants' motions to dismiss resulting in a dismissal of Plaintiffs' federal claims with prejudice, and declining to exercise supplemental jurisdiction over Plaintiffs' state law claims, which were remanded to Texas state court on September 30, 2024. (RE.50.) The District Court's jurisdiction was established under 28 U.S.C. §1331 as a civil proceeding arising under the laws of the United States, specifically 42 U.S.C. §1983 and 42 U.S.C. §1988.

Under 28 U.S.C. §1291 the Court of Appeals has jurisdiction from all final decisions of the federal district courts. The Appellants filed a timely Notice of Appeal on October 28, 2024. (RE.49)

II. STATEMENT OF THE ISSUES FOR REVIEW

1. Whether the district court erred when effectively ruling that Defendants can violate federal law and place Plaintiffs under coercive pressure to inject federally funded investigational drugs undergoing clinical trials.

2. Whether the district court erred when ruling that Houston Methodist could not plausibly be a state actor for Rule 12(b)(6) purposes.

3. Whether the district court erred by dismissing Plaintiffs' Complaint under Rule 12(b)(6) by failing to accept Plaintiffs' factual allegations as true.

4. Whether the district court erred in dismissing the case with prejudice.

III. STATEMENT OF THE CASE

Plaintiffs-Appellants ("Plaintiffs") are current and/or former healthcare workers licensed by the State of Texas ("State") and were at all times pertinent, formerly employed by Defendant-Appellee Houston Methodist ("Houston Methodist"), a state-licensed medical facility.

Defendants-Appellees are Brian Daniel, Chairman of the Texas Workforce Commission ("TWC") ("Mr. Daniel") for declaratory judgment only[1]; The Methodist Hospital d/b/a Houston Methodist Hospital and Houston Methodist The Woodlands Hospital; Dr. Marc Boom, President and CEO of Houston Methodist; Robert A. Phillips, Executive Vice President and Chief Physician Executive; and the Houston Methodist voting Board of Directors.

Mr. Daniel is a Declaratory Judgment Defendant wherein Plaintiff Bob Nevens ("Mr. Nevens") is seeking a declaration against Defendant that the State cannot condition access to public benefits on the relinquishment of constitutional rights and refusing federally funded INDs is a right subject to the Due Process Clause and as such TWC cannot take benefits properly paid to Mr. Nevens after he exercised his constitutional right to refuse the injection of the federally funded COVID-19 investigational new drugs ("IND").

[1] Plaintiffs do not appeal the dismissal of the claims against Cecile Erwin Young.

Houston Methodist, Dr. Boom, and Dr. Phillips are Defendants because they agreed to act jointly with Texas to perform for the federal government under the federally funded CDC COVID-19 Vaccination Program ("CDC Program") and, upon information and belief, personally signed the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement") and deprived Plaintiffs of their rights relating to that program.

This case arises from the CDC Program, which was designed to distribute and administer federally owned EUA/PREP Act investigational new drugs ("EUA/PREP Act drugs") to individuals within the State under a nationally declared emergency. The CDC Program provides Plaintiffs with the right to learn of the drug's risks, benefits, and alternatives and of the right to accept or refuse without incurring a fee, penalty, or losing a benefit to which they are otherwise entitled, which Defendants willfully violated by establishing an *ultra vires* mandate that Plaintiffs be injected with EUA/PREP Act drugs under threat of penalty. Plaintiffs refused Defendants' unconstitutional requirement, leading Defendants to deprive Plaintiffs of their Fourteenth Amendment rights owed to them by the federal government and Texas under the CDC Program.

In 2020, the United States Government ("USG") purchased all COVID-19 drugs that were being promoted as "vaccines." These drugs held four significant legal distinctions: (1) the USG owned the drugs until they entered into a human, (2)

the FDA classified them as investigational, which means the drugs did not have a legal indication for safety and efficacy to treat, cure, or prevent any known disease, (3) the HHS Secretary only allowed their introduction into commerce under emergency expanded access protocols that explicitly require only voluntary use, (4) the HHS Secretary listed the drugs as PREP Act countermeasures, requiring Plaintiffs to voluntarily waive their right to bring a personal injury action in the event they are injured by the drugs or their administration.

The USG established the CDC Program as an emergency public function to administer these drugs. This Program operated under specific federal frameworks—21 U.S.C. §360bbb-3, *et seq*. (the EUA Statute), 42 U.S.C. §247d-6d, e (the PREP Act), 45 C.F.R. Part 46 (the Common Rule), the Belmont Report, 10 U.S.C. §980, and Supreme Court case precedent involving bodily autonomy—designed to protect individual rights regarding investigational drugs. Central to these protections were two critical informed consent conditions required of Defendants when offering Plaintiffs an opportunity to use the EUA/PREP Act drugs: (1) ensuring Plaintiffs' freedom from pressure and (2) accepting Plaintiffs' voluntary choice without applying pressure or a penalty, which were governmental functions under the CDC Program.

Texas agreed to implement the CDC Program, with discretionary authority limited to recruiting Vaccination Providers and providing logistics coordination. The

State's role specifically included the ministerial duty of accepting Plaintiffs' chosen option on the USG's behalf. Texas delegated that duty to Houston Methodist after Houston Methodist signed the CDC Provider Agreement, thereby making Houston Methodist a state actor in the joint function of implementing the CDC Program. Crucially, neither Texas nor Houston Methodist could legally condition the use of the drugs on the deprivation of Fourteenth Amendment rights regarding privacy, bodily autonomy, due process, or property.

From the moment Texas agreed to jointly implement the CDC Program, the Texas HHS, through Ms. Young, and the Texas Workforce Commission, through Mr. Daniel, established a state-enforced custom of allowing Vaccination Providers such as Houston Methodist to pressure individuals to be injected with the INDs and to penalize those who exercised their constitutional and federal statutory rights to refuse.

Despite agreeing to only offer these drugs under voluntary conditions, Houston Methodist violated its promises to Texas and the USG and imposed its mandate on individuals who entered their premises (i.e., employees, volunteers, contractors, vendors). These actions directly violated the CDC Program's informed consent requirements by imposing economic-based pressure to participate in what was legally required to be a voluntary program involving investigational drugs. The mandate unconstitutionally penalized Plaintiffs for exercising their right to refuse

under the Fourteenth Amendment, CDC Program, EUA Statute, PREP Act, 10 U.S.C. §980, and Federal Wide Assurance agreements Houston Methodist had with the federal government and Texas.

The district court dismissed all claims, failing to accept as true Plaintiffs' factual allegations and failing to address Plaintiffs' constitutional and statutory allegations. Given the clear violation of federal program requirements and constitutional rights, this dismissal constitutes reversible error.

Reversal is warranted because the District Court accepted *Defendants'* version of the facts as being true on a Rule 12(b)(6) Motion to Dismiss, rather than accepting Plaintiffs' version, and because it ruled in error on the law.

A. Legislative Background

The federal government's desire to prevent nonconsensual use of investigational drugs is longstanding. In 1938, Congress enacted the Food, Drug, and Cosmetic Act, explicitly prohibiting the introduction of a drug into commerce for general commercial marketing until it is approved for general commercial marketing by the FDA. (21 U.S.C. §355(a)).

In 1972, the public became aware of the human rights abuses committed by the federal government's executive branch against African-American males, which abuse allowed more than 128 participants to suffer until death for the sole reason of enabling researchers to study the effects of syphilis on human anatomy (i.e., the

Tuskegee Experiment)[2].(ROA.202) Forty of the participants' wives contracted the disease, and 19 of their children were born with congenital syphilis. (ROA.202) In 1973, Senator Edward Kennedy conducted hearings exposing human rights atrocities committed by the executive branch against the poor, women, Indians, minorities, the mentally disabled, and other disadvantaged persons.[3] (ROA.203) Recognizing the magnitude of the subject matter, Congress enacted the 1974 National Research Act, which mandated the creation of federally authorized institutional review boards ("IRB") to conduct third-party reviews of research activities to protect the public from future human rights atrocities. (ROA.204) The Act also mandated the creation of a Commission to establish the nature and legal definition of informed consent. (ROA.226) It required the HHS Secretary to promulgate the Commission's findings within a regulatory framework, specifically to define the legal nature of informed consent. (ROA.226)

In 1978, the Commission published its findings in the Belmont Report, in which the HHS Secretary, under command from Congress, established 45 C.F.R.

[2] CDC. About The Untreated Syphilis Study at Tuskegee. The U.S. Public Health Service Untreated Syphilis Study at Tuskegee. Published September 4, 2024. Accessed November 19, 2024. https://www.cdc.gov/tuskegee/about/index.html

[3] Examples of federally funded research abuses include (1) the US Navy spraying San Francisco with a bacterial agent to study biowarfare (Operation Sea-Spray), (2) Chester Southam of Sloan-Kettering injecting live cancer cells into 300 healthy human female prisoners without informed consent, (3) Saul Krugman of Willowbrook State School in Staten Island, New York, deliberately infecting mentally disabled children with hepatitis by feeding them extracts made from infected feces, (4) the Atomic Energy Commission (AEC) injecting newborns with radioactive iodine in their thyroid glands, (5) whole body radiation experiments on the poor, disabled, minorities, and Alaskan Inuit Indians over decades by the AEC. (ROA.203)

Part 46, known as the "Common Rule." (ROA.226) The Common Rule embodies Congress's full intent whenever an individual is offered an IND. Congress requires the totality of the federal budget to filter through the Common Rule (45 C.F.R. §46.122) and requires adherence to the regulatory scheme of its federal agencies, departments, the military (10 U.S.C. §980), and any person acting on its behalf (45 C.F.R. §46.101(a)). Congress has never added to or taken away from any part of the regulation and relies upon the Common Rule when enacting laws involving federally funded investigational drugs.[4] (42 U.S.C. §289g(b)(3)). Despite the Common Rule only being "regulations," they operate as federal law because the National Research Act does not contain statutes of conduct; rather, it only mandates that the HHS Secretary establish that conduct on behalf of the U.S. Congress through the regulatory framework.

In 2001, Congress established the Office of Human Rights Protection (OHRP), which established the Federal Wide Assurance program, requiring any person acting on behalf of the federal government to comply with the Common Rule and the Belmont Report, without exception when offering investigational drugs to humans predicated upon that person accessing federal funds or operating on its behalf. (ROA.254) Today, an estimated 30,000 active FWA agreements with the

[4] "HHS HUMAN SUBJECT REGULATIONS.—The term 'HHS Human Subject Regulations'' means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations)." PUBLIC LAW 114–255—DEC. 13, 2016 ("Cures Act" Section 3203).

federal government exist. Texas operates under FWA00008616, (ROA.1408) and Houston Methodist operates under FWA00000438. (ROA.1408). Defendants' FWAs mean they provided the USG with written assurance that they will (1) comply with the Belmont Report, (2) comply with 45 C.F.R. Part 46, and (3) always obtain an individual's legally effective informed consent without exception. (ROA.1408-09)

B. Legally Effective Informed Consent

The federal government has complete and exclusive authority over the legal conditions under which a person obtains, promotes, and administers an investigational drug to a human. (ROA.1358-1361) No state, political subdivision, or private party can access, promote, or otherwise administer an IND outside the USG's complete and exclusive control. (ROA.1358-1361)

The primary duty of any person acting on behalf of the USG when offering humans investigational new drugs (e.g., the Pfizer-BioNTech COVID-19 Vaccine) is to obtain the individual's legally effective informed consent, as detailed under 45 C.F.R. §46.116 and the Belmont Report. (ROA.1358-1361)

Legally effective informed consent comprises two components. (ROA.1358-1361) First, when a person operating under the USG's authority offers investigational drugs to an individual, they must ensure that the individual is not under coercion, undue influence, unjustifiable pressure, sanctions, or threats of penalty to accept. (ROA.1358-1361) Second, when the individual gives or withholds

their consent, the person must perform the ministerial duty of accepting that individual's freely given consent without penalty or pressure. (ROA.1358-1361)

The Belmont Report (ROA.1347-1349) outlined what the Commission considered "the nature and definition of informed consent" as follows:

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

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;
>
> 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," 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. (ROA.1347-1349)

Legally Effective Informed Consent, according to the Belmont Report, can be broken down into its basic formula: (1) individuals must not be under pressure to use investigational drugs, (2) individuals consent only because they believe the drug may benefit their personal health goals, and (3) the conditions of 1 and 2 are met before the individuals are administered the drug. (ROA.1347-1349)

45 C.F.R. §46.116 requires the person offering the federally funded or authorized drugs to ensure "that participation is voluntary" and "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." (ROA.1437)

A "human subject" is broadly defined as (1) a living individual, (2) from whom data is obtained and used, and (3) from whom identifiable private information is known. (45 C.F.R. §46.102(e)(1)(ii)) (ROA.1353). Research is also broadly

defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes." (45 C.F.R. §46.102(l)) (ROA.1350). An example of the broad definition of a research activity would include an emergency use authorization requiring the manufacturer, emergency stakeholder, and vaccination provider to obtain a person's private health information and monitor them for adverse events, which data is used to add to the "generalizable knowledge" of the product. This research requires adherence to the Common Rule and the Belmont Report requiring third-party review by an Institutional Review Board as outlined under 45 C.F.R. Part 46 because "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." (ROA.1357).

The legally effective informed consent doctrine, established 44 years ago by the USG, has evolved into a fundamental liberty interest that meets the stringent constitutional test set forth in *Washington v. Glucksberg*, 521 U.S. 702 (1997). This doctrine is both "deeply rooted" in our nation's traditions and "implicit in the concept of ordered liberty," reaching a status so fundamental that "neither liberty

nor justice would exist if [it was] sacrificed." (*Id*.) This evolution reflects the doctrine's essential role in protecting individual autonomy in federally funded medical and research contexts.

All U.S. States and Territories have agreed to comply with 45 C.F.R. Part 46 and the Belmont Report's ethical guidelines. (ROA.1361) The totality of the federal and military budgets must comply with the legally effective informed consent requirement. (45 C.F.R. §46.122; 10 U.S.C. §980) Moreover, although the Common Rule is required of the entirety of the federal government (45 C.F.R. §46.101(a)), the principle is directly incorporated within the regulatory framework of most of the USG's agencies: 22 C.F.R. Part 225 (Agency for International Development); 7 C.F.R. Part 1c (Dept. of Agriculture); 28 C.F.R. Part 46 (Dept. of Prisons); EO 12333, EO 13284, EO 13555, EO 13470 (Central Intelligence Agency); 15 C.F.R. Part 27 (Dept. of Commerce); 16 C.F.R. Part 1028 (Dept. of Product Safety Commission); 32 C.F.R. Part 219 (Dept. of Defense); 34 C.F.R. Part 97 (Dept. of Education); 10 C.F.R. Part 745 (Dept. of Energy); 40 C.F.R. Part 26 (Environmental Protection Agency); 28 C.F.R. Part 46 (Federal Bureau of Investigation); 45 C.F.R. Part 46 (Health and Human Services); 6 C.F.R. Part 46 (Dept. of Homeland Security); 24 C.F.R. Part 60 (Dept. of Housing and Urban Development); 28 C.F.R. Part 46 (Office of Justice Programs); 29 C.F.R. Part 21 (Dept. of Labor); 14 C.F.R. Part 1230 (National Aeronautics and Space Administration); 45 C.F.R. Part 690

(National Science Foundation); EO 12333, EO 13284, EO 13555, EO 13470 (Office of Director of National Intelligence); 20 C.F.R. Part 431 (Social Security Information); 49 C.F.R. Part 11 (Dept. of Transportation); 38 C.F.R. Part 16 (Dept. of Veteran Affairs); 42 C.F.R. Part 50 (Public Services Act-sterilization of persons in federally assisted family planning projects); EO 13129 (requirement to obtain informed consent of any military or civilian); 48 C.F.R. Parts 297, 235, 252 (Defense Federal Acquisition Regulation Supplement—DFARS Case 2007-D008); DoDI 3216.02 (DoD: Research Integrity and Misconduct); DoDI 6200.02 (DoD: IND regulation for military and civilian use); DoDD 5400.11-R (DoD Privacy Program); AR 70-25 (U.S. Army: Research Protocols); ALARACT 031/2008, DTG 141557Z Feb 08 (Army Human Subjects Protection Requirements); HQ MRDC IRB Policies and Procedures (U.S. Army Medical Research and Development Command which is responsible for investigational and EUA drug administration DoD-wide).

Moreover, Congress's legally effective informed consent requirements in federally funded programs created more than mere procedural guidelines—it established a legitimate property right. *Board of Regents v. Roth*, 408 U.S. 564 (1972). The ministerial duty to obtain legally effective informed consent means Congress conferred upon an individual the property right to give such consent. This right perfectly aligns with the Supreme Court's definition of protected property interests in *Board of Regents v. Roth*, 408 U.S. 564 (1972).

Under *Roth*'s framework, a protected property interest requires more than "an abstract need or desire" or "unilateral expectation"—it requires "a legitimate claim of entitlement." (*Roth*, at 577) The right to give or withhold informed consent meets this standard precisely because it stems from "existing rules or understandings" established by federal law and regulations. Just as the welfare recipients in *Goldberg v. Kelly*, 397 U.S. 254 (1970), held an entitlement grounded in statutory eligibility, individuals offered federally funded drugs under the CDC Program that are subject to 45 C.F.R. Part 46 have a statutory entitlement to exercise their informed consent rights by either accepting or refusing without penalty or pressure.

This dual character of informed consent—as both a liberty interest and a statutory property right—places it squarely within the protection of the Fourteenth Amendment's Due Process Clause. Like other constitutional rights, informed consent cannot be abridged without due process of law. The right to give or withhold legally effective informed consent thus stands as a protected property interest that requires constitutional due process protections at the level of strict scrutiny before it can be limited or taken away. See *Roth, supra*.

Therefore, when Congress enacts statutes or approves regulations involving its funded or authorized investigational drugs, it requires an individual to prospectively give their legally effective informed consent, which means that no person can come under pressure to receive them or incur a penalty for refusing them.

(ROA.1358-1361) Defendants, acting under the USG's authorization, do not have discretionary authority to exempt themselves from the duty to obtain an individual's legally effective informed consent under the CDC Program, FWA, 10 U.S.C. §980, or the Common Rule, which duty is a purely ministerial function.

C. Legal Background

i. 45 C.F.R. Part 46: "Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative." 45 C.F.R. §46.116(a)(1). The USG owned the COVID-19 INDs and required persons acting on its behalf to obtain an individual's private health information, monitor and study the individual for adverse reactions to the drugs, and add that information to the generalizable knowledge of the product to be reported to the Center for Biologics Evaluation and Research ("CBER"), an FDA department for vaccine regulation acting as the IRB for the CDC Program, requiring the CDC to comply with the Common Rule and the Belmont Report (45 C.F.R. §46.101(a)). (ROA.1358-1361) Moreover, under 45 C.F.R. §46.116, the requirement to obtain Plaintiffs' legally effective informed consent means Congress has conferred upon Plaintiffs the property right to give such consent, which right aligns with *Roth, supra*. Because the Common Rule was established at the direct request of Congress

it confers upon Plaintiffs the entitlement right to give legally effective informed consent; the regulation is subject to 42 U.S.C. §1983 remedial actions.

ii. 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." (10 U.S.C. §980) The federal government (DoD) procured the COVID-19 drugs, requiring the executive branch to obtain an individual's legally effective informed consent before being administered the drugs. (ROA.1387) The duty to obtain legally effective informed consent means that Congress conferred upon individuals the property right to give that consent under this statute. At all times material, the only drugs that the USG, Texas, and HM made available to Plaintiffs were drugs procured using DoD funding.

iii. FWA: The FWA program mandates that any entity offering humans federally funded or authorized INDs must provide to the HHS written assurance of compliance with 45 C.F.R. Part 46 and the Belmont Report regarding the duty to obtain legally effective informed consent. (ROA.1375-1380)

The obligation to obtain legally effective informed consent arises specifically from Defendants' operation under a federally funded program. Thus, the FWA Defendants entered into with the federal government represents voluntarily assumed

duties to be performed on the government's behalf. These duties create specific property rights benefiting Plaintiffs and should be subject to discovery.

iv. 21 U.S.C. §360bbb: Congress established a legal framework for accessing unapproved drugs through two key pieces of legislation. First, the "Expanded Access to Unapproved Therapies and Diagnostics" program ("Expanded Access Program") was created to provide individuals with access to investigational drugs for compassionate use, educational purposes, and emergencies under the HHS Secretary's authorization. See generally 21 U.S.C. §360bbb. (ROA.1366-1372)

To protect individual liberties, Congress established two crucial safeguards. First, it created a statutory right of refusal subject to the Fourteenth Amendment's Due Process Clause. This right ensures that Plaintiffs can decline emergency use products according to their own personal health goals. See 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). Second, it explicitly limited the HHS Secretary's authority, stating that the Secretary has no power to "require any person to carry out any activity that becomes lawful pursuant to an authorization under this section," which includes the receiving an EUA drug (21 U.S.C. §360bbb-3(l)). This dual framework demonstrates Congress's careful balance between enabling effective emergency response while preserving individual autonomy and privacy in medical decision-making.

Investigational drugs are not licensed, manufactured, labeled, or administered with a legal indication of their safety and efficacy to treat, cure, or prevent any known disease. (ROA.1354) Therefore, they fall under Supreme Court precedent regarding unwanted medical treatment.

The Supreme Court has long held:

> No right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear and unquestionable authority of law. *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250 (1891).

More recently, in *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 273 (1990), *citing In re Conroy*, 98 N.J. 321, 348, 486 A.2d 1209, 1223 (N.J. Jan. 17, 1985), the Court held:

> [O]n balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons generally are permitted to refuse medical treatment, even at the risk of death. Most of the cases that have held otherwise, unless they involved the interest in protecting innocent third parties, have concerned the patient's competency to make a rational and considered choice.

In *Washington v. Glucksberg*, 521 U.S. 702 (1997), the Court clarified:

> The right assumed in *Cruzan*, however, was not simply deduced from abstract concepts of personal autonomy. Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation's history and constitutional traditions."

"The protections of substantive due process have, for the most part, been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity." *Albright v. Oliver*, 510 U.S. 266, 272 (1994)

Moreover, when enjoining the DoD from requiring civilian and military personnel to inject investigational drugs into their bodies conditioned upon public employment and military service, Judge Sullivan of the D.C. Circuit held, "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) (ROA.1374)

When the HHS issued the first EUA[5] relating to the Anthrax investigational drug for military and civilian personnel, the Secretary made clear that punishment cannot be the result of refusing an EUA, stating that "Individuals (service members and civilians) who refuse anthrax vaccination will not be punished." (emphasis added) The absence of outside pressure ensured the EUA complied with the legally effective informed consent requirement.

The United States Supreme Court holds "[Congress's] intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that

[5] Federal Register/Vol. 70, No. 21/Wednesday, February 2, 2005/Notices 5455 IV Conditions of Authorization (ROA.1373)

Congress left no room for the States to supplement it or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)). The USG has completely regulated drugs, biologics, and medical devices since Congress enacted the 1906 Pure, Food, and Drug Act and the 1938 FDC&A. It is black letter law that no state, political subdivision, or any person acting under the USG's authority can amend the FDCA, EUAs, or the regulatory framework involving its funded investigational medical products or the emergency conditions under which they are introduced into commerce.

The D.C. Circuit Court held that a terminally ill person does not have the fundamental right to access investigational drugs because the conditions under which unapproved drugs are introduced into commerce belong to Congress and its agencies—namely, the FDA. (*Abigail Alliance v. Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007)).

A constitutional, statutory, or programmatic right of refusal becomes meaningless if its exercise triggers punitive consequences. As the Supreme Court has consistently recognized, the right to refuse unwanted medical treatment cannot coexist with penalties that effectively negate the choice. Where the exercise of such a right results in adverse consequences, the right itself becomes illusory - a mere

fiction that exists in theory but cannot be meaningfully exercised in practice. See *Frost & Frost Trucking Co. v. Railroad Comm'n of California*, 271 U.S. 583, 593 (1926) (holding it "inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence" through indirect coercion.)

Therefore, Defendants have no authority to establish a legal requirement mandating that which Congress explicitly prohibits—nonconsensual use of emergency use investigational drugs.

v. PREP Act: The PREP Act is primarily an immunity statute. (ROA.1380-1387) However, providing immunity to a person who injures another member of society burdens the Plaintiffs' right to bring a cause of action for product liability, medical malpractice, fraud, and battery; seek tort remedies for bodily harm caused by another member of society; and be made whole for damages to their finances and emotional well-being, which rights are subject to the Due Process Clause. Moreover, the PREP Act places a significant financial burden upon Plaintiffs to seek redress only in the United States District Court for the District of Columbia should they sustain injury from an act of willful misconduct. (ROA.1072)

The Supreme Court holds that a common law cause of action is a property right, stating: "The hallmark of property is an individual entitlement grounded in state law, which cannot be removed except 'for cause." *Logan v. Zimmerman Brush*

Co., 455 U.S. 422 (1982). "The first question, we believe, was affirmatively settled by the *Mullane*[6] case itself, where the Court held that a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause." *Id*. See, *Tulsa Prof. Collection Svcs. v. Pope*, 485 U.S. 478 (1988); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985).

The PREP Act itself does not deprive a person of their property interest because the Act requires only voluntary participation. (42 U.S.C. §247d-6e(c)). Instead, Defendants, acting under color of law and requiring Plaintiffs to use a covered countermeasure under threat of penalty, is the conduct that deprives Plaintiffs of their due process rights under the Act.

The PREP Act contains an express preemption provision stating: "During the effective period of a declaration under subsection (b)…no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered 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,

[6] *Mullane v. Central Hanover Bank & Trust Co*., 339 U.S. 306 (1950)

and Cosmetic Act." ("FDCA")(emphasis added)(42 U.S.C. §247d-6d(b)(8)). (ROA.1381).

The "any matter included in a requirement applicable to the covered countermeasure under… the Federal Food, Drug, and Cosmetic Act" includes the option to accept or refuse under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). Therefore, Defendants are expressly preempted from establishing or continuing in effect with a legal requirement that conflicts with a person's right to refuse an EUA product, which their mandates did. The Supreme Court holds that "[w]hen a federal statute contains an express pre-emption clause, the court should review the 'plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Chamber of Commerce of United States of America* v. *Whiting*, 563 U.S. 582, 594 (2011) (internal quotation marks omitted).

Therefore, Congress has explicitly preempted states and/or their political subdivisions from establishing legal requirements that conflict with the PREP Act's voluntary nature and the option to refuse under the Food, Drug, and Cosmetic Act ("FDCA"). (ROA.1381) This fact demonstrates that Defendants' mandates were issued only under *ultra vires* authority.

D. Factual Background

In 2020, the USG purchased all COVID-19 investigational drugs, authorized them for use under the Emergency Use Authorization Statute (21 U.S.C. §360bbb-

3), classified them as investigational, and immunized them from liability under the PREP Act. (ROA.1387) Significantly, the HHS Secretary required each COVID-19 manufacturer, the USG, emergency response stakeholders, and vaccination providers to conduct research activities and established the conditions under which the research activities would occur in each EUA letter, known as the Scope of Authorization. (ROA.1355; ROA.1387-1392)

The research obligations extended to state-level participants, who voluntarily assumed the role as the emergency response stakeholders (i.e., Texas's executive leadership) and were required to "ensure its [i.e., Pfizer-BioNTech COVID-19 Vaccine's] distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program." (ROA.1355-1358) This duty specifically required the state to ensure its recruited parties conducted the research activities on behalf of the USG. (ROA.1355-1358) At the implementation level, vaccination providers like Houston Methodist were required to report serious adverse events and cases of Multisystem Inflammatory Syndrome in children and adults. (ROA.1352)

As discussed above, the federal government's executive branch is bound without exception to obtain an individual's legally effective informed consent under the above-described conditions relating to legal requirements cited herein. There does not exist a condition under which the USG, or persons acting on its behalf, can

mandate a civilian to use an IND under threat of penalty; rather, Congress expressly preempts the establishment of such a legal requirement.

E. CDC Program

In 2020, the United States Government established the CDC Program to ensure compliance with its legal obligations regarding the COVID-19 INDs. (ROA.1387-1392) This program specifically recruited states with active FWAs, as these states were already bound by the same legal obligations governing IND administration as the USG. (ROA.1375-1380) To formalize this structure, the federal executive branch created the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement"), which Texas incorporated into official state policy when agreeing to perform for the USG under the CDC Program. (ROA.1387-1392)

Any entity administering the drugs under the State's authority must comply with the Provider Agreement and all applicable laws, regulations, and legal requirements therein. (ROA.1387-1392) This created an exclusive channel through Texas's authority—no person or entity could participate in the CDC Program outside this framework. (ROA.1387-1392) Importantly, those recruited by Texas to assist in program administration held no discretionary authority to modify the federal program conditions or any Emergency Use Authorization's "Conditions of Authorization." (ROA.1387-1392)

The Provider Agreement imposed specific constraints on program operation. (ROA.1403-1405) Recruited state actors could not charge for the drugs, ancillary supplies, or administrative fees. (ROA.1403-1405) More critically, Texas and its state actors bore legal obligations to:

1. Inform Plaintiffs of drug risks, benefits, and alternatives.

2. Advise Plaintiffs of their right to accept or refuse administration without consequence.

3. Obtain legally effective informed consent on behalf of the USG. (ROA.1403-1405)

These obligations, detailed in Section 12(a)[7] and (b)[8] of the Provider Agreement, were tied directly to the state actors' ability to bill the USG for program administration. (ROA.1403-1405) While Texas and its state actors maintained *discretionary* authority to inform the public about IND availability (when, where, and how the drugs were available), they remained bound by a *ministerial* duty to obtain legally effective informed consent from potential participants—a requirement established through Defendants' respective FWAs, each EUA, and delegation of responsibility from the USG.

[7] "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."
[8] "Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws."

This framework created specific constitutional property rights for Plaintiffs under the Fourteenth Amendment's Due Process Clause (*Goldberg v. Kelly*, 397 U.S. 254 (1970)), which deprivations are enforceable under 42 U.S.C. §1983 (*Health and Hospital Corporation of Marion Cty. v. Talevski*, 599 U.S. 166 (2023)). These federal program benefits include:

1. The right to learn about drug risks, benefits, and alternatives without external pressure

2. The right to accept or refuse drug administration without penalty or loss of existing benefits

3. The right to access emergency-authorized unlicensed drugs during declared emergencies

The constitutional protection against mandated use of unlicensed INDs under the EUA Statute rests on multiple reinforcing legal foundations. First, Congress explicitly prohibits unlicensed drugs from entering the marketplace before FDA marketing approval under 21 U.S.C. §355 but allows individuals to access the drugs voluntarily under the EUA Statute according to the conditions of authorization established by the HHS Secretary, to which Defendants must voluntarily agree to comply. This foundational restriction creates a clear federal framework that prioritizes voluntary use over mandated use, making refusal of unlicensed drugs during a declared emergency a statutory entitlement protected by the Fourteenth Amendment.

The CDC Program creates a comprehensive federal scheme protecting individual choice regarding investigational drugs. The HHS Secretary's emergency authorization cannot and does not grant state actors (like Defendants) authority to mandate investigational drug use. (ROA.1387-1392) The Supremacy Clause preempts such mandates for three distinct reasons:

1. They conflict with explicit congressional limitations on compulsory use of investigational drugs.

2. They unilaterally deprive individuals of their Fourteenth Amendment liberty interest to refuse investigational drugs.

3. They unilaterally deprive individuals of their property rights under the CDC Program.

Therefore, any laws or legal requirements—whether federal, state, or local—that conflict with an individual's right to refuse EUA/PREP Act drugs are preempted by the Supremacy Clause and must be declared unconstitutional when their application infringes upon this right to refuse, which includes the State's at-will employment laws and Defendants' mandates when used solely to punish a person for exercising their right to refuse PREP Act countermeasures. (ROA.1383). Moreover, 18 U.S.C. §245(b)(E) prohibits the state and private parties from using the force of their authority to intimidate, harass, or coerce a person from

"participating in or enjoying the benefits of any program or activity receiving Federal financial assistance."[9]

Additionally, the CDC Program, by its legal nature, required Plaintiffs to:

(1) assume greater risks to their health, legal rights, and financial security,[10]

(2) become human subjects under the federally funded COVID-19 research activities,

(3) allow their private identifiable and health information to be collected, shared, and used by unknown persons, reasons, and time,

(4) voluntarily forfeit their Fourteenth Amendment due process rights to bring a cause of action if injured under the program resulting from the drugs' being listed as countermeasures under the PREP Act by the HHS Secretary. (ROA.1387-1392)

The State, through its recruited parties, had no authority to command that Plaintiffs' consent to these legal conditions to work within the healthcare industry, but it did just that by not enforcing the terms of the CDC Program on its recruited actors. The Supreme Court has long held, "For at least a quarter-century, this Court has made clear that even though a person has no 'right' to a valuable governmental

[9] Although this is a civil and not a criminal case, criminal case law can be utilized to demonstrate that a public official is not entitled to qualified immunity.

[10] 21 U.S.C. §360bbb-3 requires potential recipients to be made aware of the risks, alternatives, and the fact that the product is only authorized by the Secretary under emergency conditions. These elements provide potential recipients with the required information to make a quality and legally effective decision to consent. Therefore, consent means the individual agrees to assume more than minimal risk as defined in 21 C.F.R. 50.3(k)

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." (*Perry v. Sindermann*, 408 U.S. 593, 92 S.Ct. 2694, 33 L.Ed.2d 570 (1972)).

Therefore, Texas could not command Plaintiffs to become human subjects in federally funded research activities, publicly disclose private health information to government contractors outside of their free consent, surrender their due process right to seek judicial relief if injured from the program, its products, or activities casually connected to a covered countermeasure, nor could it treat persons accepting the drug's administration unequally to those refusing the drugs, nor could it mandate Plaintiffs to inject unlicensed investigational new drugs into their bodies as a condition of working within the state's licensed healthcare industry.

However, through its recruited actor, Houston Methodist, the State delegated the function of the federal program but refused to enforce the constitutional obligations it owed to Plaintiffs when Houston Methodist became the first hospital in the nation to violate its federal obligations. Therefore, the execution of the CDC Program through Houston Methodist was "in practical operation" a "procedural device" the State used to "produce a result which the State could not command directly." *Speiser v. Randall*, 357 U.S. 513 (1958)

F. "Vaccination" Mandates

Houston Methodist's mandate exclusively involved drugs available through the CDC Program, making Houston Methodist's interactions with all individuals – employees or not – regarding these drugs occur under color of law because Houston Methodist was under the complete control of Texas regarding the administration of these drugs. Houston Methodist lacked any authority to modify the federal program by selecting groups (employees, contractors, vendors, volunteers) to receive these drugs under threat of penalty. Such coercive actions exceeded the delegated authority conferred by the State and could only have occurred under a State-enforced custom.

IV. SUMMARY OF THE ARGUMENT

Plaintiffs have plausibly alleged claims for deprivation of: (1) the right to refuse unwanted investigational drugs, (2) the right to refuse EUA drugs, (3) the right to refuse PREP Act countermeasures, (4) the right to be treated equally before the law, and (5) the right to privacy. Plaintiffs identified an injury related to each claim, and each claim can be redressed by the relief Plaintiffs requested. The district court dismissed the case on a Rule 12(b)(6) motion but only after it failed to accept as true facts that Defendants did not even dispute, thus disputing the facts on Defendants' behalf, demonstrating reversible error.

V. ARGUMENT

A. Standard of Review

Dismissals under Rule 12(b)(6) are reviewed *de novo*.[11] The standard for dismissal under Rule 12(b)(6) is: "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face."[12] The Fifth Circuit considers that motions to dismiss under Rule 12(b)(6) "are rarely granted and generally disfavored."[13]

B. The district court erred when refusing to acknowledge Plaintiffs' allegations that the drugs were investigational and the constitutional authority of Congress to prohibit Texas and Houston Methodist from placing Plaintiffs under pressure to be administered federally funded investigational medical products or treatments or punish such refusal.

Judge Hanks begins his ruling by stating, "This is a civil rights case brought under 42 U.S.C. §1983 ('Section 1983') by over 100 healthcare professionals who were let go for refusing to inoculate themselves against COVID-19 in violation of their employers' mandatory immunization policies." (RE.50)

Judge Hanks fundamentally mischaracterized the central issue of this case. While Judge Hanks characterized this as an employment termination dispute over "refusing to inoculate," the core legal question involves HM, a state actor,

[11] *Magee v. Reed*, 912 F.3d 820, 822 (5th Cir.2019)
[12] *Edionwe v. Bailey*, 860 F.3d 287, 291 (5th Cir.2017) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)).
[13] *Rodriguez v. Rutter*, 310 F. App'x 623, 626 (5th Cir. 2009)

unlawfully subjecting Plaintiffs to investigational drugs under the CDC COVID-19 Vaccination Program ("CDC Program"), depriving them of constitutional protections and statutory entitlements.[14]

Judge Hanks incorrectly treated the mandated drugs as approved vaccines when they were legally classified as INDs undergoing clinical trials.[15] This distinction is crucial – these drugs lacked FDA approval for use as inoculations against disease. Assigning unapproved indications to these drugs is no minor error because if a drug company did so, it would form the basis of misbranding under 21 U.S.C. §352, a prohibited act under §331, and punishable with incarceration under §333.

The district court relied on *Pearson's* holding: "Shriners correctly asserts that the plaintiffs' 'right to refuse' the vaccine never came into being because none of the Shriners parties ever actually administered the COVID-19 vaccination to any of the plaintiffs." (RE.58) Following the faulty logic of *Pearson*, which is also being appealed to this Court, Plaintiffs would have to be injected with the drugs in order to have the right to refuse being injected with the drugs. The absurdity is self-

[14] The failure to consider the drug's investigational and emergency use statuses and the applicable laws is reversible error because "[a] district court abuses its discretion when it does not consider 'a relevant factor that should have been given significant weight.'" *PHH Mortgage Corp. v. Old Republic*, 80 F.4th 555 (5th Cir., Aug. 30, 2023).

[15] Plaintiffs are not alleging that they would have been part of a clinical trial. They are alleging that the drugs being tested in the clinical trial were the same as the ones available under the CDC Program for compliance with Houston Methodist's mandate.

evident. In contrast, Plaintiffs are arguing that penalizing or pressuring their right to refuse EUA/PREP Act investigational drugs deprives them of that right, and when such deprivation occurs at the hands of persons acting under color of law, like Houston Methodist, Dr. Boom, and Dr. Phillips, then Plaintiffs may seek redress under 42 U.S.C. §1983.

Houston Methodist, operating under federal and state authority through the CDC Program, was prohibited from exerting pressure on anyone – including employees, contractors, vendors, and volunteers – to use investigational new drugs, but their policy and threats of penalty did just that, violating the ministerial duty to obtain Plaintiffs' legally effective informed consent on behalf of Texas and the USG.

Pearson also establishes legal fiction that the right to refuse only occurs when a person physically administers the drug. The right to refuse came into being the moment the FDA assigned the drug its investigational status, subjecting it to the Fourteenth Amendment's Due Process Clause involving unwanted medical treatments, and when the HHS Secretary issued the EUA requiring Defendants to inform Plaintiffs of their right to refuse,[16] and when the Executive Branch established the CDC Program offering the INDs to the public only under voluntary

[16] Texas was the "emergency response stakeholder" under each EUA and lawfully bound to ensure the "Organizations" that signed the Provider Agreement informed potential recipients of the lawful right to refuse. Houston Methodist, at the executive level, signed the Provider Agreement agreeing to comply with "any EUA" and as the "Organization" it was lawfully bound to ensure its staff informed potential users of that right.

conditions. But when Houston Methodist interacted with Plaintiffs regarding the EUA/PREP Act investigational drugs available under the CDC Program, Houston Methodist effectively advised Plaintiffs that they did not have a right to refuse because exercising that right would cost Plaintiffs their medical careers and other damages. Houston Methodist was legally obligated to inform any potential recipient of their right to refuse, irrespective of how they interacted with that person (e.g., company policy, public advertisement, etc.)

Judge Hanks' ruling effectively rewrites the deeply rooted regulatory framework governing federally funded INDs, Federal Wide Assurances, Institutional Review Boards, and the emergency conditions for their commercial introduction. By effectively accepting Houston Methodist's position that it could pressure Plaintiffs to be injected with the drugs, the court undermined Plaintiffs' foundational protections. Whether Houston Methodist directly administered the drugs is immaterial – federal law explicitly prohibits Texas and HM Defendants from placing Plaintiffs under any pressure to participate in such programs and INDs. HM Defendants can cite to no law providing them authority to place an individual under threat of penalty to use a federally funded or authorized investigational drug nor how HM Defendants are exempt from their federal obligation to perform the ministerial function of accepting Plaintiffs' chosen option on behalf of Texas and the federal government as promised under the CDC Program.

Judge Hanks' ruling, if allowed to stand, would fundamentally alter the established regulatory framework governing how the $600 billion pharmaceutical industry administers INDs to the public. The ruling effectively sanctions coerced participation in federally funded research activities by entities using federal INDs or acting on behalf of the government – a practice that has been consistently prohibited under law. This precedent would undermine longstanding protections against compulsory participation in experimental drug research and deprive a person of having the Fourteenth Amendment right under state-sponsored programs to refuse unwanted investigational medical treatments without penalty or pressure.

The Supreme Court held that "[a] district court by definition abuses its discretion when it makes an error of law." *Koon v. United States*, 518 U.S. 81, 100 (1996); *Hood ex rel. Miss. v. City of Memphis*, 570 F.3d 625, 628 (5th Cir. 2009)("[a] court abuses its discretion when its ruling is based on an erroneous view of the law."). Judge Hanks' holding that Houston Methodist could include the INDs under a policy that placed Plaintiffs under pressure to be injected with them is an "erroneous view of the law" and constitutes reversible error.

C. The district court erred when relying on *Pearson* to hold that Houston Methodist was not a state actor.

Judge Hanks' ruling that Houston Methodist was not acting under color of law, relegated to a footnote citing *Pearson*, constitutes reversible error. The district court cited *Pearson's* statement that Plaintiffs "have failed to allege any . . . manner

in which the termination of their employment may have constituted state action[.]" Plaintiffs have not alleged that "termination of their employment" is what constitutes state action. Rather, Plaintiffs have alleged that state action results from the joint action among the USG, Texas, and Houston Methodist relative to their interactions with anyone, employee or not, regarding the EUA/PREP Act investigational drugs available under the CDC Program and which factors meant that Houston Methodist owed Fourteenth Amendment and other legal obligations to any person they interacted with regarding the INDs. Therefore, the district court and *Pearson* examined state action in isolation of Plaintiffs' allegations regarding federal and state duties owed to Plaintiffs, which is reversible error.

Plaintiffs' allegations concerning the CDC Program, the investigational classification of the drugs, and federal ownership of these drugs until human administration and Houston Methodist's agreement to act on behalf of Texas under these legal conditions met the plausibility threshold for state action for purposes of overcoming Defendants' Rule 12(b)(6) motion. These factors established that the government—federal and state—owed Plaintiffs the ministerial duty of securing legally effective informed consent. Houston Methodist's policy, therefore, derived solely from *ultra vires* authority executing a state-enforced custom.

The Supreme Court's decision in *Adickes v. S. H. Kress & Co*., 398 U.S. 144 (1970), provides the governing framework: Plaintiffs "will have established a claim

under §1983 for violation of [their] equal protection rights if [they] prove[] that [they] w[ere] refused service by respondent because of a state-enforced custom." (emphasis added) Here, Houston Methodist operated under multiple federal and state obligations: not to misbrand drugs, not to coerce investigational drug use, not to deprive individuals of constitutional, statutory, and programmatic rights under the CDC Program, and to comply with FWA and IRB protocols. When Houston Methodist violated these obligations without consequence from federal authorities or Texas regulators, it acted pursuant to a state-enforced custom of non-enforcement.

The regulatory structure under the CDC Program created clear lines of delegated authority: The federal government, as owner of the drugs until administration, bore the primary duty to obtain legally effective informed consent. It delegated this duty to Texas, which in turn delegated to Houston Methodist. Texas retained oversight responsibility for its delegees' program implementation. By willfully failing to enforce compliance, Texas established the state-enforced custom that enabled Houston Methodist to deprive Plaintiffs of their constitutional, statutory, and property rights—rights ultimately owed to them by the State.

The *Adickes* Court stated, "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" because "[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."

Plaintiffs spent considerable space explaining in detail how Houston Methodist was a state actor, which the trial court did not address under the erroneous belief that the hospital could include the investigational drugs under compulsive conditions. (ROA.1395-1418)

Although novel, the CDC Program was established as an emergency public function requiring the USG and its delegated agents to owe constitutional, statutory, and regulatory obligations to all individuals involved with its INDs. The USG delegated these obligations to Texas, which voluntarily participated under its sovereign prerogative. See *Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 160 (1978). Texas further delegated its federally-mandated duties to private entities like Houston Methodist.

Critically, Texas—not Houston Methodist—bore the primary responsibility to perform under the federal program, owing both Fourteenth Amendment and programmatic obligations to Plaintiffs throughout. See *Jackson v. Metropolitan Edison Co*., 419 U.S. 345, 353 (1974) (establishing state obligations in delegated public functions to private parties). The program's structure created mutual benefits:

Texas received federal funding for administering drugs to the public, while Houston Methodist obtained monetary benefits from the federal government through Texas.

This arrangement created a symbiotic relationship between Texas and Houston Methodist, involving joint conduct in medical research, informed consent procedures, drug administration, adverse event reporting, documentation requirements, and federal billing services. Through these coordinated activities with recruited partners like Houston Methodist, Texas realized $321 billion in unexpected federal revenue (ROA.1401), underscoring the integrated nature of this public-private partnership.

Therefore, "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). "[W]hen private individuals or groups are endowed by the State with powers or functions governmental in nature, they become agencies or instrumentalities of the State and subject to its constitutional limitations" *Evans v. Newton,* 382 U.S. 296, 299, 86 S.Ct. 486, 15 L.Ed.2d 373 (1966). Moreover, when Texas allowed Houston Methodist to violate its agreement with the State depriving Plaintiffs of their constitutional rights, Houston Methodist "[m]isuse[d] [its] power, possessed by virtue of state law and made possible only because [it was] clothed with the authority of state law" and its "action" must be considered to have been "taken 'under color

of" state law." *United States v. Classic*, 313 U.S. 299, 326 (1941), citing *Ex parte Virginia,* 100 U.S. 339 and *Home Telephone & Telegraph Co. v. Los Angeles,* 227 U.S. 278 (1913).

As the Fourth Circuit Court of Appeals eloquently stated in *Modaber v. Culpeper Memorial Hospital, Inc.,* 674 F.2d 1023 (4th Cir., March 24, 1982), "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[,][citation omitted] for the state's direct benefit when it shares the rewards and responsibilities of a private venture with the state." *Id., citing Jackson v. Metropolitan Edison, Co*., *supra*, and *Burton v. Wilmington Parking Authority*, 365 U.S. 715, 723-24 (1961).

These facts were not addressed by the district court nor in *Pearson*, yet Judge Hanks exclusively relied on facts alleged in *Pearson* to resolve facts alleged in the case at bar.

D. The district court erred when dismissing Plaintiffs' Complaint under Rule 12(b)(6).

Judge Hanks' assertion that "a complaint may be dismissed if it clearly lacks merit—for example, where there is an absence of law to support a claim of the sort made" (RE.53) misapplies the law to the present case. The district court erroneously presumed that Texas and Houston Methodist could coerce Plaintiffs to receive

COVID-19 INDs and penalize their refusal—despite explicit prohibitions under the Fourteenth Amendment, the CDC Program, IRB requirements, and FWAs.

This misconception precluded meaningful consideration of Plaintiffs' claims regarding constitutional, statutory, contractual, and programmatic federal duties owed by the State to Plaintiffs, which obligations were delegated to Houston Methodist. The court's subsequent analysis is particularly problematic as it proceeds from this flawed premise to mischaracterize Plaintiffs' arguments. Rather than addressing Plaintiffs' actual claims—grounded in the drugs' investigational classification and comprehensive regulatory framework—the court reduced Plaintiffs' argument to a simple employment dispute over "vaccine" requirements, as if the drugs were FDA-licensed for that indication.

The Fifth Circuit has consistently held that at the pleading stage, Plaintiffs need only allege "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary claims or elements." *Flagg v. Stryker Corporation*, 14-31169 (5th Cir., April 26, 2016). Here, Plaintiffs met this standard by alleging sufficient factual matter that, taken as true, establishes: (1) agreements between the federal government and Texas, and between Texas and Houston Methodist, ensuring individuals would not face pressure to receive COVID-19 INDs or punishment for refusing them; (2) Houston Methodist's role as a state actor under the CDC Program;

and (3) Plaintiffs' right to refuse without penalty. These allegations surpass mere speculation and satisfy Rule 12(b)(6)'s plausibility requirement.

The district court's dismissal of all of Plaintiffs' counts rests on two flawed premises: first, that Texas and its recruited parties owed no constitutional, statutory, or programmatic duties to Plaintiffs under the CDC Program; and second, that an entity acting on behalf of the federal government could lawfully coerce individuals to receive federally funded emergency use drugs and penalize their refusal. This ruling not only fails to accept Plaintiffs' factual allegations as true, but more troublingly disregards Congress's explicit statutory prohibitions against such coercive conduct—the departure from which warrants reversal.

E. The district court erred when it relied on cases that were not on point factually or were decided erroneously on the law.

Bridges v. Houston Methodist Hospital (Bridges I) is not "materially identical to this one." (RE.53). *Bridges I* was brought in state court seeking a declaratory judgment that a violation of federal law was an exception to Texas's at-will employment doctrine under *Sabine Pilot* and seeking a private right of action under the EUA Statute. Plaintiffs herein do not allege wrongful termination under *Sabine Pilot*, nor are they attempting to bring a private right of action under the EUA Statute, which *Bridges I* found was procedurally improper. By contrast, the instant case is brought pursuant to 42 U.S.C. §1983, which is mutually exclusive with a private right of action under a statute, for damages arising out of the deprivation of

Constitutional rights and federal statutory rights conferred upon Plaintiffs in the EUA Statute and the PREP Act. Therefore, the *Bridges I* ruling does not apply to the claims brought herein.

As for *Pearson*, see Plaintiffs' discussion, *supra*.

The district court's reliance upon the Sixth Circuit's holding in *Norris v. Stanley*, 73 F.4th 431, 438 (6th Cir. 2023)(RE.57), which focused on "the interaction between the medical provider and the person receiving the vaccine," is equally inapplicable, for the reasons set forth above addressing the district court's ruling that one must be injected to have the right to refuse injection. (RE.57) Moreover, the EUA statute does not assign informed consent duties to "medical providers." Rather, it empowers the HHS Secretary to establish conditions of authorization that bind all entities volunteering to participate in the Program. In this case, the EUA letters designated the Texas HHS department as "emergency response stakeholder" responsible for ensuring compliance with these conditions within its jurisdiction, specifically through "Organizations" like Houston Methodist that executed the Provider Agreement as outlined in the August 23, 2021 EUA (ROA.1728-1735) and repeated through the issuance of other EUAs for all times material. Individual medical providers at Houston Methodist are bound by the dictates of the Provider Agreement signed by their CEO to comply with "any EUA" to implement these conditions on behalf of the State.

Judge Hanks' reliance on *Norris* compounds this error by using that case to effectively engage in improper fact-finding at the pleading stage. (RE.57-58) Using the *Norris* ruling to dispute Plaintiffs' allegations that Texas and Houston Methodist, as an Organization under the Provider Agreement, bore duties to inform Plaintiffs of their rights and obtain freely given consent, the district court improperly resolved factual disputes in Defendants' favor—which warrants reversal.

Sweeney v. University of Colorado Hospital Authority (RE.59-60, 62) effectively held that Colorado is not preempted by the Supremacy Clause, the PREP Act's express preemption language, nor the Fourteenth Amendment from mandating the federally funded INDs. Moreover, the court held that the state could constitutionally mandate that individuals be injected under threat of penalty, which ruling is a clear violation of the Separation of Powers doctrine and Plaintiffs' constitutional rights. That ruling is on appeal to the Tenth Circuit.

The Ninth Circuit's decision in *Maney v. Brown*, 91 F.4th 1296, 1303 (9th Cir. 2024) (RE.59) addressed only a governor's discretionary authority to prioritize PREP Act drugs for prison guards above inmates. The court did not examine the Act's express preemption provisions, which is the core issue underlying Plaintiffs' PREP Act claims herein. This critical distinction renders *Maney* inapposite, where Plaintiffs herein do not challenge prioritization of distribution but rather challenge Houston Methodist's authority to rescind the right to refuse for certain individuals

(employees, visitors, contractors, etc.) in violation of the Act's express preemption provision.

The district court improperly relied on *Boysen v. PeaceHealth* to resolve disputed factual matters. (RE.60) *Boysen* held, "There is no allegation that state Defendants expended Department of Defense funds or were obligated to inform Plaintiffs of information, but failed to provide such information." By citing a District of Oregon ruling on allegations specific to that case to dismiss factual allegations in the present case, Judge Hanks misapplied the Rule 12(b)(6) standard. Plaintiffs specifically alleged that the mandated drugs were procured with Department of Defense funding—a fact they can establish through DoD contracts and expert testimony, but which should have been accepted as true on a Motion to Dismiss. (ROA.1654)

Furthermore, *Boysen's* extraordinary holding that "the common belief of the people of the state" determines drug safety and efficacy misreads *Jacobson*. By claiming that *Jacobson* "did not look to the text of a mandate, or any licensing label" to evaluate the smallpox vaccine's status, the *Boysen* court effectively nullified over a century of congressional legislation and executive branch regulation of drugs. It is the erroneous belief that the "people of the state" and not the legislative and executive branches of the federal government determine the conditions under which INDs are introduced into commerce that led *Boysen* to state, "Plaintiffs have failed

to allege sufficient facts from which they could obtain relief from state Defendants based on this statute." (RE.60) *Boysen*, currently on appeal to the Ninth Circuit, represents a clear violation of the Separation of Powers doctrine and cannot properly support dismissal in this case.

Jacobson v. Massachusetts, 197 U.S. 11 (1905) (RE.65), has no controlling authority because 119 years of subsequent comprehensive federal regulation expressly prohibit the mandatory administration of federally funded INDs. While Plaintiffs herein exhaustively detailed this regulatory framework, Judge Hanks improperly disregarded this distinction between *Jacobson's* state-licensed smallpox vaccine and federally controlled EUA/PREP Act investigational drugs subject to explicit statutory and regulatory restrictions against coerced use.

Furthermore, the *Boysen*, *Pearson*, and *Sweeney* courts did not rule on Plaintiffs' preemption claims under the Supremacy Clause or the PREP Act's express preemption claims, did not discuss how the CDC Program placed the State under a ministerial duty to obtain Plaintiffs' legally effective informed consent on the USG's behalf, foreclosed discovery of facts by dismissing the complaint under Rule 12(b)(6), and dismissed the cases with prejudice while effectively amending the federal regulatory scheme that completely prohibits all Defendants from placing individuals under threat of penalty to refuse federally funded INDs.

F. The district court erred when holding that Plaintiffs may not enforce rights secured by Congress under 42 U.S.C. §1983 under the CDC Program and applicable laws.

CDC Program: As discussed, the CDC Program provides Plaintiffs with the benefit of accepting or refusing federally funded drugs, which benefits are property rights (*Roth, supra*) subject to the Due Process Clause enforceable under §1983 (*Talevski, supra*).

EUA Statute: Congress created specific individual rights under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(II) that constitute protected property interests (*Roth, supra*) and implicate the liberty interest in refusing unwanted medical treatment (per *Cruzan* and *Glucksberg, supra*). These rights are subject to Due Process Clause protection. The language establishing an "option to accept or refuse" meets the Supreme Court's test in *Talevski, supra*, for rights-creating language enforceable under §1983. Significantly, Congress provided no remedial scheme under the FDCA for an individual to enforce violations of this right of refusal. Such violations are not enumerated as prohibited acts under 21 U.S.C. §331 and thus cannot be enforced through §337. Therefore, §1983 provides the appropriate mechanism to vindicate these Fourteenth Amendment property and liberty interests when individuals are deprived of their right to refuse EUA/PREP Act investigational drugs. Moreover, no court has considered the property or liberty interests implicated under the option

to accept or refuse, which option belongs exclusively to Plaintiffs with which no other person has the authority to interfere.

PREP Act: The district court failed to address the PREP Act's express preemption clause, which prohibits States from establishing or enforcing laws and legal requirements that conflict with any provision in the FDCA, including the "option to accept or refuse" in the EUA Statute. This rights-creating language, establishing an individual's right to choose, is therefore enforceable through §1983 because that option has been incorporated into the PREP Act's statutory requirement. Moreover, the PREP Act does not contain an enforcement provision such as the one under 21 U.S.C. §337; therefore, the option to accept or refuse language can be enforced under §1983.

10 U.S.C. §980: Congress would not mandate that informed consent be obtained if Congress did not first confer upon the potential recipient the property right to give informed consent. Therefore, "informed consent" is a property right held by Plaintiffs to give or withhold, the deprivation of which is actionable under §1983.

45 C.F.R. §46.116: The Common Rule was established at Congress's specific direction but did not establish required conduct. Instead, Congress authorized the HHS Secretary to do so on its behalf, which he did by establishing the right to give legally effective informed consent. The lack of a right to give informed consent

would render meaningless the entire federal framework of IRBs, FWAs, and the substantial body of legislation that relies on the Common Rule and effectively nullify decades of established human subject protection law. However, under *Roth's* definition that a property right stems from "rules or understandings that secure certain benefits and that support claims of entitlement to those benefits," the right to give informed consent is subject to the Due Process Clause. Plaintiffs contend that the duties listed under 45 C.F.R. §46.116 provide Plaintiffs with "rules or understandings" that they can "consider whether or not to participate" (45 CFR 46.116(a)(2)) and give their "legally effective informed consent" (45 CFR 46.116(a)(1)) with the understanding 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…" (45 CFR 46.116(b)(8)), which rules and understandings are property rights for Plaintiffs' benefit subject to a §1983 remedy.

G. The district court erred when dismissing Plaintiffs counts under Rule 12(b)(6)

The district court's assertion that "Plaintiffs do not have a fundamental right to refuse vaccination" mischaracterizes Plaintiffs' allegations and avoids the central constitutional issue. While the right to refuse FDA-licensed vaccines may be debatable, there is no question that Plaintiffs possess constitutional rights to: decline unwanted investigational medical treatments, refuse to be human subjects in

federally funded research, maintain the privacy of their health information, and preserve their Fourteenth Amendment right to judicial remedy for injuries. The district court's overly narrow framing of the issue as merely "vaccine refusal" disregards these well-established constitutional protections against coerced use of EUA/PREP Act investigational drugs, which protections Texas promised to secure on behalf of the USG, and Houston Methodist promised to secure on behalf of Texas.

The Supreme Court held in *Dennis v. Higgins*, 498 U.S. 439 (1991) that "we have given full effect to its broad language, recognizing that §1983 'provide[s] a remedy, to be broadly construed, against all forms of official violation of federally protected rights' and 'we refused to limit the phrase to 'personal' rights, as opposed to 'property' rights.'" (citing *Lynch v. Household Finance Corp.,* 405 U.S. 538 (1972)). *Dennis* also held: "The right to enjoy property without unlawful deprivation, no less than the right to speak or the right to travel, is, in truth, a 'personal' right, whether the 'property' in question be a welfare check, a home, or a savings account." (*Dennis v. Higgins, supra.)*

Under *Talevski*, the Supreme Court made clear that spending legislation is subject to §1983 remedy when the legislation creates unambiguous rights for an individual. The only prerequisite is that the underlying spending law must unambiguously confer a substantive, individual "right." The EUA Statute and PREP Act contain such individually conferred rights.

Count I – Subjected to Investigational Drug Use: Plaintiffs hold the right to refuse investigational drug treatments under the Fourteenth Amendment and the statutory entitlement and property rights under the CDC Program's applicable laws to give their legally effective informed consent, which rights are subject to §1983 remedy.

Count II – Equal Protection: The Equal Protection Clause "is essentially a direction that all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr*., 473 U.S. 432, 439 (1985). "[W]e have explained that '[t]he purpose of the equal protection clause of the Fourteenth Amendment is to secure every person within the State's jurisdiction against intentional and arbitrary discrimination, whether occasioned by express terms of a statute or by its improper execution through duly constituted agents.' *Sioux City Bridge Co*., [260 U.S. 441], 445 (quoting *Sunday Lake Iron Co.* v. *Township of Wakefield,* 247 U.S. 350, 352 (1918))." *Village of Willowbrook v. Olech*, 528 U.S. 562 (2000).

Judge Hanks's statement that "'courts have routinely rejected the argument that vaccine mandates will trigger heightened scrutiny under the Equal Protection Clause and have instead applied rational basis review.' *Brown*, 567 F. Supp. 3d at 1227," is derived from the erroneous view that Houston Methodist can list unlicensed EUA/PREP Act investigational drugs under a "vaccine mandate." Congress explicitly prohibits nonconsensual use of its investigational drugs even

during a nationally declared emergency, and Texas and Houston Methodist promised the USG never to offer the drugs outside of voluntary conditions, which negates any claim of a legitimate state interest. Judge Hanks's legal reasoning subjects the federal constitution, federal laws, federal agreements, and Plaintiffs' rights to the whims of a state governor issuing an emergency. However, **"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)

Neither Texas nor Houston Methodist could treat Plaintiffs who exercised the right to refuse EUA/PREP Act investigational drugs differently than other healthcare workers who exercised the right to accept. Such violations trigger the strict scrutiny standard. Plaintiffs alleged, "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" (ROA.1414), which is an unconstitutional condition that cannot exist in a free, equitable, and fair society.

Count III – Due Process: Plaintiffs asserted "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." (ROA.1409). Plaintiffs were deprived of their right to refuse under the CDC Program without an opportunity "to present [their] case and have its merits fairly judged." *Logan v. Zimmerman Brush Co*., 455 U.S. 422 (1982).

Houston Methodist deprived Plaintiffs of their right to refuse unwanted INDs and punished Plaintiffs for refusing to surrender their Fourteenth Amendment right to sue if injured by the Program, its products, or its administration, which are substantive due process violations.

Count IV – Spending Clause:

The CDC Program was federally funded. It required Texas and Houston Methodist to inform Plaintiffs of the drug's risks, benefits, alternatives, and their right to refuse. The language of these requirements aligns with *Talevski*, and the benefits meet *Roth's* requirement that they be considered property rights. As explained in *Dennis*, property rights are subject to §1983 remedy.

The drugs were subject to 45 C.F.R. §46.122, and thus, persons offering them were bound to comply with 45 C.F.R. §46.116 because they were agents of Texas who were under a legal obligation to perform the duty of accepting Plaintiffs' legally effective informed consent, a property right held by Plaintiffs.

The drugs were procured using DoD funding and thus subject to duties owed by the USG and persons acting on its behalf under 10 U.S.C. §980 to obtain Plaintiffs' property and liberty interest to give informed consent.

Count V – Breach of Contract:

Plaintiffs do not appeal the dismissal of Count V.

Count VI – Preemption of State Employment Torts:

Texas voluntarily assumed obligations under the CDC Program that required obtaining consent from individuals regarding legal conditions implicating the rights discussed above. The PREP Act's express preemption clause prohibits Texas from continuing in effect with any law that conflicts with either the Act's voluntary participation requirements or the option to refuse under the EUA. Despite this preemption, Texas allowed the at-will employment doctrine to remain in effect, enabling its delegated actors to use this state law to undermine the federally protected right to refuse. This application of state law directly conflicts with the PREP Act's preemption provisions, invalidating Houston Methodist's reliance on the at-will employment doctrine to circumvent its federal program obligations, and thus, their termination of Plaintiffs for the sole reason of exercising their right to refuse was unlawful.

Count VII - Outrage: Plaintiffs stand by their claims.

Count VIII – Implied Private Right of Action: Although Plaintiffs brought a §1983 claim for Counts I through IV, they contend that this Court should create a judicially implied private right of action under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) 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).

Plaintiffs do not appeal their declaratory judgment request against HHSC but do appeal the district court's failure to address the declaratory judgment request against TWC, (RE.50-68) which is actively seeking to take unemployment benefits paid to Plaintiff Bob Nevens. Texas has no authority to condition access to public benefits on relinquishing constitutional rights[17], nor does it have authority to take the money paid to Bob Nevens based on him exercising a constitutional right that Texas and Houston Methodist agreed to protect on behalf of the USG.

H. With Prejudice Dismissal

The district court erred in dismissing Plaintiffs' Complaint with prejudice, denying them leave to amend to address the court's ruling. While Plaintiffs' Second Amended Complaint added declaratory judgment requests against Texas, the allegations against Houston Methodist remained unchanged since the Amended Complaint that asserted federal causes of action only after the case was removed

[17] *Frost & Frost Trucking Co, supra; Perry v. Sindermann, supra.*

from state court. As stated in *Great Plains Tr. v. Morgan Stanley Dean Witter*, 313 F.3d 305, 329 (5th Cir. 2002), "district courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable." While Plaintiffs disagree with the district court's ruling, the district court should have allowed Plaintiffs an opportunity to refine their claims and clarify their legal arguments to address the district court's concerns. As this Court recently emphasized, "[D]ismissal with prejudice 'is an extreme sanction that deprives a litigant of the opportunity to pursue his claim[,]' . . . this Court has limited district courts' discretion to dismiss claims with prejudice." *Shah v. Novelis*, 23-40231 (5th Cir., April 23, 2024).

VI. CONCLUSION

The Court should reverse and render a decision holding that (1) Defendants were prohibited from pressuring Plaintiffs to be injected with federally funded EUA/PREP Act investigational drugs and from penalizing them when they refused, (2) Houston Methodist was operating under color of law when interacting with Plaintiffs regarding the COVID-19 EUA/PREP Act drugs available under the CDC Program, (3) Defendants' actions deprived Plaintiffs of their constitutional and federal statutory rights, and (4) Plaintiffs plausibly stated causes of action.

Alternatively, Plaintiffs should be allowed to amend in light of *Great Plains* and *Shah*, *supra*.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on December 23, 2024, I presented a copy of the foregoing pleading to the Clerk of Court for filing and uploading to the CM/ECF system, which will send separately notification of such filing to all counsel of record: Dan Patton and Mike Burke of Scott Patton, PC, Constance H. Pfeiffer and Andrew T. Ingram of Yetter Coleman, LLP, and Joseph Keeney of the Office of the Attorney General. Also, Mr. Patton will receive a copy via email at dpatton@scottpattonlaw.com, Ms. Pfeiffer will receive a copy via email at cpfeiffer@yettercoleman.com, Mr. Ingram will receive a copy via email at aingram@yettercoleman.com, and Mr. Keeney will receive a copy via email at joseph.keeney@oag.texas.gov.

/s/ David Joseph Schexnaydre
DAVID JOSEPH SCHEXNAYDRE

CERTIFICATE OF COMPLIANCE WITH RULE 32(g)

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because, excluding the parts exempted by FRAP 32(f), this document contains 12,923 words.

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Dated: December 23, 2024

/s/ David Joseph Schexnaydre
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