IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

JENNIFER BRIDGES, *et al*	§	
	§	
Plaintiffs,	§	
	§	
V.	§	**Civil Action No. 4:21-CV-01774**
	§	
THE METHODIST HOSPITAL D/B/A THE METHODIST HOSPITAL SYSTEM, AND HOUSTON METHODIST THE WOODLANDS HOSPITAL,	§	
	§	
Defendants.	§	

PLAINTIFFS' OPPOSITION TO MOTION TO DISMISS

TO THE HONORABLE UNITED STATES DISTRICT COURT:

JENNIFER BRIDGES, *et al.* ("Plaintiffs") in the above-referenced case file this Opposition to Defendants' Motion to Dismiss Plaintiff's Original Petition.

INTRODUCTION

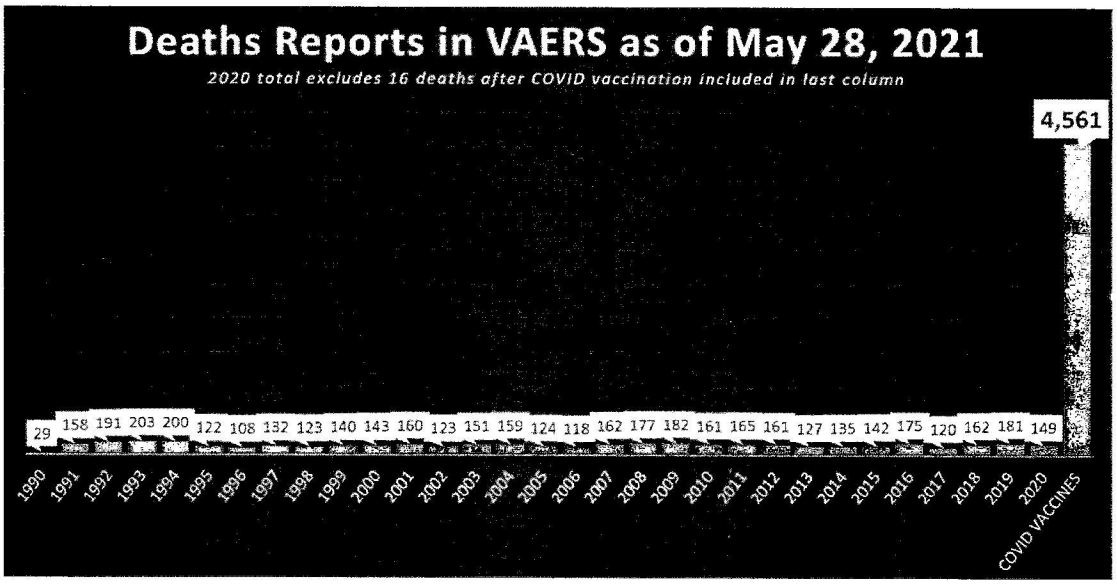
This is a case of first impression. The Defendants cited no law that applies to a situation where a medical institution employer is coercing employees to participate as human subjects in investigational medical clinical trials.

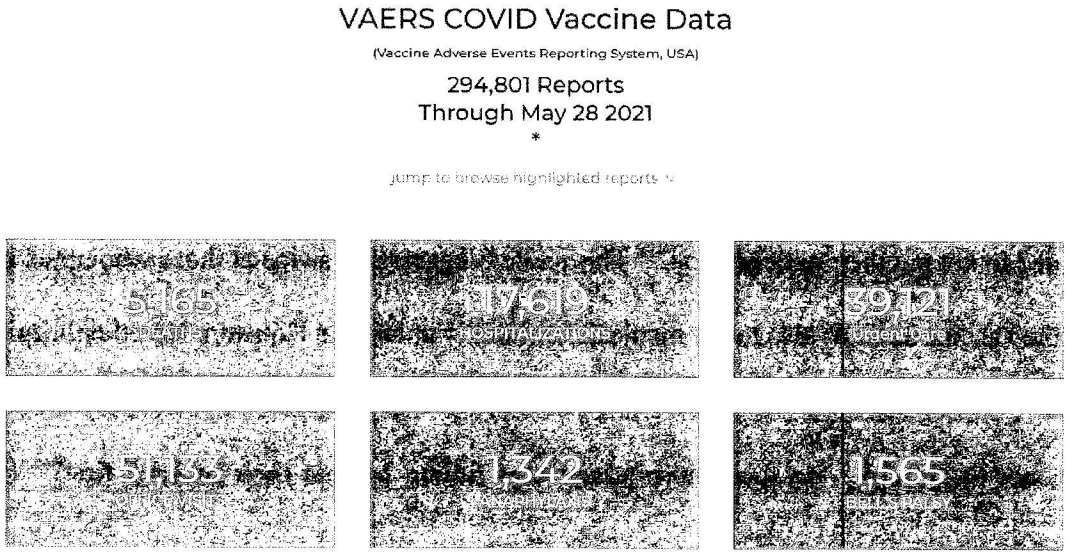
In an email to employees after the mandatory vaccine deadline lapsed, CEO Dr. Marc Boom stated, "I wish the number could be zero, but unfortunately, a small number of individuals have decided to not put their patients first."[1] This passive-aggressive swipe at those who opted out of taking the vaccine extends also to the medical community at large in Houston. No other hospital system has a vaccine mandate, not Memorial Hermann, not Texas Children's Hospital, not M.D. Anderson, not St. Joseph. Are these hospital systems failing to "put their patients first?" The

[1] *See* Exhibit 1, text of the June 8, 2019 email from CEO Marc Boom to Methodist employees.

answer is "no," there is no failure. **If this were *truly* about putting patients first, every single hospital system, medical provider, facility, clinic, and office would have banded together to mandate vaccines.** Yet, there stands Methodist Hospital, alone, claiming it is unique in "putting patients first." At the middle of this public relations stunt are the Plaintiffs in this lawsuit.

Plaintiffs opted out of this:





Based on VAERS[2] as of May 28, 2021, there were reported:

5,165 deaths, and

17,619 hospitalizations.[3]

By comparison, from July 1, 1997, until December 31, 2013, VAERS received 666 adult death reports for all vaccines.[4]

With approximately 50% of the U.S. population vaccinated, mortality is not the only serious adverse event that has been reported after the COVID-19 vaccine. Additional morbidity reported to the CDC and verified with a permanent VAERS number include:

39,121 urgent care visits

51,133 office visits

1,342 cases of anaphylaxis

1,565 cases of Bell's Palsy

5,317 life threatening events

1,892 heart attacks

756 cases of myocarditis/pericarditis

1,392 cases of thrombocytopenia/low platelet

571 miscarriages

13,574 severe allergic reactions

3,994 disabling illnesses.[5]

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[2] In 1990, the Vaccine Adverse Event Reporting Systems ("VAERS") was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines.
[3] VAERS may be publicly accessed at https://www.openvaers.com/covid-data.
[4] *Id. See also* Exhibit 2 Pedro L. Moro, Jorge Arana, Mria Cano, Paige Lewis, and Tom T. Shimabukuro, Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013, VACCINES, CID 2015:61 (September 2015).
[5] https://www.openvaers.com/covid-data.

Based on the above data (from a CDC-monitored database), one wonders whether CEO Boom is risking employees *becoming* patients that Methodist can "put first."

GREAT CASES, LIKE HARD CASES, MAKE BAD LAW

The underlying fact scenario in this case is unlike anything seen in American jurisprudence. Getting this wrong will have grave, wide-spread consequences. The issue of compulsory vaccinations led to one of the darkest days in American jurisprudence when the U.S. Supreme Court upheld a law requiring forced sterilization of those deemed "unfit."[6] The Court shockingly held, "The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes . . . three generations of imbeciles is enough."[7] Will this issue before this Honorable Court lead to yet another dark day?

In his dissent in *Northern Securities Co. v. U.S.*, 193 U.S. 197 (1904), Justice Holmes observed, "Great cases, like hard cases, make bad law. For great cases are called great, not by reason of their real importance in shaping the law of the future, *but because of some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment*."[8]

In the instant case, there is an "overwhelming interest which appeals to the feelings and distorts the judgment." The pandemic certainly created an overwhelming interest. And as a result of that overwhelming interest, distortions of judgment are rampant. The vaccine mandate is just such a distortion of judgment. In fact, it is a complete lack of judgment and failure to objectively observe the basic, factual circumstances.

There are fundamental facts significant to this matter. It starts with the undisputed, inarguable proposition that **the currently available vaccines for COVID-19 are in**

[6] *Buck v. Bell*, 274 U.S. 200 (1927).
[7] Id. at 207.
[8] Emphasis added.

investigational use in the United States.[9] Under 21 U.S.C. § 360bbb-3 these vaccines are "unapproved products" still in the clinical trial phase.[10] The "fact sheets" for each of the 3 currently used vaccines in the U.S. all unequivocally state:

- There is no [FDA] approved vaccine to prevent COVID-19.[11]
- The [Pfizer/Moderna/Janssen] COVID-19 Vaccine is an unapproved vaccine . . .[12]

Again, this is undisputed.

Logically, that means that anyone taking the currently available vaccines is part of the ongoing "clinical trial." Each fact sheet clearly states: [Pfizer/Moderna/Janssen] COVID-19 Vaccine is still being studied clinical trials.[13]

It is interesting to note that in the fact sheets, Pfizer, Moderna, and Janssen direct those taking their vaccines to report any adverse event to VAERS.[14]

So, the Plaintiffs were mandated by their employer, a hospital system authorized *and paid* to administer the vaccine (still under clinical trials), to subject themselves to an ongoing clinical trial, or risk the prospect of losing their jobs. This is a clear violation of federal regulations as explained below.

In 45 C.F.R. 46.102, a clinical trial is defined as a "research study."

In 45 C.F.R. 46.101, the regulations concerning medical testing with human subjects applies to research, *i.e.*, clinical trials, involving human subjects *that is subject to any federal department or agency*. The vaccines are subject to FDA regulation. And, that research involves

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[9] *See* 21 U.S.C. § 360bbb-3. *See also* Exhibit 3, Declaration of Dr. Peter A. McCullough, MD, MPH.
[10] *See* Vaccine Fact Sheets for three U.S. vaccine manufacturers attached as Exhibit 4.
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.*

human subjects – Methodist Hospital employees.

To put it plainly, according to federal regulations, Methodist employees are human subjects in medical research subject to federal regulation, and therefore, this regulation applies to Defendants.

Considering the above definitions and scope, 45 C.F.R. 46.116 provides general requirements for informed consent. Subsection (a) outlines the informed consent requirements. First, legally effective informed consent is required. Second, and most importantly, that informed consent **cannot be sought under circumstances that involve coercion or undue influence**.

While it should go without saying, the prospect of losing one's job is coercion or undue influence.[15] And, not only did these Plaintiffs lose their jobs, but they were also terminated for "conduct" reasons.[16] The decision of whether to participate in a clinical trial did not only end current employment but will most likely affect *future* job prospects given the threat of termination for "conduct" reasons. This is coercion and undue influence.

In summary, Methodist Hospital attempted (and succeeded in some cases) in coercing employees to be human subjects in a clinical trial. In doing so, Defendants violated federal regulations. The Code of Federal Regulations applies to Methodist in the exact same way it applies to an 18-wheeler driver required to keep logs.

An important policy consideration also bears mentioning: the Nuremberg Code. While this policy consideration will most likely result in uninformed, media-led *ad hominen* attacks, it is surprisingly applicable to the current facts, and is a concept recognized by the U.S. Supreme Court as recently as 2018.[17] Pfizer is no stranger to the implications of the Nuremberg Code. *Abdullahi*

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[15] *See* Exhibit 5, Declaration of Jennifer Bridges.
[16] *Id.*
[17] In *Jesner v. Arab Bank, PLC*, 138 S.C.t 1386 (2018), the U.S. Supreme Court dealt with the issue of whether to extend the Alien Tort Act to foreign corporations. The case was against Arab Bank, PLC which

v. Pfizer, Inc., 562 F.3d 163 (2nd Cir. 2009). In that case, it was alleged that Pfizer conducted involuntary medical experiments on humans when it gave an experimental antibiotic on children in Nigeria 1996.[18] The Plaintiffs' claims were grounded in part on the Nuremberg Code, "which states in its first principle that "[t]he voluntary consent of the human subject is absolutely essential."[19] After discussing the history of the Nuremberg trials, the court found that, "states throughout the world have shown through international accords and domestic law-making that they consider the prohibition on nonconsensual medical experimentation identified at Nuremberg as *a norm of customary international law*."[20] In fact, Nuremberg-influenced language appears in 45 C.F.R. 46.116. This is an internationally recognized concept, and one that is directly at play in the facts of this case. Defendants, by attempting to coerce Plaintiffs into a clinical trial for an investigational vaccine, violated a norm of customary international law.

Another important policy consideration are statutes that govern the Department of Health and Human Services, including the FDA, in dealing with clinical trials. Drugs and biologics, which include vaccines, are licensed by the Food and Drug Administration ("FDA"). Until these products are licensed, they are, by definition, experimental.[21] To be licensed, manufacturers submit extensive data to the FDA from the drug's clinical trial to show it is safe and effective. Nevertheless, Congress recognized the need for the FDA to authorize the use of certain experimental products in an emergency situation - even before they are shown to be safe and

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allegedly financed terrorist organizations. The Plaintiffs were US citizens injured by acts of terrorism. The ultimate holding was that it was up to Congress to extend the ATA to foreign corporations. However, throughout the opinion, the US Supreme Court acknowledged the ongoing relevance of the Nuremberg Code.

[18] *Id.* at 168.

[19] *Id.*

[20] *Id.* at 179 (emphasis added).

[21] 21 U.S.C. 360bbb-3.

effective.[22] Until they are approved, Congress made the policy decision that members of the public should not be forced to receive an unapproved product, i.e., experimental product.[23] It required that every recipient of the pre-approval experimental product must be informed of the known risks and benefits and then be **given the choice** whether to receive or refuse that product.[24]

Individuals must be provided the "**option to accept or refuse** administration of any product released under an EUA.

Reflecting this federal law, the FDA's guidance document regarding EUAs explains that "the statute [21 U.S.C. 360bbb-3] requires that the FDA ensure that recipients [of emergency use products] are informed ... [t]hat they have the option to accept or refuse the EUA product." This rule also reflects a cornerstone of medical ethics that, for all unlicensed medical products, obtaining the uncoerced voluntary consent of the individual is essential.

The relevance and gravity of these violations cannot be overstated.

ARGUMENT

In spite of clear violations of federal regulations and a norm of customary international law, Defendants continue to argue they are entitled to coercively *mandate* the COVID-19 vaccine. It is important to note that there is a significant difference between "mandating" and "encouraging." Defendants cited an EEOC guideline that employers may *mandate* employees be vaccinated. However, this guideline does not have the force of law, nor is it persuasive for this court. It is simply the uninformed edict of an agency head. Additionally, Defendants cite the OSHA website "frequently asked questions" (not a regulation) to support the proposition that OSHA is *encouraging* the vaccination. Defendant cited to no statute, regulation, or case law allowing the

[22] *Id.*
[23] *Id.*
[24] *Id.*

mandating of an unapproved product in a clinical trial. That, along with a 100+-year-old U.S. Supreme Court case is the only "law" cited by Defendants on this issue.

Defendants' reliance on *Jacobson v Commonwealth of Massachusetts*, 197 U.S. 11 (1905) is misplaced. *Jacobson* is clearly distinguishable. First, the FDA had not been created at the time of that decision.[25] There was no such thing as an unapproved product, human subject, or clinical trial. That is key in the instant case. *Jacobson* did not involve the implications of coercing someone to be subject to medical experiments. Methodist is attempting to coerce employees to participate in clinical trials as human subjects. That was not the fact pattern in *Jacobson*. The only consequence in *Jacobson* was a $5 fine.[26] Secondly, the smallpox vaccine had been around in some form since the early 1800's.[27] The Court was not dealing with a vaccine that had quite literally been rushed to market at "warp speed."[28]

The smallpox vaccine was a simple concept of introducing a similar but less dangerous virus into the subject to help them build an immunity to a virus that had a 30% mortality rate.[29] As set out in detail in the Exhibit 3, Declaration of Dr. Peter A. McCullough, MD, MPH, the investigational SARS-CoV-2 vaccines manufactured by Pfizer and Moderna contain laboratory synthesized mRNA in a lipid package and theadeno viral DNA in JNJ in viral vector. This mRNA/adeno viral DNA enters the host's cells and takes over the cells causing them to produce the Wuhan spike protein which elicits the development of antibodies.[30] The Wuhan spike protein,

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[25] https://www.fda.gov/about-fda/fda-basics/when-and-why-was-fda-formed.
[26] *Id.* at 12.
[27] https://www.cdc.gov/smallpox/history/history.html.
[28] https://public3.pagefreezer.com/browse/HHS%20%E2%80%93%C2%A0About%20News/20-01-2021T12:29/https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html.
[29] https://www.cdc.gov/smallpox/history/history.html.
[30] *See* Exhibit 6: Suzuki YJ, Gychka SG. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines. *Vaccines (Basel)*. 2021;9(1):36. Published 2021 Jan 11. doi:10.3390/vaccines9010036.

independent of the SARS-CoV-2 virion, has been demonstrated to be pathogenic or damaging to blood vessels, organs (brain, heart, lungs, liver, bone borrow) and to be directly thrombogenic by causing hemagglutination and thrombosis. The human host cells respond to the Wuhan spike protein and elicit cell signaling otherwise known as inflammation.[31] The Wuhan spike protein is produced in an uncontrolled fashion without limits on duration. The mRNA/adeno viral DNA vaccines may also affect the host cells which may result in cellular dysfunction and death.[32] Researchers in the cited study recommend that the long-term consequences be monitored carefully for these experimental vaccines, especially when they are administered to otherwise healthy individuals.[33] Scientists further conclude that further investigations on the effects of the SARS-CoV-2 spike protein on human cells and appropriate experimental animal models are warranted.[34] *Jacobson* was decided in 1905. The situation with the current vaccines is appreciably different enough to make *Jacobson* a relic of the past.

Defendants, as major medical facilities, must be aware of 45 C.F.R. 46.116 and their duties to provide appropriate, legal, and ethical informed consent. The Plaintiffs have alleged sufficiently in their Original Petition that Defendants committed an illegal act. Yet, Defendants argue that a claim has not been stated under *Sabine Pilot*. Defendants fail to acknowledge the stark novelty of the instant case. Again, this is a case of first impression.[35] And, the implications of dismissing this

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[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.* ("However, we need to consider their long-term consequences carefully, especially when they are administered to otherwise healthy individuals as well as young adults and children. In addition to evaluating data that will become available from SARS-CoV-2 infected individuals as well as those who received the spike protein-based vaccines, further investigations of the effects of the SARS-CoV-2 spike protein in human cells and appropriate animal models are warranted.")
[35] There are no court decisions stating whether private employers may mandate vaccines or other drugs authorized under an EUA. In early March 2021, in the US District Court, District of New Mexico, a detention center employee filed a complaint seeking a temporary restraining order and preliminary injunction against Dona Ana County. The employee argued that the County's mandatory COVID-19 vaccination requirement for first responders is preempted by the EUA statute, 21 USC § 360bbb-3, and

case are enormous.

In *Sabine Pilot v. Service, Inc. v. Hauck*, the Supreme Court of Texas created a public policy exception to the employment-at-will doctrine.[36] This exception allows an employee to sue for wrongful termination if she is fired for the sole reason that she refused to perform an illegal act.[37] In this instance, employees have been suspended and are facing certain termination in 14 days.[38]

It has been irrefutably established that the Defendants are in violation of federal regulations by coercing with undue influence the participation in clinical trials.[39] The failure of the employee to participate with this scheme will lead to the wrongful discharge. The Plaintiffs, mostly nurses within the Defendants' medical facilities have duties to comply with laws and regulations, including 45 C.F.R. 46.116. Plaintiffs argue that the currents facts and evidence fall under the spirit

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violates his 14th Amendment right to a zone of privacy. The County/defendant filed a response to the motion for an injunction on March 15, 2021, explaining the EUA statute 21 USC § 360bbb-3 at most requires vaccine recipients to be informed of the consequences of refusing the vaccine. In response to the Fourteenth Amendment argument, the County/defendant cited numerous authorities holding that the argument that mandatory vaccination program violates the Fourteenth Amendment was "foreclosed by the Supreme Court's decision in *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905)." Just four days after the defendant/County filed the response brief, the plaintiff filed a notice withdrawing the motion for injunction on March 19, 2021. Thus, the Court did not rule on any of these issues. In one other case that mentions the EUA statute relative to COVID-19, *Aviles v Blasio,* 20 CIV. 9829 (PGG), 2021 WL 796033 (SDNY Mar. 2, 2021), parents sued the City of New York seeking a preliminary injunction requiring the reopening of all public schools for in-person instruction and forbidding the City from requiring students to take COVID-19 tests for in person instruction. The Southern District of New York denied the motion, holding that the students were not deprived of any constitutional rights because they were offered remote learning, and their parents could opt out of COVID-19 testing and still receive remote instruction. In a footnote the Court dismissed the parents' argument that the COVID tests are EUA products, and thus cannot be mandatory under 21 USC § 360bbb-3, because the testing program is premised on parental consent and is not mandatory. The Court did not reach the issue of whether the statute would prohibit the school from requiring testing if it were a mandatory requirement.

[36] 687 S.W.2d 733, 735 (Tex. 1985).

[37] *Texas Dep't of Human Servs. v. Hinds*, 904 S.W.2d 629, 633 (Tex. 1995); *see Safeshred, Inc. v. Martinez,* 365 S.W.3d 655, 664 (Tex. 2012) ("A plaintiff may not bring a *Sabine Pilot* claim immediately after being asked to perform an illegal activity but must first refuse and be fired.").

[38] *See* Exhibit 5. *See also* Plaintiffs' Original Petition, and exhibits, including the Methodist human resources policy involving the vaccine mandate.

[39] 45 C.F.R. 46.116

of *Sabine Pilot*, and that this matter should not be dismissed.

STANDARD

When evaluating a motion to dismiss, the Court must treat the complaint's factual allegations as true and afford the plaintiff the benefit of all inferences that can be derived from the facts alleged."[40] Construing all of the plaintiff's factual allegations as true, to survive a Rule 12(b)(6) motion to dismiss, the claim to relief must be "'plausible on its face,' enough to 'nudge [the] claims across the line from conceivable to plausible.'"[41] "[D]ismissal is inappropriate unless the plaintiff can prove no set of facts in support of his claim which would entitle him to relief."[42] Plaintiffs' Original Petition, and any amendment, is plausible on its face and Defendants' Motion to Dismiss should be denied.

Respectfully submitted,

/s/ Jared R. Woodfill
Jared R. Woodfill
State Bar No. 00788715
WOODFILL LAW FIRM, P.C.
3 Riverway, Suite 750
Houston, Texas 77056
Tel: (713) 751-3080
Fax: (713) 751-3058
woodfillservice@gmail.com (service)
jwoodfill@woodfilllaw.com (non-service)
Counsel for Plaintiffs

[40] *Citizens for Resp. & Ethics in Washington v. U.S. Dep't of Hous. & Urb. Dev.*, 415 F. Supp. 3d 215, 221 (D.D.C. 2019).
[41] *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).
[42] *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002).

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing pleading has been served on all counsel of record through the Court's electronic filing system, on June 10, 2021.

/s/ Jared R. Woodfill
Jared R. Woodfill