UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

JERI PEARSON, ELIZABETH KLEM, BEN HOMAN, and ROB FOWLER	*	
Plaintiffs,	*	
VERSUS	*	CIVIL ACTION 3:23-cv-387
SHRINERS HOSPITALS FOR CHILDREN SHRINERS HOSPITALS FOR CHILDREN -- TEXAS, BEVERLY BOKOVITZ, FRANCES FARLEY, JERRY GANTT, JOHN McCABE, PHILLIP GRADY, AND CECILE ERWIN YOUNG	*	
Defendants	*	

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

PLAINTIFFS' OPPOSITION TO CECILE ERWIN YOUNG'S MOTION TO DISMISS
(ORAL ARGUMENT REQUESTED)

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of May, 2024, I presented the foregoing pleading to the Clerk of Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ David J. Schexnaydre
DAVID J. SCHEXNAYDRE

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Plaintiffs brought a § 1983 cause of action alleging that Ms. Young had a personal duty to ensure the State and her State Actors offered the federally funded investigational drugs only under voluntary conditions to any person under their authority. Plaintiffs alleged that they had the exclusive right to accept or refuse the federal COVID-19 investigational drugs without consequence, irrespective of their chosen option. Moreover, Plaintiffs alleged that Ms. Young recklessly abandoned her duties to enforce the rights of the Plaintiffs among her State Actors, including Shriners, leading to a State-enforced custom that Shriners acted upon when discriminating against Plaintiffs' constitutional, statutory, and third-party beneficiary rights. Ms. Young disputed none of these facts other than claiming the drugs were not investigational, which claim cannot reconcile with the FDA's official published notice in the Federal Register. The case before the court is straightforward. Ms. Young had a duty to ensure the State and her State Actors performed the ministerial function of accepting the Plaintiffs' chosen option without consequence, which they refused to perform with reckless disregard for the Plaintiffs' health, safety, and rights. The Complaint only needs to show that Ms. Young and her State Actors had a duty to perform for the State and that such failure led to a State custom that the State Actors relied upon when depriving Plaintiffs of their Fourteenth Amendment rights of equal protection, due process, and privacy and their statutory right to refuse a product authorized under the EUA statute or the PREP Act and their fundamental right to bodily integrity to refuse an investigational new drug without consequence. Ms. Young disputes none of these claims, and therefore, her motion to dismiss should be denied.

ARGUMENT

Ms. Young's reliance on *Three Expo Events, L.L.C. v. City of Dallas*, 907 F.3d 333 (5th Cir. 2018) and the Fifth Circuit's reliance on *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992) to justify its ruling, are not applicable to the instant action (Doc 25, p. 16). Both cases involved plaintiffs who did not claim direct injury by the government's actions. The *Lujan* court stated,

> "When the suit is one challenging the legality of government action or inaction, the nature and extent of facts that must be averred (at the summary judgment stage) or proved (at the trial stage) in order to establish standing depends considerably upon whether the plaintiff is himself an object of the action (or forgone action) at issue. If he is, there is ordinarily little question that the action or inaction has caused him injury and that a judgment preventing or requiring the action will redress it."

By contrast, Plaintiffs herein claimed that Ms. Young's willful failure to fulfill duties owed to them under the State-run CDC Program directly led to their damages (See Doc 20, p.15). Plaintiffs are the "object of the action at issue" because Ms. Young was completely responsible for the State-run CDC Program and its implementation. When she knew that her State Actors violated the law, she had a duty to correct the unconstitutional conduct. Still, she refused, leading to Plaintiffs' injuries, which is evident when she states, "Defendant Young merely made it *possible* for Shriners to terminate Plaintiffs"[1] (Doc 25, p. 17), which means Ms. Young was personally involved in the challenged conduct.

[1] Ms. Young cited to *TF-Harbor, LLC v. City of Rockwall,* which provides no support for her position because the *TF-Harbor* Plaintiffs clearly did not claim direct injury from governmental actions as the court noted, "TF–Harbor concedes that its injury is only indirectly caused by the Ordinance." The court also held that the "Ordinance," as applied, was not unconstitutional. *TF-Harbor, LLC v. City of Rockwall*, 18 F. Supp. 3d 810, 820 (N.D. Tex. 2014)

Ms. Young is incorrect when asserting that "Plaintiffs' claims fail on 'traceability' grounds. Plaintiffs do not contend that Defendant Young directly harmed them in any way...their main complaint is that she did not intervene to stop a third party's alleged unlawful acts—namely, Shriners' vaccine mandate for its employees, which led to Plaintiffs' employment being terminated." (Doc 25, p. 16) Actually, Plaintiffs contend that Ms. Young "directly" harmed them through her State-enforced custom (Doc 20, ¶¶ 63,67, 68, 70). Second, Ms. Young did not:

- "**ensure its** [federally owned COVID-19 EUA/PREP Act drugs'] distribution and **administration**, [were] **consistent** with the terms of this [EUA] letter and CDC's COVID-19 Vaccination Program,"[2] (emphasis added) by her State Actors;

- "instruct"[3] them how to lawfully "administer the vaccine under the EUA,"[4]

- "closely monitor activities at the local level **to ensure** the COVID-19 Vaccination Program is implemented throughout the jurisdiction **in adherence** with federal guidance and requirements,"[5] (emphasis added)

- "help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure)[6], or,

- "ensure" the State Actors "compl[ied] 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"[7] (Emphasis added).

Additionally, Plaintiffs alleged that "Ms. Young's State Actors, such as Shriners, placed State-licensed healthcare workers, contractors, and volunteers under 'sanctions,'

[2] Doc 20, p. 16, ¶ 57
[3] *Id*.
[4] *Id*.
[5] Doc 20, p. 7, ¶ 23(6)
[6] *Id*., ¶ 23(7)
[7] Doc 20, p. 9, ¶ 28(6)

'coercion,' 'undue influence,' and 'unjustifiable pressures' to accept the federally funded investigational drugs in violation of the rights created for those individuals by the EUA statute (i.e. right to refuse), the PREP Act (i.e., right to be educated about the voluntary nature of the program), and the CDC Program"[8] and that "Ms. Young's willful, wanton, and reckless disregard for the duties of her office led to a State-enforced custom that Shriners acted in accordance with when penalizing Plaintiffs for exercising their right to refuse the federally owned COVID-19 EUA/PREP Act drugs, which is the direct and proximate cause of Plaintiffs' financial, emotional, and legal injuries."[9] It cannot be disputed that, had Ms. Young performed her duties and enforced the CDC Program and the State's FWA, the State-enforced custom would not have been established.

Therefore, despite Ms. Young incorrectly claiming that "Plaintiffs offer no allegations showing that Defendant Young's conduct had a 'determinative or coercive effect' on Shriners"[10] because she "merely made it *possible* for Shriners to terminate Plaintiffs," Plaintiffs have the standing to seek judicial relief against her because the damages sustained by Plaintiffs are directly traceable to Ms. Young's established unlawful custom and this court has jurisdiction to provide the relief Plaintiffs seek. Thus, the cases Ms. Young cites on standing are not applicable or controlling in the instant action.

Ms. Young cites *Hamilton v. Kindred*, 845 F.3d 659, 663 (5th Cir. 2017), proposing that Plaintiffs claim "bystander liability," which they do not. Ms. Young was not a bystander; she was fully in charge and lawfully bound to fulfill her duties. However, even

[8] Doc 20, p. 16, ¶ 59
[9] Doc 20, p. 18, ¶ 67
[10] Doc 25, p. 17

if the bystander liability doctrine were to be applied in the instant action, Ms. Young knew that her recruited parties were violating Plaintiffs' Constitutional and federal rights, and she had more than a reasonable opportunity to prevent the harm but chose not to act, thus meeting the *Whitley* test.[11] The fact that the Texas Workforce Commission (TWC) acted upon Ms. Young's custom when depriving Texans of their unemployment benefits, and even requiring others to repay paid benefits, for the sole reason of refusing the federally owned COVID-19 EUA/PREP Act drugs supports a bystander liability claim against Ms. Young. Ms. Young had a duty to intervene but willfully chose not to do so, causing severe financial, emotional, and physical suffering of all healthcare workers, including Plaintiffs, deprived of their Constitutional rights to equal protection of laws and due process and federal statutory rights. No other persons had more knowledge of Plaintiffs' rights involving the federal COVID-19 drugs than Ms. Young and her State Actors, and she knew TWC's actions were unlawful.

B. "Personally Involved" claims

Ms. Young's assertion that personal involvement is an essential element of a civil rights claim is accurate (Doc 25, p.17), and the Ninth and Fifth Circuit Court of Appeals held that "a person 'subjects' another to the deprivation of a constitutional right, within the meaning of section 1983, if he does an affirmative act, participates in another's affirmative acts, or omits to perform an act which he is legally required to do that causes the deprivation of which complaint is made."[12] Ms. Young participated in another's affirmative acts (i.e.,

[11] *Hamilton v. Kindred*, 845 F.3d 659, 663 (5th Cir. 2017), citing *Whitley v. Hanna*, 726 F.3d 631 (5th Cir. 2013)
[12] *Johnson v. Duffy*, 588 F.2d 740, 743 (9th Cir. 1978), citing *Sims v. Adams,* 537 F.2d 829 (5th Cir. 1976)

penalizing health workers refusing EUA/PREP Act drugs) by omitting to perform an act she was legally required to do.

At all times material, Ms. Young had the knowledge, legal requirement, and force of law to correct and/or prosecute her State Actors under civil[13] and criminal charges regarding their mandatory participation policies, which the State Actors prospectively agreed not to establish. She did nothing but watch her State Actors destroy the lives of the State's healthcare workers to rake in tens of billions of dollars in revenue for the State and her State Actors. Many lawsuits could have been avoided had Ms. Young instructed her State Actors on their duties under the CDC Playbook, CDC Program, Provider Agreement, and the State's FWAs. Ms. Young's reckless disregard for the law destroyed careers, families, and personal lives and cost the State and this court untold resources. Ms. Young did not discuss these facts in her motion to dismiss because it proves she is not entitled to qualified immunity for knowingly violating the law through an abuse of power via willful inaction.

Ms. Young's claim that she was not "personally involved"[14] (Doc 25, p. 17) in the challenged conduct fails for reasons discussed above and in the Second Amended Complaint (SAC), generally. (It is also improper to raise factual defenses on a Motion to Dismiss.) The failure to perform a duty owed is actionable. The initial inquiry starts by

[13] The State Actors were committing fraud against Texas by requiring healthcare workers to be injected involuntarily with the federally owned COVID-19 EUA/PREP Act drugs. Moreover, the State Actors were presenting the investigational drugs as if they were FDA-licensed with a legal indication, in violation of state laws.
[14] "Defendant Young merely made it *possible* for Shriners to terminate Plaintiffs." Doc 25, p. 17

asking if the State had a duty[15] to act when its State Actors established a policy creating a penalty for individuals who refused to participate in the State's CDC Program. The answer is plainly yes. Courts have long held that inaction of duty can be attributed to an official State policy for purposes of § 1983.[16],[17] The Supreme Court held, "The State has so far insinuated itself into a position of interdependence with Eagle that it must be recognized as a joint participant in the challenged activity, which, on that account, cannot be considered to have been so "purely private" as to fall without the scope of the Fourteenth Amendment."[18] The *Burton* Court recognized that although the State did not establish the

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

[16] "Powers alleges that the Public Defender engages in an across-the-board policy or custom of doing nothing to protect its indigent clients' constitutional rights not to be jailed as a result of their inability to pay court-ordered fines. Unlike the plaintiff in *Polk County*, Powers does not seek to recover on the basis of the failures of his individual counsel, but on the basis of an alleged agency-wide policy or custom of routinely ignoring the issue of indigency in the context of non-payment of fines. Although we acknowledge that requesting indigency hearings is within a lawyer's 'traditional functions,' the conduct complained of is nonetheless 'administrative' in character for the reasons already described: Powers maintains that the Public Defender's inaction is systemic and therefore carries the imprimatur of administrative approval. . . .He argues that the Public Defender systematically violates class members' constitutional rights by failing to represent them on the question of indigency. Given the reasoning of *Polk County*, it makes sense to treat this alleged policy or custom as state action for purposes of § 1983. The existence of such a policy, if proven, will show that the adversarial relationship between the State and the Public Defender--upon which the *Polk County* Court relied heavily in determining that the individual public defender there was not a state actor—has broken down such that the Public Defender is serving the State's interest in exacting punishment, rather than the interests of its clients, or society's interest in fair judicial proceedings." *Powers v. Hamilton County Public Defender Com'n*, 501 F.3d 592, 613, 614 (6th Cir. 2007).

[17] "The personal involvement of a supervisory defendant may be shown by evidence that…the defendant created a policy or custom under which unconstitutional practices occurred, or allowed the continuance of such a policy or custom" *Colon v. Coughlin*, 58 F.3d 865, 873 (2d Cir. 1995); ("Supervisors can be held liable for: 1) their own culpable action or inaction in the training, supervision, or control of subordinates; 2) their acquiescence in the constitutional deprivation of which a complaint is made; or 3) conduct that showed a reckless or callous indifference to the rights of others." *Cunningham v. Gates*, 229 F.3d 1271, 1292 (9th Cir. 2000); "when supervisory liability is imposed, it is imposed against the supervisory official in his individual capacity for his own culpable action or inaction in the training, supervision, or control of his subordinates" *Clay v. Conlee*, 815 F.2d 1164, 1170 (8th Cir. 1987); "absent participation in challenged conduct, supervisor can be liable only if subordinate committed constitutional violation and supervisor's action or inaction was 'affirmatively linked' to violation in that it constituted supervisory encouragement, condonation, acquiescence, or gross negligence amounting to deliberate indifference." *Bisbal-Ramos v. City of Mayaguez*, 467 F.3d 16, 25 (1st Cir. 2006)

[18] *Burton v. Wilmington Pkg. Auth*, 365 U.S. 715, 81 S. Ct. 856 (1961)

policy itself that "no State may effectively abdicate its responsibilities by either ignoring them or by merely failing to discharge them whatever the motive may be" and "**[b]y its inaction**, the Authority, and through it the State, has not only made itself a party to the refusal of service, but has elected to place its power, property and prestige behind the admitted discrimination" (emphasis added). The State turned to Ms. Young to fulfill its duties under the CDC Program, and Ms. Young personally "abdicated [her] responsibilities by…ignoring them" and by "failing to discharge them" through "inaction" thus placing the "power, property, and prestige" of her authority behind the State Actors'[19] unlawful "vaccine" policies relying on the exclusive use of the federally owned COVID-19 EUA/PREP Act drugs.

"Personal involvement" only requires that Ms. Young be personally and lawfully responsible for "ensur[ing]" her recruited parties complied with their ministerial duties and to "closely monitor" their implementation of the CDC Program in accordance with the Fourteenth Amendment for the protection of Texans. Therefore, Ms. Young's inaction directly deprived healthcare workers of their "rights, privileges or immunities secured by the Constitution and laws"[20] when her State Actors refused to perform the ministerial duty of accepting healthcare workers' option under the EUA statute, which failure violated the Provider Agreement, the State's FWA, and those healthcare workers' rights to equal protection and due process owed to them by the State and thus Ms. Young. Her inaction

[19] "Private conduct is fairly attributable only when the state has had some affirmative role, albeit one of encouragement short of compulsion." *Frazier v. Bd. of Trustees of Northwest Miss*, 765 F.2d 1278, 1286 (5th Cir. 1985); see, *Missouri v. Biden*, 83 F.4th 350 (5th Cir. 2023) (social media decision).
[20] 42 U.S.C. § 1983

directly established the State-enforced custom that Ms. Young's State Actors could penalize a healthcare worker when refusing the federally owned COVID-19 EUA/PREP Act drugs. Moreover, her inaction led to such a strong custom that the TWC routinely denied public benefits (unemployment) to healthcare workers who refused the drugs, even though that same worker could not be lawfully terminated for refusing the EUA/PREP Act investigational drugs. The State enforced Ms. Young's custom, giving it the force of law.

C. Right to Refuse Investigational Drugs and Maintain Employment

Ms. Young completely ignores the gravamen of the case, which is that the only drugs available to Plaintiffs were the federally owned investigational drugs[21] having severe legal[22] and health risks[23] associated with them when stating, "There is not any right of continued employment while refusing vaccination." (Doc 25, p. 18) Ms. Young implies that the federal COVID-19 investigational drugs can come under a "vaccination" requirement, which is false. Moreover, Plaintiffs did not challenge whether an employer can condition employment upon a true "vaccination policy." Plaintiffs only challenged Ms. Young's State Actors establishing an "injection with EUA/PREP Act investigational drugs policy," an allegation Ms. Young concedes by not disputing it.

Ms. Young mischaracterizes Plaintiffs' claim when stating, "Plaintiffs' Section 1983 claims are based solely on the proposition that Plaintiffs had a federally protected property interest in 'their employment, employment-related benefits…'" The statement mischaracterizes Plaintiffs' claims. Plaintiffs' claims are based on the Constitutional,

[21] Doc 20, p. 2, ¶ 2
[22] Doc 20, p. 23, ¶ 93
[23] Doc 20, p. 25, FN 49

statutory, and third-party beneficiary (i.e., from the Provider Agreement) right to refuse federally owned EUA/PREP Act investigational drugs without incurring a penalty imposed or pressured by Shriners. This is not an employment cause of action; it is a Constitutional and federal rights cause of action as noted in Plaintiffs' unambiguous language under Counts (Doc 25, Counts I-VII).

Ms. Young mischaracterized Plaintiffs' claim by inserting her own words in place of Plaintiffs' when stating, "Plaintiffs' Section 1983 claims are based solely on the proposition that Plaintiffs had a federally protected property interest in 'their employment, employment-related benefits, and use of their State-issued healthcare licenses' and their 'fundamental right to refuse [a vaccine].'"[24] Plaintiffs' actual statement ends with "fundamental right to refuse an investigational drug,"[25] not "a vaccine." Ms. Young lacks the power to change the classification of an investigational drug to that of a licensed vaccine, which violates 21 U.S.C. § 331(a) and the TX Health & Safety Code § 431.021(a,b) misbranding laws.[26] In an unrelated case, the Texas Attorney General (AG) filed a petition in state court seeking $1M in fines relating to Texas' misbranding laws, providing this court context to Ms. Young's dangerous claim.[27] The AG stated, "Once FDA

[24] Doc 25, p. 19
[25] Doc 20, p. 24, ¶ 94
[26]" Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called 'off-label' uses – i.e., any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter." - Justice Department Announces Largest Health Care Fraud Settlement in Its History. Justice.gov. Published September 2, 2009. Accessed November 12, 2023. https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history
[27] *State of Texas, ex rel. Tarik Ahmed v. Tris Pharma, Inc*., 23-1030, 71st JDC, Harrison County, TX.

has approved a drug's NDA for a specific condition—an 'indication for use' in FDA terminology—the drug's sponsor is legally only authorized to promote the drug for that particular indication." Suppose a person promotes an investigational drug as if it has a licensed indication with the intent of causing another person to take it. (21 C.F.R. §201.128) In that case, the person violates federal FDCA and Texas' misbranding laws. Ms. Young knows that such an act is unlawful. It is concerning that at all times material, she and her State Actors promoted the federally owned investigational drugs as if they were FDA-licensed, with the intent of causing individuals to be injected with those drugs under the false belief that they were something other than what was on their label. Additionally, one drug has more than one trillion potential contraindications involving more than 19,000 FDA-licensed drugs and hundreds of diseases and their combinations. That is why Congress preempted Ms. Young and her State Actors from depriving Plaintiffs' right to refuse the drugs, and it is why the HHS Secretary stated in unambiguous language that the drugs were "an investigational vaccine not licensed for any indication" (Doc 20, P. 12 ¶ 37), which means the drug is under investigation to become a licensed vaccine but it is not yet one. An EUA drug can never be lawfully considered a "vaccine" because it cannot be "licensed" for its intended use under the EUA statute (21 U.S.C. §360bbb-3(a)(2)(A)).

Ms. Young is plain wrong when claiming, "More than one hundred years of legal precedence indicate that no such right exists." (Doc 25, p. 19) The statement cannot reconcile with the State of Texas providing an assurance under its FWA and the CDC Program that it would NEVER compel a person to come under compulsory use with a federally funded investigational new drug. A State, having its prerogative to participate in

a federal program, cannot ignore its duties under the program once it willfully participates, and nothing in "one hundred years of legal precedence" proves otherwise.

Ms. Young cites *Jacobson v. Massachusetts*, 197 U.S. 11, 26-27, 39 (1905) (Doc 25, p. 19) but it does not help her case. *Jacobson* is inapplicable because it does not address the mandatory use of federally funded investigational drugs, EUA drugs, or PREP Act countermeasures, nor can it be applied to the terms and conditions under the CDC Program, because that Program and those statutes did not exist in 1905.

Ms. Young's claim her actions should be considered under a "rational basis review" is nonsensical. Congress created laws for the "[e]xpanded access to unapproved therapies and diagnostics"[28] for reasons of education, compassion, and emergency use. Then, by enacting Project Bioshield, Congress provided the means to introduce into commerce unlicensed medical products for broad access during a nuclear, chemical, biological, or pandemic event.[29] However, despite a national emergency, Congress was unambiguous that no person could come under a mandatory requirement to use the products or have a penalty imposed on them when refusing. Additionally, the Executive branch, FDA, CDC, HHS, COVID-19 manufacturers, and Texas agreed to only offer the products under voluntary conditions to protect humans offered the federally funded investigational products and for the additional reason that anyone involved in the product's manufacture, distribution, or administration were immunized from suit should individuals incur injury

[28] 21 U.S.C. §360bbb *et. seq*.
[29] "Project Bioshield" amended 21 U.S.C. §360bbb-3 for the purpose of allowing the DoD to develop medical countermeasures (MCM) to respond to chemical, biological, radiological, and nuclear events and to introduce those unlicensed products into commerce under a declared emergency (Public Law No. 108-276 07/21/2004).

from their use. Therefore, Ms. Young is contending that she and her State Actors were somehow authorized to arbitrarily ignore the legal requirements of the State-run program, federal law, and the Fourteenth Amendment. Neither Ms. Young nor her State Actors were elected by the People nor empowered by Congress to amend statutory law by *ultra vires* acts. Ms. Young's State Actors' "vaccination" policies, relying exclusively upon the use of federally owned EUA/PREP Act investigational drugs, were unlawful, unconstitutional, and only enforced under *ultra vires* authority. Ms. Young does not once deny Plaintiffs' claims that they had the right to refuse the federal drugs, or that her State Actors were prohibited and preempted from establishing a policy requiring mandatory use; still, she contends that her inaction and her State Actors' *ultra vires* "vaccination" policies should be reviewed under "rational basis," which is outrageous because we are dealing with a fundamental right, which requires "strict scrutiny," and there is no basis whatsoever to violate that fundamental right with EUA/PREP Act investigational drugs for a disease with a 99.95% survival rate.

Ms. Young continues to imply that an investigational drug can come under a "vaccination" requirement (Doc 25, p. 19) without directly asserting such a baseless claim when stating, "In a novel attempt to circumvent established legal precedent, Plaintiffs appear to be claiming a federally protected right to continued employment at Shriners" by referencing Plaintiffs claim at Doc 20, ¶ 95 stating, "The Policy deprived Plaintiffs of their fundamental right to refuse an investigational drug without penalty." However, Ms. Young ignores Plaintiffs' assertion at ¶ 97 that Shriners was completely preempted from establishing an "*ultra vires*" policy of penalizing Plaintiffs by terminating their

employment for refusing to be injected with federally owned COVID-19 EUA/PREP Act investigational drugs.

Ms. Young desperately attempts to turn this case into an employment dispute, which it is not. Termination from employment is one of the claimed injuries, but this case is about the Constitutional and federal statutory right of Plaintiffs to refuse the federally funded COVID-19 investigational drugs without penalty or pressure because (1) the drug is classified as investigational, (2) Ms. Young had a duty to protect Plaintiffs' right to refuse when involved in the federal program offered through her State Actors, (3) the drugs were only offered under a State program providing Plaintiffs the statutory authority to accept or refuse without consequence, (4) Ms. Young and her State Actors were completely preempted by the Supremacy Clause, the express preemption language under the PREP Act, the Field Preemption doctrine, the terms of the Provider Agreement, and their FWAs from mandating their use, (5) the Fourteenth Amendment right to be treated equally under the law, and (6) the right to due process when and if Plaintiffs were deprived of their property interest under the Fourteenth Amendment, Provider Agreement, and their fundamental right to bodily integrity when refusing investigational medical products.

Ms. Young is attempting to have it both ways. On one hand, Ms. Young does not dispute the Plaintiffs' claim that they had the "right to refuse federally funded investigational drugs" without consequence (Doc 20, p. 1 ¶) while, on the other hand, implying that her State Actors could require nonconsensual use of the federally funded investigational drugs. She attempts this feat by changing the legal classification of the

drugs, replacing Plaintiffs' words with her own, and citing cases having no application to the instant action.

Wise v. Inslee (Doc 25, pp. 19) offers her no help. A court ruling on the authority of a general vaccination requirement is not the same as this court ruling on a requirement to be injected with federally funded investigational drugs that do not have a legal indication to treat, cure, or prevent any known disease and having severe legal, financial, and health consequences to the end user as previously discussed.

Jensen v. Biden (Doc 25, p. 19, bottom) is not applicable because it did not consider the use of investigational drugs under a vaccination policy. Ms. Young does not cite a case establishing the right of a public or private employer to mandate the use of an investigational drug. There is zero jurisprudence for Ms. Young's baseless, implied claim.

Ms. Young is wholly incorrect when claiming, "The 'right' Plaintiffs allege Defendant Young violated simply does not exist anywhere in American jurisprudence."[30] (Doc 25, p. 20) Ms. Young is well aware of her duties under the State's FWA and the CDC Program when she, or persons she authorizes, offer humans EUA/PREP Act investigational drugs. Ms. Young cannot produce a constitutional provision, federal or state statute, treaty, or federal or state regulation, nor any case law, providing any person authority to amend the FDCA and/or the emergency protocols issued by the HHS Secretary to require another person to involuntarily consent to the use of an investigational drug and surrender their Fourteenth Amendment rights to due process (i.e., litigation rights) should they incur injury

[30] Doc 20, Count Four, demonstrates the extent to which Congress has gone to protect humans involved who are offered investigational new drugs.

from the use of a countermeasure because that right "does not exist anywhere in American jurisprudence." Ms. Young has responsibility and control for all matters relating to the health of citizens of the State of Texas (Texas Health and Safety Code § 12.0001, *et. seq*.). She knows that an individual can never come under compulsion by any other person to use an investigational new drug. Therefore, it is puzzling why she continually implies that fact stating, "Plaintiffs appear to be claiming a federally protected right to continued employment at Shriners." (Doc 25, p. 19)

It is black letter law that Ms. Young's State Actors had no authority to establish a prohibited act (e.g., the act of refusing an EUA a drug) under 21 U.S.C. § 331, assign a penalty (e.g., termination from employment) under 21 U.S.C. § 333, and enforce those *ultra vires* conditions under their personal version of the FDCA, nor could they amend the "voluntary nature"[31] of the PREP Act, which their mandatory policies did, nor could they amend the "conditions of authorization" for each drug under EUA, which their mandatory policies did. Ms. Young does not attempt to demonstrate by what statutory authority she allowed her State Actors to amend federal law.

Plaintiffs did not mischaracterize the COVID-19 drugs as "investigational," as Ms. Young claims (Doc 25, p. 20). It is the FDA, in its December 11, 2020, EUA letter that advised Pfizer, "This is an investigational vaccine not licensed for any indication." (Doc 27-1) This is a stubborn fact for certain, and one Ms. Young refuses to address. Although Ms. Young claims the drugs were not investigational, she provides no support of the drugs'

[31] Doc 20, p. 14 ¶ 47

classification or why the FDA was wrong to assign the drugs their investigational status.[32] The federally-owned COVID-19 EUA/PREP Act drugs were labeled investigational by the FDA, the only agency empowered by Congress to determine a drug's classification. That fact is irrefutable.

Ms. Young is incorrect when asserting, "Plaintiffs fail to explain the legal significance" between an investigational drug and a licensed vaccine. Plaintiffs specifically set forth the legal distinctions between a drug under EUA and the PREP Act. (Doc 20, p. 23, ¶ 93) Moreover, the SAC explains a federally funded investigational drug's historical, legislative, and legal distinctions. (See Doc 20.)

Ms. Young utilizes creative writing when stating, "Pfizer- BioNTech COVID-19 vaccine received full FDA authorization on August 23, 2021" (Doc 25, p. 20). The lowercase "v" refers to Pfizer's vaccine technology in general without reference to a specific drug label and its applicable laws, and it is why Ms. Young refuses to reference the licensed label by its name — COMIRNATY®. The FDA approved COMIRNATY® on August 23, 2021, for general commercial marketing. Still, on that same day, the FDA issued another EUA for the Pfizer-BioNTech COVID-19 Vaccine drug (uppercase "V," Pfizer's formal name for its investigational drug) because COMIRNATY® was not introduced into commerce for general commercial marketing. Approved for general commerce and introduced into commerce for general commercial marketing are two

[32] The FDA informed Pfizer Inc. that it "must submit to Investigational New Drug application (IND) number 19736" for the Pfizer-BioNTech COVID-19 Vaccine drug because it was "legally distinct" from COMIRNATY® and that it "will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates" of its research findings. (Doc 20-3, Letters G, N, and FN 8). The FDA issued similar EUAs for all of the federally owned COVID-19 drugs for all times material.

different things. Once a drug receives its Biologics License Approval ("BLA"), it must have its label approved and it must ship a test lot to the FDA for approval, among a plethora of other regulatory requirements, which typically take months to complete.[33] Plaintiffs can and will produce documentation from Peter Marks, Director of the Center for Biologics Evaluation and Research ("CBER") in charge of vaccine regulation, United States Food and Drug Administration ("FDA"), stating that the two drugs WERE NOT *legally* interchangeable, only *medically*, should Ms. Young make that assertion. Additionally, Plaintiffs can and will produce at trial documentation from Pfizer, Inc., and the CDC, proving that Pfizer did not manufacture or introduce into commerce its original or tris-sucrose licensed formulations under its National Drug Codes (NDC)[34] should Ms. Young make the claim COMIRNATY® was available to Plaintiffs, which it was not. No licensed COVID-19 drugs were available to Plaintiffs at any material time. (Doc 20, p. 21 ¶ 83).

However, what this court should note is that Ms. Young's argument implies that the HHS Secretary has been involved in felonious activities by issuing EUAs[35] for the "Pfizer-BioNTech COVID-19 Vaccine" drug starting on and after the FDA approved COMIRNATY®, which Congress prohibits once an FDA-licensed drug is available for COVID-19 (21 U.S.C. §360bbb-3(C)(3)). Ms. Young cannot prove her claim that "Plaintiffs cannot credibly allege they were required to ever take any 'investigational

[33] See Doc 20-3.
[34] The FDA assigned Pfizer, Inc., NDAs for COMIRNATY®, which was not introduced into commerce at any pertinent time.
[35] EUAs for the Pfizer-BioNTech COVID-19 Vaccine drug were issued on (August 23, 2021), (September 22, 2021), (October 20, 2021), (November 19, 2021), (December 9, 2021), (December 16, 2021), (January 3, 2022), (March 29, 2022), (May 17, 2022), (June 17, 2022), (July 8, 2022), (August 31, 2022), (October 12, 2022), (December 8, 2022), (March 14, 2023), (April 18, 2023), and on (April 28, 2023) for 12 years of age and older.

drug'" when her State Actors created mandatory use policies. The State sanctioned that behavior by denying unemployment benefits to refusers of the drug. Factually, the first hospital in the nation to require the investigational new drugs was Houston Methodist in April 2021, months before COMIRNATY® was licensed for commerce, paving the way for others to follow in the unlawful conduct resulting from Ms. Young's inaction.

45 C.F.R. Part 46

Plaintiffs addressed 45 C.F.R. Part 46 in its Opposition to Shriners Defendants' Motion to Dismiss, which are adopted here by reference. (Doc 27, p. 31, Letter L) Additionally, however, and respectfully, Judge Hughes was wrong when conflating 45 C.F.R. Part 46 with clinical trials. Clinical trials are conducted under the FDA (21 C.F.R. §§ 50,56) for the purposes of a manufacturer receiving BLA approval. 45 C.F.R. Part 46 applies to persons using unlicensed drugs for research activities authorized by the HHS Secretary. Ms. Young misconstrues Plaintiffs' claim when stating, "There is not any credible claim that Defendant Young, or any defendant herein, was engaged in research by implementing vaccine requirements." (Doc 25, p. 21) The required byproduct of the CDC Program, run in Texas by Ms. Young's Department, requires research activities under the Provider Agreement, EUA statute, and EUA letters. Rather than repeat their position on "research" here, Plaintiffs incorporate their argument in their opposition to Shriners' Motion to Dismiss. (See Doc 27, Section D, pp. 10-11).

21 U.S.C. §360bbb-3 § 1983 and EUA Letters

As with the arguments related to 45 C.F.R. 46, Plaintiffs adopt their argument in Opposition to Shriners Defendants' Motion to Dismiss regarding the EUA statute, § 1983, and EUA Letters. (Doc 27, Letter I, p. 27)

A. Option to Refuse

Ms. Young's claim on p. 25-26 is incorrect for reasons previously discussed herein and in the Plaintiffs' Second Amended Complaint, generally.

B. Equal Protection

Plaintiffs invoke the "class of one"[36] doctrine, as Plaintiffs were healthcare workers involved in the State-run CDC Program and were discriminated against by Ms. Young's custom, depriving Plaintiffs of their constitutional and statutory rights and state benefits[37] for the sole reason that Ms. Young and her State Actors did not like Plaintiffs' choice to refuse and discriminated against them only for that reason. Ms. Young was responsible for ensuring that her State Actors accepted the healthcare workers' chosen option. Still, she allowed those State Actors to discriminate against refusers for no reason other than financial greed. The discrimination isn't employment discrimination; it flows from involvement with the State-run CDC Program. Plaintiffs were not terminated for conduct relating to their employment, they were deprived of their rights for refusing to participate

[36] "[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., supra,* at 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)

[37] The right to be informed of the risks/benefits/alternatives of the product without incurring a fee, penalty, or loss of benefits and to be free from outside pressure to participate.

in Ms. Young's CDC Program. Moreover, once the State agreed to provide the benefits, it was required to provide them in an equal manner and Ms. Young's inaction deprived Plaintiffs of their Equal Protection rights. [38]

C. Due Process

Ms. Young has refused to discuss the case's merits involving the CDC Program and the rights afforded to Plaintiffs. Therefore, Ms. Young's assertions in Doc 25, pp. 27-29, should be given no weight because she ignores the merits of Plaintiffs' due process claims.

Plaintiffs had a property interest in the right to refuse under the Provider Agreement, the EUA statute, the State's FWA, and the fact the drug was FDA-classified as an investigational drug. Moreover, Plaintiffs had a property interest in the Provider Agreement because they had the expectation of being informed of the risks/benefits/alternatives to the product and informed of their right to accept or refuse the drug without incurring a fee or being placed under pressure or threatened with a penalty should they refuse. Additionally, Plaintiffs had a property interest in due process itself, which Ms. Young's State-enforced custom deprived them of by requiring Plaintiffs to surrender their right to seek judicial relief if injured by a countermeasure as a condition of enjoying the benefits of the State's CDC Program and continued employment within the healthcare industry.

D. Unconstitutional Condition Doctrine

> "It would be a palpable incongruity to strike down an act of state legislation which…seeks to strip the citizen of rights guaranteed by the federal Constitution, but to uphold an act by which the same result is accomplished under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to

[38] *Goldberg v. Kelly*, 397 U.S. 254 (1970)

> withhold. It is not necessary to challenge the proposition that, as a general rule, the state, having power to deny a privilege altogether, may grant it upon such conditions as it sees fit to impose. But the power of the state in that respect is not unlimited; and **one of the limitations is that it may not impose conditions which require the relinquishment of constitutional rights.** If the state may compel the surrender of one constitutional right as a condition of its favor, it may, in like manner, compel a surrender of all. **It is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence** (emphasis added)."[39]

The State, Ms. Young, and her State Actors established the unconstitutional condition of requiring healthcare workers (i.e., Plaintiffs) to surrender their Fourteenth Amendment rights to due process if injured by the countermeasure, privacy (e.g., must hand over private identifiable health information to researchers), equal protection (i.e., penalties for those who refuse, but not those who accept), and fundamental right to bodily integrity (i.e., right to refuse investigational drugs), as a condition to continue employment, receive unemployment benefits, and to participate in the federal program. Ms. Young's actions effectively create a blueprint whereby the State can require private parties to accomplish what the State cannot. "Broadly stated, the rule is that the right to continue the exercise of a privilege granted by the state cannot be made to depend upon the grantee's submission to a condition prescribed by the state which is hostile to the provisions of the federal Constitution."[40]

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[39] *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593-94 (1926)

[40] *Western Union Tel. Co. v. Kansas*, 216 U.S. 1, 47, 48 S., 30 S. Ct. 190 (1910); *Western Union Tel. Co. v. Foster*, 247 U.S. 105, 114, 38 S. Ct. 438, 1 A. L. R. 1278 (1918). *U.S. v. Chicago, M., St. P. &P. Railway Co*., 282 U.S. 311, 328-329 (1931).

E. Right to Privacy

Plaintiffs' SAC demonstrates that Ms. Young's State Actors could not invade the Plaintiffs' health privacy by requiring them to inform whether they participated in a private investigational medical procedure, especially since those State Actors were under a legal obligation to accept the Plaintiffs' chosen option without any additional conditions.

F. Breach of Contract

The Provider Agreement required Ms. Young and her State Actors to perform the ministerial function of informing Plaintiffs of the risks, benefits, and alternatives to the EUA drugs without pressure to be injected. Whether Plaintiffs accepted or refused, being informed was specifically owed to them and outlined under 12(a) of the contract. Moreover, 12(a) required all State Actors to "comply with all applicable requirements as set forth by the [FDA]," which includes to perform the ministerial function of accepting Plaintiffs' option. Ms. Young was personally responsible for ensuring all private parties signed the Provider Agreement as a condition of becoming a State Actor, and she was to "monitor" their implementation of the contract for the benefit of Plaintiffs as discussed in the CDC Playbook, Provider Agreement, and each EUA.

G. Wrongful Termination

Ms. Young cites cases that do not address an employer mandating the use of federal investigational drugs. The Texas at-will employment doctrine is preempted by the

Supremacy Clause, the Field Preemption doctrine regarding emergency use drugs,[41] and the express preemption language under the PREP Act[42] when the doctrine conflicts with or interferes in any requirement applicable under the statutes, including the option to accept or refuse. Plaintiffs do not claim a public policy exception to the at-will doctrine; they claim the doctrine is completely preempted.

The *Chauvin* court (Doc 25, p. 33) erred by not considering how the statute preempts the Plaintiff from exercising their Fifth and/or Fourteenth Amendment Due Process rights should they become injured by the product and how that constitutional requirement relates to the statute's express preemption language ensuring the "voluntary nature" of the program.[43] The *Chauvin* court failed to consider that the cause of action did not result from physical injury but one of mandatory participation in the PREP Act program itself, in which Congress expressly preempted the "private party" from interfering.[44] The private party employer in *Chauvin* then used the State's at-will employment law to penalize the Plaintiff for refusing to surrender his due process rights and his consent rights under the Act. Congress expressly protected the right to refuse by preempting the use of the state employment law for the purpose of "impos[ing] a duty that was inconsistent—i.e., in conflict—with federal law." *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461,

[41] *Arizona v. United States*, 567 U.S. 387, 399 (2012) ("[Congress's] intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that 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.'") (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947))
[42] Doc 20, p. 14 ¶ 48
[43] The HHS Secretary must "educate…[participants] with respect to...the voluntary nature of the program." (42 U.S.C. § 247d-6e(c)) (emphasis added).
[44] "Congress enacts a law that imposes restrictions or confers rights on private actors; a state law confers rights or imposes restrictions that conflict with the federal law; and therefore the federal law takes precedence and the state law is preempted." *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018)

1480 (2018) citing *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 133 S. Ct. 2466, 186 L. Ed. 2d 607 (2013) (emphasis added).

The PREP Act's express preemption language at 42 U.S.C. § 247d-6d(b)(8) extends to any requirement "applicable" to the FDCA including the option to accept or refuse which "confer[ed] on private entities [i.e., Plaintiffs]…a federal right to engage in certain conduct subject only to certain (federal) constraints." Thus, Ms. Young was completely preempted from interfering because the federal government completely occupies the field of the release of emergency use (i.e., EUA) products and because Congress provided immunity to products under the PREP Act. A State is preempted from enforcing the use of the at-will employment doctrine by a private party to mandate participation because "it concerns a clash between a constitutional exercise of Congress's legislative power and conflicting state law." (*Id.*). The court declined to answer the question of how the fundamental due process rights of the Plaintiff under the PREP Act "does not create a federal cause of action or any rights, duties, or obligations" when the State allowed a private party to use a law that interferes in the Act's federal goal of only voluntary participation. The PREP Act expressly preempted states and private parties from "continu[ing] in effect with respected to a covered countermeasure"[45] a "law or legal requirement" conflicting with the voluntary nature of the PREP Act.

[45] *Chauvin v. Terminix Pest Control*, No. 22-3673 Section "H," 2023 U. S. Dist. LEXIS 204345, at *13-14 (E. D. La. Nov. 15, 2023)

H. Intentional Infliction of Emotional Damage

Defendant's inaction led to her State Actors (i.e., Shriners) issuing policies intentionally inflicting emotional distress upon Plaintiffs, despite Defendant informing healthcare workers and Shriners that they could NOT require use of EUA/PREP Act investigational drugs nor place an individual under threat of penalty before, during, or after refusing, which led to Shriners to inflicting the emotional distress set forth in the SAC.

I. Implied Private Right of Action

Plaintiffs assert that Congress implied a private right of action under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) when creating a right for their benefit that is deeply rooted in American culture, history, and fundamental bodily integrity rights involving investigational medical products and for the same reasons the federal judiciary created a judicial private right of action under Title VI and IX exists in the instant action.

J. Qualified Immunity

Ms. Young raised the affirmative defense of qualified immunity but declined to address Plaintiffs' allegations regarding the State's CDC Program, FWA, and her ministerial duties[46] under them. If a Defendant refuses to address Plaintiffs' allegations while concurrently claiming immunity, a court cannot grant that immunity since the Defendant did not demonstrate how her actions were "reasonably objective" in relation to the allegations.[47] In effect, Ms. Young treats qualified immunity as absolute immunity by failing to demonstrate how she was entitled to it regarding the challenged conduct (i.e.,

[46] Doc 20, p. 16 ¶¶ 54-61
[47] *Atteberry v. Nocona General Hosp*., 430 F.3d 245 (5th Cir. 2005)

refusal to perform the ministerial function of accepting Plaintiffs' informed consent). Plaintiffs alleged that Ms. Young was responsible for the State's CDC Program, had ministerial duties to perform, and was required to "ensure" her State Actors filled out the Provider Agreement and to "monitor" their implementation of that program down to the "local level" to "ensure" the State Actors complied with its terms, including "requirements in any EUA that covers COVID-19 Vaccine."[48] Moreover, Plaintiffs specifically alleged that Ms. Young breached her duty to ensure that she and her State Actors performed the ministerial function of accepting Plaintiffs' chosen option under the EUA statute, the Provider Agreement, the EUAs, 45 C.F.R. § 46.116, the FWA, and according to Plaintiffs' fundamental right to bodily integrity because the FDA classified the drugs as investigational. Ms. Young does not demonstrate how such allegations fail to state a claim against her. She does not dispute that she has such a duty, nor even that she breached it. She simply claims she cannot be held liable because of qualified immunity.

Contrary to her claim, Ms. Young is not entitled to qualified immunity. **First**, Ms. Young had "fair warning"[49] under the law when she was provided information regarding her duties relating to healthcare matters for the State of Texas under the CDC Program.

[48] Doc 20-2.

[49] "[G]eneral statements of the law are not inherently incapable of giving fair and clear warning, and in other instances, a general constitutional rule already identified in the decisional law may apply with obvious clarity to the specific conduct in question, even though 'the very action in question has [not] previously been held unlawful'" and "[T]he object of the 'clearly established' immunity standard is not different from that of 'fair warning' as it relates to law 'made specific' for the purpose of validly applying §242. The fact that one has a civil and the other a criminal law role is of no significance; both serve the same objective, and in effect the qualified immunity test is simply the adaptation of the fair warning standard to give officials (and, ultimately, governments) the same protection from civil liability and its consequences that individuals have traditionally possessed in the face of vague criminal statutes. To require something clearer than 'clearly established' would, then, call for something beyond 'fair warning.'" *United States v. Lanier*, 520 U.S. 259, 117 S. Ct. 1219 (1997)

The CDC Playbook provided Ms. Young with knowledge of her duties under the CDC Program, and she had knowledge of those duties because she was required to recruit the State Actors and ensure they filled out the Provider Agreement and maintain that Agreement on file for three years.[50] She was informed of her duties as the "emergency response stakeholder" under each EUA, which required her to ensure that Plaintiffs were informed of their right to accept or refuse federally owned COVID-19 EUA/PREP Act investigational drugs.[51] **Second**, the challenged conduct does not involve any discretionary functions of Ms. Young or her State Actors, only their ministerial duty to accept the Plaintiffs' chosen option, which Ms. Young's State Actors refused to perform under her approval.[52,53] Moreover, Congress was explicit that the HHS Secretary is empowered to authorize the emergency use of unlicensed drugs during a declared emergency. Still, he cannot require mandatory participation in any activity involving those products, thus the reason to inform Plaintiffs of their option and accept without condition or penalty their choice. **Third**, "inaction" (Doc 25, p. 37) is not an acceptable ground for qualified immunity, nor is it applicable when acting outside the scope of one's official authority. [54,55]

[50] Doc 20, p. 7, ¶ 23
[51] Doc 20, pp. 15-16, ¶ 56,57,58
[52] "Qualified immunity is only available when an official acts 'within the scope of [his or her] discretionary authority.' *Brooks v. George County,* 84 F.3d 157, 164-65 (5th Cir. 1996) (quoting *Cronen v. Tex. Dep't of Human Servs.,* 977 F.2d 934, 939 (5th Cir. 1992))" *Atteberry v. Nocona General Hosp*, 430 F.3d 245, 257 (5th Cir. 2005)
[53] The Ninth Circuit held that government officials are "unprotected" from qualified immunity when they refuse to perform a ministerial function, such as allowing a person to fill out a license application (*Groten v. California*, 251 F.3d 844 (9th Cir. 2001)). The act of accepting Plaintiffs' chosen option is purely ministerial.
[54] The Tenth Circuit held that qualified immunity is not a defense for an official that "failed to actually comply with the statute upon which they purportedly relied" (*Roska v. Sneddon*, 437 F.3d 964 (10th Cir. 2006)).
[55] The Eleventh Circuit granted qualified immunity to a teacher who reprimanded a child for raising a fist in the air during the pledge of allegiance because the teacher was acting under discretionary authority but denied her that same immunity when encouraging children to pray because her actions were outside the scope of her authority (*Holloman v. Harland*, 370 F.3d 1252 (11th Cir. 2004)).

Fourth, clearly established law dictates that no person outside of Congress can establish prohibited acts (21 U.S.C. § 331) or assign penalties (21 U.S.C. § 333) under the FDCA,[56] which Ms. Young and her State Actors did when amending the EUA by nullifying Plaintiffs' right to refuse. Additionally, public officials may not act under *ultra vires* authority to establish a condition requiring Plaintiffs to surrender their Constitutional protections to enjoy a benefit of the State or federal program, which Ms. Young and her State Actors did when requiring Plaintiffs to surrender the Constitutional rights to equal protection and due process to enjoy the benefits under the CDC Program.[57] Ms. Young used her position of power to establish an unconstitutional condition to "produce a result which the State could not command directly." *Speiser v. Randall*, 357 U.S. 513 (1958). **Fifth**, it is established that a person may not promote a drug outside of its legal indication with the intent to cause another person to use that product under the false belief that the product is something other than what is on its label.[58] Ms. Young and her State Actors established a custom of promoting the investigational drugs as if they were labeled as safe, effective, and FDA-licensed for COVID-19. Ms. Young cannot identify a time when the State or any medical facility therein could legally place an individual under threat of penalty for refusing to be injected with an investigational drug, much less condition employment or public benefits, because such an act has always been unlawful. **Finally**, qualified immunity is not granted to those who "knowingly violate the law," which is the

[56] U.S. Constitution, Art. 1, § 1: "All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives."
[57] *Doyle v. Continental Insurance Company*, 94 U.S. 535 (1876); *Frost Trucking Co. v. Railroad Comm'n*, 271 U.S. 583 (1926); *Hanover Fire Ins. Co. v. Harding*, 272 U.S. 494 (1926).
[58] *Kordel v. United States*, 335 U.S. 345 (1948)

only logical conclusion to be derived from Ms. Young's declining to respond to the Plaintiffs' allegations and the supporting documentation relating to her duties regarding the federally funded investigational drugs and willful failure thereof.[59] Ms. Young is not entitled to qualified immunity in the instant action.

For the reasons stated herein, Ms. Young's Motion to Dismiss should be denied.

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[59] *Malley v. Briggs*, 475 U.S. 335 (1986)