

- **Plaintiffs’ “Violation of At-Will Employment Doctrine/Public Policy Exception” claim is not a recognized cause of action under Texas law;**
- **Plaintiffs’ “Violation of At-Will Employment Doctrine/Public Policy Exception” claim fails because Houston Methodist’s actions are consistent with public policy;**
- **Plaintiffs’ “Violation of At-Will Employment Doctrine/Public Policy Exception” claim is barred because an employee who alleges a *Sabine Pilot* claim cannot advance additional claims;**
- **Plaintiffs’ Request for Declaratory Judgment fails as a matter of law because Plaintiffs do not have standing to sue for an alleged violation of the Federal Food, Drug, and Cosmetic Act or a violation of 45 C.F.R. § 46.101, *et seq.*;**
- **Plaintiffs’ Request for Declaratory Judgment fails as a matter of law because the federal Declaratory Judgment Act does not provide an independent cause of action;**
- **Plaintiffs’ Request for Declaratory Judgment fails as a matter of law because the plain text of § 360bbb-3(e)(1)(A) clearly indicates that it is a directive to the Secretary of Health and Human Services—not a private employer; and**
- **Plaintiffs’ Declaratory Judgment claim fails as a matter of law because the Federal Preemption Doctrine does not preempt Houston Methodist’s HR95 – Mandatory COVID-19 Vaccine Procedure – Phased Implementation.**

II. BACKGROUND

Houston Methodist comprises a leading academic medical center in the Texas Medical Center, seven community hospitals and numerous related health care organizations serving the greater Houston area. The Houston Methodist system employs more than 26,000 people. Each hospital is staffed by committed personnel who exemplify Houston Methodist’s I CARE values: integrity, compassion, accountability, respect, and excellence. Patient safety, quality of care, and service are Houston Methodist’s highest priorities.

On March 31, 2021, Houston Methodist became the first major health care system in the United States to require mandatory COVID-19 vaccinations for its employees.¹ Houston Methodist’s COVID-19 vaccination policy is memorialized in HR95 – Mandatory COVID-19 Vaccine Procedure – Phased Implementation (the “Policy”).² Dr. Marc Boom, Houston Methodist’s President and Chief Executive Officer, announced the mandatory policy for all employees in his April 2021 President’s Letter.³

In his letter, Dr. Boom noted that “[m]andating the vaccine was not a decision we made lightly.”⁴ He reflected on how Houston Methodist was one of the first to mandate the flu vaccine in 2009, and continuing Houston Methodist’s history of putting patient safety first, Dr. Boom stated that “we must do our part to keep patients and ourselves safe.”⁵ By mandating the COVID-19 vaccine, Houston Methodist will “send a strong message that we’re doing everything possible to keep patients safe. We’d also be role models for those who may be hesitating to get a vaccine.”⁶

Frontline workers, at Houston Methodist and across the country, have battled courageously against COVID-19, working long hours to keep patients alive.⁷ Houston Methodist’s employees have done so “at risk to their own health regardless of the many

¹ Dkt. 12-3, at p. 2.

² Dkt. 12-4, at pp. 1-8.

³ Dkt. 12-3, at pp. 1-3.

⁴ Dkt. 12-3, at p. 1.

⁵ Dkt. 12-3, at p. 1.

⁶ Dkt. 12-3, at p. 2.

⁷ Dkt. 12-3, at p. 2.

precautions [Houston Methodist] take[s] to keep them safe.”⁸ At the time of Dr. Boom’s letter, over 564,000 Americans had died as a result of the virus, not counting those who have lost their lives indirectly as a result of the virus.⁹ As of this filing, according to the Centers for Disease Control and Prevention (“CDC”), over 594,000 Americans have died of COVID-19. While researchers and physicians have made tremendous strides in finding new treatments and cures to prevent the worst outcomes from COVID-19, Dr. Boom explained to Houston Methodist employees that “our best shot at defeating it continues to be vaccinating enough Americans to create herd immunity.”¹⁰

Dr. Boom concluded his letter with the following excerpt from an editorial he wrote, summarizing Houston Methodist’s sacred duty to its patients and the community:

Let’s give patients the peace of mind they deserve knowing that our hospitals are safe from COVID-19.

Requiring mandatory vaccinations isn’t just about safety. It’s also about being examples for those who are hesitant to get vaccinated. Leaders at all levels have championed the vaccine and are doing everything to educate those reluctant to receive the vaccine. By mandating vaccines, health care institutions will show the world that we trust the safety and efficacy of the vaccine, hopefully setting an example that others will follow.

Most health care workers will agree that the path toward any sort of return to “normal” must be firmly centered on vaccinating as many Americans as possible to create herd immunity. Not only must we help get us there by administering the vaccine, but also by setting an example for others to follow. I hope other health care systems and employers will quickly join Houston Methodist in making the vaccine mandatory for staff. The sooner we’re able to end this pandemic, the fewer lives we will continue to lose to it and the closer we can get to normal.¹¹

⁸ Dkt. 12-3, at p. 2.

⁹ Dkt. 12-3, at p. 3.

¹⁰ Dkt. 12-3, at p. 2.

¹¹ Dkt. 12-3, at p. 3.

Houston Methodist began vaccinating employees on a voluntary basis on December 11, 2020.¹² At the time the Policy was announced, eighty-four percent (84%) of Houston Methodist’s employees were already vaccinated.¹³

Plaintiffs—some of whom allege to be employees of Houston Methodist and some who do not¹⁴—filed this suit, alleging Houston Methodist’s COVID-19 vaccination policy is invalid because it requires “mandatory immunization of all covered Houston Methodist (HM) employees.”¹⁵ While the Policy is being implemented in two phases, the end result is the same—Houston Methodist is requiring its employees be vaccinated from the COVID-19 virus, unless an exemption is granted on religious or medical grounds.¹⁶

The Policy requires Phase 1 employees to be fully vaccinated by April 15, 2021, unless the employee requested an exemption.¹⁷ Additionally, the Policy requires Phase 2 employees

¹² Dkt. 12-3, at p. 2.

¹³ Dkt. 12-3, at p. 1.

¹⁴ Six (6) of the one hundred eighteen (118) Plaintiffs do not even allege they are employed by Houston Methodist Hospital, Houston Methodist The Woodlands Hospital, or any other hospital or entity within Houston Methodist. Specifically, Plaintiff Jeffrey Hinton alleges he is employed by 3M Medical Solutions; Amanda Blanton alleges she is employed by Advanced Surgical Assistants; Kimberly Rensi alleges she is employed by Cardiva Medical Inc.; James McCann II alleges he is employed by Texas Orthopedic Advancement; Brian Clegg alleges he is employed by Aemonetics; and Robert Morin alleges he is employed by Houston Metro Police - Woodlands. *See* Dkt. 12, at pp. 15–22. Additionally, some eighty-three (83) Plaintiffs in this matter are not even employed by Houston Methodist Hospital or Houston Methodist The Woodlands Hospital. *See* Dkt. 12, at pp. 10–21. Because these Plaintiffs do not allege they are employed by either Houston Methodist Hospital or Houston Methodist The Woodlands, these Plaintiffs cannot state an employment-based claim against Houston Methodist Hospital or Houston Methodist The Woodlands for “wrongful discharge.” *See Safeshred, Inc. v. Martinez*, 365 S.W.3d 655, 659 (Tex. 2012) (“In *Sabine Pilot*, we recognized a narrow exception to the at-will employment doctrine allowing employees to sue their employers if they are discharged . . .”); *see also Physio GP, Inc. v. Najfeh*, 306 S.W.3d 886, 888 (Tex. App.—Houston [14th Dist.] 2010, no pet.) (refusing to extend *Sabine Pilot* to hold “an individual, as opposed to the employer,” liable for wrongful discharge); *Reddy v. Superior Glob. Sols., Inc.*, No. 4:11-CV-845, 2012 WL 6569800, at *7 (E.D. Tex. Oct. 2, 2012) (“Thus, the Individual Defendants did not employ Plaintiff and are not subject to liability for a claim for tortious wrongful termination in violation of public policy.”).

¹⁵ Dkt. 12, at ¶ 1.

¹⁶ Dkt. 12, at ¶¶ 1–10; *see also* Dkt. 12-4, at pp. 1–8.

¹⁷ Dkt. 12, at ¶ 2; *see also* Dkt. 12-4, at p. 2.

to be fully vaccinated by June 7, 2021, unless the employee requested an exemption.¹⁸ Employees were permitted to receive the vaccine from the employee's respective Employee Health Department free of charge (e.g., at Houston Methodist The Woodlands Hospital's Employee Health Department) or from a third-party provider (e.g., CVS) of the employee's choice.¹⁹ If the employee received the COVID-19 vaccine from a third-party provider, the employee only has to provide proof of vaccination to comply with the Policy.²⁰ The Policy does not require any specific COVID-19 vaccine, only that the vaccine inoculate against Sars-Cov-2 (COVID-19) infection.²¹

If an employee fails to request an exemption or provide proof of vaccination by the applicable deadline, the employee will be placed on unpaid suspension for up to fourteen (14) days so the employee can come into compliance.²² If the employee remains out of compliance after the fourteen (14) day suspension, Houston Methodist will terminate the individual's employment pursuant to the Policy.²³

Plaintiffs allegedly include Phase 1 employees who have already been terminated and Phase 2 employees who are still employed but subject to the Policy and its deadlines.²⁴ Plaintiffs brought this lawsuit to challenge the validity and prevent enforcement of the Policy.

¹⁸ Dkt. 12, at ¶ 10; *see also* Dkt. 12-4, at p. 3.

¹⁹ Dkt. 12-4, at p. 2..

²⁰ Dkt. 12-4, at p. 2.

²¹ Dkt. 12-4, at p. 1.

²² Dkt. 12-4, at p. 6.

²³ Dkt. 12-4, at p. 6.

²⁴ *See* Dkt. 12, at p. 3.

Plaintiffs’ assert, among other things, Houston Methodist’s Policy forces its employees “to serve as human ‘guinea pigs’ to increase [Houston Methodist’s] profits.”²⁵ Claiming a violation of the Nuremberg Code,²⁶ Plaintiffs also liken the Policy to the forced medical experiments “performed on unwilling victims of Nazi Germany’s concentration camps.”²⁷

Plaintiffs’ First Amended Complaint rests on three claims: wrongful discharge under the *Sabine Pilot* exception, violation of the Texas at-will employment doctrine, and a request for declaratory relief. All of Plaintiffs’ claims are baseless on their face and fail as a matter of law. Plaintiffs’ First Amended Complaint should be dismissed with prejudice in its entirety.

III. STANDARD OF REVIEW

Rule 12(b)(6) must be read in conjunction with Rule 8(a), which requires “a short and plain statement of the claim showing that the pleader is entitled to relief.”²⁸ A complaint must contain “enough facts to state a claim to relief that is plausible on its face.”²⁹ Rule 8 does not require detailed factual allegations but it demands more than conclusory, unsupported allegations.³⁰ A claim is facially plausible if the plaintiff pleads sufficient facts that would allow the court to draw a reasonable inference that the defendant is liable for the misconduct alleged.³¹ The plausibility standard requires more than a sheer possibility that the defendant

²⁵ Dkt. 12, at ¶ 12.

²⁶ The Nuremberg Code is a set of ethical standards and codes for medical practice and research created during the Nuremberg trials after World War II. See generally George J. Annas, *The Legacy of the Nuremberg Doctors’ Trial to American Bioethics and Human Rights*, 10 MINN. J.L. SCI. & TECH. 19, 23-28 (2009).

²⁷ Dkt. 12, at pp. 7 & 26–27.

²⁸ FED. R. CIV. P. 8(a)(2).

²⁹ *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

³⁰ *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555).

³¹ *Id.*

has acted unlawfully.³² Naked assertions without “further factual enhancement” do not suffice.³³

IV. ARGUMENT & AUTHORITIES

A. Houston Methodist Is Entitled To Mandate The COVID-19 Vaccine

For well over a century, the general rule in Texas, as in most American jurisdictions, is absent a specific agreement to the contrary, employment may be terminated by the employer or the employee at will, for good cause, bad cause, or no cause at all.³⁴ There is no law (and Plaintiffs cite no legal authority) that prohibits a private employer’s ability to require vaccinations as a condition of employment.

To be sure, there are many federal laws (and state and local laws) that govern employer-employee relations for public and private employers. However, none of those laws are implicated in Plaintiffs’ claims, likely because the agencies tasked with interpreting and enforcing such laws have endorsed employer vaccination policies. For example, **the Equal Employment Opportunity Commission (“EEOC”), which is responsible for interpretation and enforcement of federal non-discrimination laws, updated its public guidance on May 28, 2021, by stating employers may require that employees be vaccinated for COVID-19, subject to reasonable accommodations for employees with disabilities or a sincerely held religious belief that precludes them from being vaccinated.**³⁵ The Occupational Health and Safety Administration (“OSHA”), which is

³² *Id.*

³³ *Id.*

³⁴ *City. of Dallas v. Wiland*, 216 S.W.3d 344, 347 (Tex. 2007).

³⁵ See U.S. EQUAL EMP. OPPORTUNITY COMM’N, TECHNICAL ASSISTANCE MANUAL ON WHAT YOU SHOULD KNOW ABOUT COVID-19 AND THE ADA, THE REHABILITATION ACT, AND OTHER EEO LAWS, updated May 28, 2021, at §

responsible for workplace safety, has also stated that it is “working diligently to encourage COVID-19 vaccinations.”³⁶

Similarly, while Houston Methodist is a private actor, there is precedent for even government actors to require vaccinations under rare but exigent circumstances. The United States Supreme Court has observed that a person’s liberty interest from physical restraint is not absolute, and there are “manifold restraints to which every person is necessarily subject for the common good.”³⁷ **This principle is reflected in earlier cases in which the Supreme Court held that involuntary quarantine for contagious diseases and a state-imposed requirement of mandatory vaccination do not violate due process.**³⁸

In *Jacobson v. Commonwealth of Massachusetts*, the Supreme Court considered a claim that the state’s compulsory vaccination law—enacted amidst a growing smallpox epidemic—violated the defendant’s Fourteenth Amendment right “to care for his own body and health in such way as to him seems best.”³⁹ The Court rejected this claim. Famously, it explained that the “liberty secured by the Constitution . . . does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint.”⁴⁰ Rather, “**a community has the right to protect itself against an epidemic of disease which**

K.5., available at <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws> (emphasis added).

³⁶ See UNITED STATES DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, FREQUENTLY ASKED QUESTIONS, available at <https://www.osha.gov/coronavirus/faqs#vaccine>.

³⁷ *Kansas v. Hendricks*, 521 U.S. 346, 357 (1997) (quoting *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905)).

³⁸ See *Jacobson*, 197 U.S. at 25 & 29 (mandatory vaccination for smallpox); see also *Compagnie Francaise De Navigation a Vapeur v. La. State Bd. of Health*, 186 U.S. 380, 396–97 (1902) (permitting involuntary quarantine of persons suffering from communicable diseases) (emphasis added).

³⁹ *Jacobson*, 197 U.S. at 26.

⁴⁰ *Id.*

threatens the safety of its members.”⁴¹ In describing a state’s police power to combat an epidemic, the Court explained:

[I]n every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.⁴²

There is no law, governmental agency, or public policy that prevents Houston Methodist from mandating a vaccine for the protection of its patients, its employees, and the community.

B. Plaintiffs Fail To State A Claim Under *Sabine Pilot*

Plaintiffs fail to state a claim upon which relief can be granted for wrongful termination under the *Sabine Pilot* exception to the employment at-will doctrine.

Texas courts have created only one narrow exception to the employment at-will doctrine in *Sabine Pilot Serv., Inc. v. Hauck*, which prohibits an employer from terminating an employee “for the sole reason that the employee refused to perform an illegal act.”⁴³ Stated differently, *Sabine Pilot* protects only those employees who are terminated solely because they refused to commit an act which carries criminal penalties.⁴⁴ To state a *prima facie* case for a *Sabine Pilot* wrongful termination claim, Plaintiffs must show that they: (1) were required to commit an illegal act which carries criminal penalties; (2) refused to engage in the illegality; (3)

⁴¹ *Id.* at 27.

⁴² *Id.* at 29.

⁴³ 687 S.W.2d 733, 735 (Tex. 1985).

⁴⁴ *Ed Rachal Found. v. D’Unger*, 207 S.W.3d 330, 332 (Tex. 2006); *Winters v. Houston Chronicle Pub. Co.*, 795 S.W.2d 723, 724 (Tex. 1990) (holding employee “was not unacceptably forced to choose between risking criminal liability or being discharged” and did not fall within *Sabine Pilot*); *see also Sabine Pilot*, 687 S.W.2d at 735 (“We now hold that public policy, as expressed in the laws of this state and the United States which carry criminal penalties, requires a very narrow exception to the employment-at-will doctrine . . .”).

were discharged; and (4) the sole reason for the discharge was the refusal to commit an unlawful act.⁴⁵

Plaintiffs do not specifically identify the “illegal act” they have “refused” to perform in their First Amended Complaint. Plaintiffs instead allege that some of them have been terminated and others are in danger of being terminated for “refusing to take an experimental vaccine that is being provided under an [EUA].”⁴⁶ Put simply, Plaintiffs’ *Sabine Pilot* claim fails because it is not an “illegal act” to receive a COVID-19 vaccine.

When asked at the Court’s June 4, 2021 hearing what “illegal act” Plaintiffs refused to perform, Plaintiffs’ counsel referred to 21 U.S.C. § 360bbb-3. This statute charges the Secretary of Health and Human Services⁴⁷ with establishing conditions on an emergency use authorization necessary or appropriate to protect the public health.⁴⁸ This mandate includes conditions designed to ensure that health care professionals administering an EUA-approved product, and those to whom such a product is administered, are aware of the nature of the authorization, the risks and benefits of the product, and alternatives to the product.⁴⁹ It also requires the Secretary of Health and Human Services to establish conditions to ensure that the individual receiving the product is informed of his or her “option to accept or refuse administration of the product” and “of the consequences, if any, of refusing administration of the product.”⁵⁰ In their Response to Houston Methodist’s Motion to Dismiss Plaintiffs’

⁴⁵ See *White v. FCI USA, Inc.*, 319 F.3d 672, 676 (5th Cir. 2003).

⁴⁶ Dkt. 12, at p. 3.

⁴⁷ 21 U.S.C. § 321(d).

⁴⁸ 21 U.S.C. § 360bbb-3(e)(1)(A).

⁴⁹ 21 U.S.C. § 360bbb-3(e)(1)(A)(i)–(ii).

⁵⁰ *Id.* § 360bbb-3(e)(1)(A)(ii)(III).

Original Petition, Plaintiffs argue that Houston Methodist has also violated 45 C.F.R. § 46.116 and that their allegations “fall under the spirit of *Sabine Pilot*.”⁵¹

Under Plaintiffs’ theory, taking their allegations as true, they would be the *victims* of an illegal act—they would not be *refusing* to perform an illegal act, which is fatal to their case. The alleged violations of the EUA and the Code of Federal Regulations by Houston Methodist cannot give rise to a *Sabine Pilot* wrongful termination claim as matter of law. As a result, the Court should dismiss Plaintiffs’ *Sabine Pilot* wrongful termination cause of action.

C. Plaintiffs’ “Violation of At-Will Employment Doctrine/Public Policy Exception Claim” Fails As A Matter Of Law

Plaintiffs’ “Violation of At-Will Employment Doctrine/Public Policy Exception” claim fails because it is not a recognized cause of action under Texas law. *Sabine Pilot* is the only public policy exception to the at-will employment doctrine, and Texas courts have since “steadfastly refused” to engraft other exceptions.⁵² Plaintiffs’ “Violation of At-Will Employment Doctrine/Public Policy Exception” claim should be dismissed for this reason alone.

Even if Texas did recognize a general “public policy” exception to the at-will employment doctrine, Plaintiffs have failed to state a claim because Houston Methodist’s actions in this case are consistent with public policy. As noted above, the United States Supreme Court has long recognized that vaccinations—even when mandated by the state—are not oppressive or arbitrary as long as such a mandate does not “go so far beyond what was

⁵¹ Dkt. 13, at pp. 11–12.

⁵² *Sanyer v. E.I. Du Point De Nemours and Co.*, 430 S.W.3d 396, 399 (Tex. 2013) (quoting *Sabine Pilot*, 687 S.W.2d at 734); *see also Tex. Farm Bureau Mut. Ins. Cos. v. Sears*, 84 S.W.3d 604, 609 (Tex. 2002) (refusing to create negligence exception to at-will doctrine).

reasonably required for the safety of the public.”⁵³ More recently, **the EEOC has recognized the propriety of employers requiring a COVID-19 vaccination for all employees entering the workplace.**⁵⁴ Vaccines are also encouraged by other agencies such as OSHA.⁵⁵ Therefore, requiring Plaintiffs to receive a COVID-19 vaccination is not violative of any public policy and is in harmony with the most-recent guidance from federal agencies responsible for interpreting and enforcing federal employment laws.

Plaintiffs’ claim also fails for another, independent reason: they have already alleged a wrongful termination claim under *Sabine Pilot*. The Fifth Circuit has long recognized that “an employee who alleges wrongful discharge for refusing to perform a criminal act [under *Sabine Pilot*] cannot advance additional claims.”⁵⁶ This is because, under *Sabine Pilot*, “the refusal to perform an illegal act must be the sole reason for the plaintiff’s discharge” and any other theory of recovery relating to a plaintiff’s termination would be mutually exclusive.⁵⁷ Here, Plaintiffs have alleged the sole reason for their discharge was their refusal to commit or engage in an

⁵³ *Jacobson*, 197 U.S. at 28.

⁵⁴ U.S. EQUAL EMP. OPPORTUNITY COMM’N, TECHNICAL ASSISTANCE MANUAL ON WHAT YOU SHOULD KNOW ABOUT COVID-19 AND THE ADA, THE REHABILITATION ACT, AND OTHER EEO LAWS, at § K.5., available at <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws> (emphasis added).

⁵⁵ See UNITED STATES DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, FREQUENTLY ASKED QUESTIONS, available at <https://www.osha.gov/coronavirus/faqs#vaccine>.

⁵⁶ *Pease v. Pakboed Corp.*, 980 F.2d 995, 997 n.1 (5th Cir. 1993); see also *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 952–53 (5th Cir. 1994) (holding assertion of False Claims Act claim precluded the plaintiff’s *Sabine Pilot* claim and affirming district court’s dismissal of *Sabine Pilot* claim); *Guthrie v. Tjico Indus.*, 941 F.2d 374, 379 (5th Cir. 1991) (after affirming summary judgment rendered on age discrimination claim based on termination of employment, holding that *Sabine Pilot* claim was also properly dismissed because these two claims were mutually exclusive).

⁵⁷ *Guthrie*, 941 F.2d at 379.

illegal act.⁵⁸ As a result, Plaintiffs cannot pursue their Violation of At-Will Employment Doctrine/Public Policy Exception claim.⁵⁹

The third independent reason Plaintiffs' Violation of At-Will Employment Doctrine/Public Policy Exception claim should be dismissed is because Plaintiffs' allegation that Houston Methodist violated 21 U.S.C. § 360bbb-3(e)(1)(A) and 45 C.F.R. part 46 is implausible as a matter of law.⁶⁰ As noted throughout this Motion, the text of § 360bbb-3(e)(1)(A) only imposes obligations on the Secretary of Health and Human Services, not private employers.⁶¹ Section 360bbb-3(e)(1)(A) does not impose any obligations on Houston Methodist as a private employer. Similarly, as explained below, 45 C.F.R. part 46, also known as "The Common Rule" applies to clinical trials and research. Plaintiffs have failed to allege any facts or cite any authority that part 46 applies to Houston Methodist in any capacity, let alone as a private employer,⁶² or that the vaccinations at issue constitute a "clinical trial" or "research." More importantly, however, even if the alleged violations were plausible under

⁵⁸ Dkt. 12, at ¶ 26.

⁵⁹ *See Pease*, 980 F.2d at 997 n.1.

⁶⁰ In their First Amended Complaint, Plaintiffs purport to quote 21 U.S.C. § 360bbb-3(e)(1)(A). *See* Dkt. 12, at ¶ 29. While Plaintiffs appear to have accurately quoted the text of 21 U.S.C. § 360bbb-3(e)(1)(A)(i)-(ii), subsections (i) and (ii) each contain subsections (I)-(III). The text of subsections (i)(I)-(III) and (ii)(I)-(III) is included, but these provisions are mislabeled as consecutive romanettes. It is therefore unclear specifically what sections of the statute Plaintiffs allege Houston Methodist has violated.

⁶¹ 21 U.S.C. § 360bbb-3(e)(1)(A) ("... the Secretary ... shall ... establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health ...").

⁶² For example, Plaintiffs do not allege that Houston Methodist received a "certification" as described in 45 C.F.R. § 46.102. Nor do Plaintiffs allege that Houston Methodist provided the written assurance that it will comply with the requirements of 45 C.F.R. §§ 46.101, *et seq.*

the statute or regulations, there is no authority that would permit this Court to recognize a new exception to Texas' at-will employment doctrine for such violations.⁶³

Therefore, Plaintiffs' Violation of At-Will Employment Doctrine/Public Policy Exception claim should be dismissed.

D. Plaintiffs' Declaratory Judgment Fails As A Matter Of Law

Plaintiffs' request for declaratory judgment fails as a matter of law and should be dismissed because Plaintiffs do not have standing to sue for an alleged violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") or of 45 C.F.R. §§ 46.101, *et seq.*

In order to bring a claim in federal court, separate from the threshold matter of jurisdiction, Plaintiffs must "have a right of action to initiate that claim."⁶⁴ In other words, a party's standing "factors into the court's jurisdictional limits under Article III of the Constitution."⁶⁵ Plaintiffs' Count Three seeks relief under Federal Rule of Civil Procedure 57 and the Texas Declaratory Judgment Act.⁶⁶ The Texas Declaratory Judgment Act is a procedural—not substantive—statute.⁶⁷ Accordingly, the Court should construe the claim as one brought under the federal Declaratory Judgment Act.⁶⁸

⁶³ *See, e.g., Spencer v. Roche*, 659 F.3d 142, 151 (1st Cir. 2011) ("Massachusetts has never recognized such a tort . . . and it is not our place to create new causes of action under state law[.]"); *Anderson v. Marathon Petroleum Co.*, 801 F.2d 936, 942 (7th Cir. 1986) (recognizing that "federal court is not the place to press innovative theories of state law.");

⁶⁴ *Harris Cty. Texas v. Merscorp Inc.*, 791 F.3d 545, 552 (5th Cir. 2015) (citing *Nat'l R.R. Passenger Corp. v. Nat'l Ass'n of R.R. Passengers*, 414 U.S. 453, 455–56 (1974)).

⁶⁵ *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) ("The core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III."); *see also* U.S. CONST. art. III, § 2).

⁶⁶ Dkt. 12, at ¶ 34.

⁶⁷ *Utica Lloyd's of Tex. v. Mitchell*, 138 F.3d 208, 210 (5th Cir. 1998).

⁶⁸ 28 U.S.C. §§ 2201 & 2202; *see also Honey Holdings I, Ltd. v. Alfred L. Wolff, Inc.*, 81 F. Supp. 3d 543, 555 (S.D. Tex. 2015).

Plaintiffs seek a declaration under 21 U.S.C. § 360bbb-3(e)(1)(A) that the provision “does not permit Defendants to coerce an employee to accept an FDA unapproved vaccine on penalty of termination or other sanctions;” that the “doctrine of federal preemption invalidates and voids the ‘Mandatory COVID-19 Vaccination Directive’ of Defendants” (i.e., the Policy), thereby rendering the Policy “invalid”; and that the Policy violates 45 C.F.R. §§ 46.101, 46.102, and 46.116.⁶⁹

Section 360bbb-3 is a codified provision of the FDCA.⁷⁰ The FDCA, however, provides no private right of action: “[A]ll such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States.”⁷¹ Plaintiffs have no standing to sue Houston Methodist for an alleged violation of the FDCA, including under 21 U.S.C. § 360bbb-3. Plaintiffs’ “true goal is to privately enforce alleged violations of the FDCA,” but “no such private right of action exists.”⁷² Nor do The Common Rule regulations under 45 C.F.R part 46 provide Plaintiffs with a private right of action.⁷³

⁶⁹ Dkt. 12, at ¶ 26.

⁷⁰ See generally 21 U.S.C. §§ 301–399i.

⁷¹ 21 U.S.C. § 337(a); see also *Morris v. PLIVA, Inc.*, 713 F.3d 774, 778 (5th Cir. 2013) (“First, the Federal Food, Drug, and Cosmetic Act provides no private right of action for these violations.”).

⁷² *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (citing 21 U.S.C. § 337(a) and opinions from the Third and Fourth Circuit Courts of Appeal).

⁷³ *Thomas v. Catlin*, 141 F. App’x 673, 674 (9th Cir. 2005) (citing *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001)) (“The district court properly held Thomas failed to state a claim under 45 C.F.R. §§ 46.101, *et seq.*, the federal statute regulating research involving human subjects, because the statute does not confer a private right of action.”); *Robinett v. United States*, 62 F.3d 1433, 1995 WL 473105, at *1 (Fed. Cir. 1995) (“We note that 45 C.F.R. part 46 and OSHA do not create any private right of action to recover damages.”); *U.S. ex rel. Hartwig v. Medtronic, Inc.*, No. 3:11CV413-CWR-LRA, 2014 WL 1324339, at *14 n.16 (S.D. Miss. Mar. 31, 2014) (“The ‘common rule’ regulations, 45 C.F.R. § 46.101 *et seq.*, govern the protection of human subjects in research supported by the federal government. No private right of enforcement exists anywhere in their text or history.”); see also *See Bilinski v. Wills Eye Hosp.*, No. CV 16-02728, 2016 WL 6247569, at *2 (E.D. Pa. Oct. 26, 2016) (“Likewise, all claims asserted under the federal regulations regarding the ‘Protection of Human Subjects’ in research . . . are dismissed because the relevant statute does not provide a private cause of action.”).

Neither can Plaintiffs create a right that otherwise does not exist merely by recasting the claim as a declaratory judgment. The federal Declaratory Judgment Act “alone does not create a federal cause of action.”⁷⁴ Rather, the federal Declaratory Judgment Act “only authorizes a federal court to ‘declare the rights and other legal relations of any interested party seeking such declaration.’”⁷⁵ The federal Declaratory Judgment Act “enlarged the range of remedies available in the federal courts” but “did not create a new right to seek those remedies.”⁷⁶

The federal Declaratory Judgment Act “does not provide an independent cause of action” but “rather is only an avenue for relief in a ‘case of actual controversy within the court’s jurisdiction.’”⁷⁷ Because federal jurisdiction is lacking under 21 U.S.C. § 360bbb-3 and 45 C.F.R. § 46.101, *et seq.*, and because the Declaratory Judgment Act is procedural and does not create an independent private right of action, Plaintiffs’ Count Three must be dismissed as a matter of law.⁷⁸

Furthermore, it should be noted that even the substance of Plaintiffs’ requested declarations can easily be dispensed with as a matter of law. Plaintiffs’ first requested declaration is that 21 U.S.C. § 360bbb-3(e)(1)(A) “does not permit Defendants [Houston Methodist] to coerce an employee to accept an FDA unapproved vaccine on penalty of

⁷⁴ *Harris Cty.*, 791 F.3d at 552.

⁷⁵ *Id.* (quoting 28 U.S.C. § 2201(a)).

⁷⁶ *Id.* (quoting *Skelly Oil Co. v. Phillips Petrol. Co.*, 339 U.S. 667, 671 (1950)).

⁷⁷ *Id.*

⁷⁸ *Id.*; see *Thomas*, 141 F. App’x at 674; *Robinett*, 62 F.3d 1433, 1995 WL 473105, at *1; *Bilinski*, 2016 WL 6247569, at *2; *U.S. ex rel. Hartwig*, 2014 WL 1324339, at *14 n.16.

termination or other sanctions.”⁷⁹ The plain text of § 360bbb-3(e)(1)(A) clearly indicates that it is a directive to the Secretary of Health and Human Services—not a private employer:

With respect to the emergency use of an unapproved produced, **the Secretary**,⁸⁰ to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following . . .⁸¹

The provisions on which Plaintiffs rely are related to “Required Conditions” to be established by the Secretary of Health and Human Services when issuing an Emergency Use Authorization. While those conditions include “appropriate conditions designed to ensure that individuals to whom the product is administered are informed . . . of the option to accept or refuse administration of the product, [and] of the consequences, if any, of refusing administration of the product,”⁸² the statute does not place any conditions on a private employer or regulate a private employer’s right to require COVID-19 vaccinations as a prerequisite to employment (subject to exemptions under other federal laws).

For this same reason, Plaintiffs’ second requested declaration is nonsensical⁸³ and should be dismissed. Plaintiffs’ second requested declaration is that “the doctrine of federal preemption invalidates and voids the ‘Mandatory COVID-19 Vaccination Directive’ of Defendants” (i.e., the Policy).⁸⁴ The federal preemption doctrine derives from the Supremacy

⁷⁹ Dkt. 12, at ¶ 26.

⁸⁰ See 21 U.S.C. § 321(d) (definition of “Secretary”).

⁸¹ 21 U.S.C. § 360bbb-3(e)(1)(A) (emphasis added).

⁸² *Id.*

⁸³ Plaintiffs’ inartful pleading of “federal preemption” may have resulted from the copying of the claim from (at least one) similar complaint that was against state actors—not a private employer. See, e.g., No. 2:21-cv-00179, *Isaac Legaretta, et al. v. Fernando Macias, et al.*, pending in U.S. District Court, District of New Mexico (filed on Feb. 28, 2021).

⁸⁴ Dkt. 12, at ¶ 26.

Clause of the Constitution⁸⁵ and provides that a state statute is invalid if it is superseded or pre-empted by federal law.⁸⁶ Federal preemption, under the Supremacy Clause, does not apply to a personnel/employee policy of a private employer. That is not to say that the federal government cannot or does not regulate employment practices of private employers—because it most certainly does. However, as stated above, none of the federal employment-related statutes prohibit mandatory vaccination policies so long as such policies provide certain exemptions (such as for religious or medical objections), and no such federal employment-related statute is at issue in this case.

The substance of Plaintiffs’ requested declaration that Houston Methodist violated “The Common Rule,” 45 C.F.R. §§ 46.101, .102, and .116, *et seq.*,⁸⁷ fares no better. The Common Rule governs the “Protection of Human Subjects” and applies to clinical trials, which is defined as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions”⁸⁸ Research, in turn, is defined as “a systematic investigation, including research development, testing, and evaluation **designed to develop or contribute to generalizable knowledge.**”⁸⁹ Plaintiffs have failed to allege any facts or cite any authority that part 46 applies to Houston Methodist in any capacity, let alone as a private

⁸⁵ U.S. CONST. art. VI, cl. 2.

⁸⁶ *See generally Hines v. Davidowitz*, 312 U.S. 52, 62–67 (1941).

⁸⁷ Dkt. 12, at ¶ 30.

⁸⁸ 45 C.F.R. § 46.102(b).

⁸⁹ *Id.* § 46.102(j) (emphasis added).

employer,⁹⁰ or that the vaccinations at issue constitute a “clinical trial” or “research.” Nor have Plaintiffs alleged that The Common Rule applies to the emergency use vaccinations at issue. Indeed, § 360bbb-3 requires the Secretary of Health and Human Service to establish specific conditions concerning the administration of any EUA-authorized product.⁹¹

For these reasons, Plaintiffs fail to allege a plausible claim in Count Three of their First Amended Complaint, and it should be dismissed.

V. CONCLUSION

Based on the foregoing, Houston Methodist requests the Court grant its Motion to Dismiss, dismiss all of Plaintiffs’ claims, and grant all other relief the Court deems appropriate.

Respectfully submitted,

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⁹⁰ For example, Plaintiffs do not allege that Houston Methodist received a “certification” as described in 45 C.F.R. § 46.102. Nor do Plaintiffs allege that Houston Methodist provided the written assurance that it will comply with the requirements of 45 C.F.R. §§ 46.101, *et seq.*

⁹¹ *See id.*

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CERTIFICATE OF SERVICE

I certify that on June 11, 2021, a true and correct copy of this pleading was served on all counsel of record by the Court's ECF filing system.

/s/ Daniel Patton

Daniel Patton