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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA

AMERICA'S FRONTLINE DOCTORS, et al,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 2:21-cv-702-CLM
	)	
The UNITED STATES OF AMERICA, et al,	)	
	)	
Defendants.	)	

MOTION FOR PRELIMINARY INJUNCTION WITH SUPPORTING BRIEF

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MOTION FOR PRELIMINARY INJUNCTION

"[T]he sole object and only legitimate end of government is to protect the citizen in the enjoyment of life, liberty, and property, and when the government assumes other functions it is usurpation and oppression." Art. 1, §35, Alabama Constitution. "[T]his enumeration of certain rights shall not impair or deny others retained by the people; and, to guard against any encroachments on the rights herein retained, we declare that everything in this Declaration of Rights is excepted out of the general powers of government, and shall forever remain inviolate." Art. 1, §36, Alabama Constitution.

One right encompassed within the "liberty" provisions of the Alabama Constitution "includes the right[] . . . to bodily integrity". *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). It is "fundamental in American jurisprudence, that the individual may control what shall be done with his own body." *Canterbury v. Spence*, 150 U.S. App. D.C. 263, 464 F.2d 772, 780 (D.C. Cir. 1972). These liberty interests include "the right to marry, to have children, to direct the education and upbringing of one's children, to marital privacy, * * * [and] to bodily integrity". *Crawford v. State*, 92 So. 3d 168, 171 (Ala. Crim. App. 2011). After all, "[a] competent person has the constitutional right to choose or refuse medical treatment, and that right extends to all relevant decisions concerning one's health." *In re Guardianship of Browning*, 568 So. 2d 4, 12 (Fla. 1992).

Last spring on April 29, House Speaker Nancy Pelosi disclaimed the authority of Congress to impose vaccine mandates,[1] but legal events regarding this COVID pandemic have been quickly evolving ever since. Those who oppose mandatory vaccines chiefly rely on their constitutional right to control what gets injected into their bodies, while those who promote the vaccines assert that such is a constitutional power of government. And the clash between these diametrically opposed contentions manifested when President Biden issued two Executive Orders on September 9: Executive Orders 14042 ("EO 14042") and 14043 ("EO 14043") (copies of which are attached hereto as Exs. 1 and 2).

This motion is predicated on several counts in the amended complaint (ECF 32-1). Count VI of that complaint challenges the validity of EO 14042 and EO 14043, asserting that the statutory foundation for these Orders is inadequate to support what these Orders seek to accomplish: the imposition of vaccine mandates. In short, this count contends that President Biden is attempting via these Orders to exercise legislative power which has not been delegated to him. In Count VI of the amended complaint, the plaintiffs seek a declaratory judgment regarding the validity of these Orders.

Count II of the amended complaint is premised on the well recognized right to

[1] See: https://www.youtube.com/watch?v=25w0m3p2vCk (last visited Nov. 16, 2021).

"bodily integrity." In this count, the plaintiffs assert that this constitutional right is being purposely abridged by these Orders as well as other actions directly arising from the actions of the defendants, and the plaintiffs contend that because of this constitutional right, they cannot be forced to take a vaccine over their objection.

In Count III of the amended complaint, the Plaintiffs challenge the "emergency use authorizations" (herein "EUA") granted in reference to the 3 vaccines that are currently being made available and administered to the American public: the Pfizer-BioNTech vaccine, the Moderna vaccine, and the Johnson & Johnson/Janssen vaccine. Two federal laws codified at 21 U.S.C. § 331 and 21 U.S.C. § 352(j) make penal the "misbranding of drugs."[2] By October 22, 2020, the FDA was clearly aware that the vaccines that had been developed under its supervision and were soon to be approved were dangerous and likely to cause death to many vaccine recipients, and this great danger of inordinate deaths has proven to be true. Because of these known adverse events, plaintiffs believe that the EUAs are invalid and they challenge the same via this lawsuit.

Pursuant to Rule 65, F.R.Cv.P., the Plaintiffs respectfully move this court for a preliminary injunction, as further described below, and after hearing, they request

[2] As explained *infra*, "misbranding" essentially means that when a drug or vaccine is used in the manner as directed on the manufacturer's product label or promotional materials but is still dangerous, it is "misbranded."

that the court grant such.

STANDARD FOR INJUNCTION

In *Jones v. Governor of Florida*, 950 F.3d 795, 806 (11th Cir. 2020), the various factors that need to be shown in order for a party to obtain a preliminary injunction were set forth:

> "A district court may grant preliminary injunctive relief only when a party establishes each of four separate requirements:
>
> "(1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest."

Moreover in a motion for injunctive relief, a party may challenge public health officials and their various decrees issued in response to an alleged health crisis: "'if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of courts to so adjudge, and thereby give effect to the Constitution.'" *Robinson v. Attorney General*, 957 F.3d 1171, 1178 (11th Cir. 2020) (quoting *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905)). After all, "just as constitutional rights have limits, so too does a state's power to issue executive orders limiting such rights in times of emergency." Id.

FACTS RELEVANT FOR THIS MOTION

Angelia Desselle took a vaccine on January 5, 2021, and has been seriously injured as a result (ECF 15-8). As she has stated: "I have lost my job, the ability to drive or go out in public for fear of a convulsion starting. This vaccine has basically taken my life without killing me." Shawn Vidiella, a certified nursing assistant, took a vaccine on January 4, 2021 (ECF 15-9). She "ended up visiting five emergency rooms and traveled as far away from home as Vanderbilt in Nashville, Tennessee seeking help. Nobody was able to help me. I was told I had a variety of different problems: psychogenic movement disorder, conversion disorder, panic attack, PTSD, stress. On January 11, 2021, I was finally admitted into Deaconess Gateway Neurology. I was examined by a psychologist before I was even seen by a neurologist, and an MRI was ordered. The MRI came back normal and I was discharged. The full-body convulsions were continuous for 12 days. To date, I have tremors and uncontrollable body movements almost daily. I experience convulsions several times a week and sometimes several times a day." She has lost her job, and was denied worker's compensation.

Brittany Galvin apparently got COVID-19 in early 2021, and was extremely sick as a result (ECF 15-10). But because of social pressure, she took the first Moderna shot on March 28, 2021 and the second one on May 4, 2021. At the time she signed her declaration submitted in this case, she had been seriously injured and

was at Advent Carrollwood Hospital in Tampa as a patient. "My neurologist gave me a diagnosis of Guillain Barre Syndrome, Acute Neuropathic POTS, pericarditis, gastroparesis and aseptic meningitis. He attributes my condition to the shot. I have already lost the reflects in my ankles and knees. I was told my neurologist made a report to VAERS." She considers her decision to take the shot as "the biggest mistake I have ever made".

Diane Hallmark received a vaccine shot on February 12, 2021, and another on March 10 (ECF 15-11). Both she and her husband have been hospitalized as a result of the shots. "I still needed assistance with basic things such as getting out of bed, walking and going to the bathroom. I started physical therapy in my daughter's home and began to learn to walk and do things once again. I regained some limited function, but I still struggle with the function of my lower limbs and with vertigo and dizziness such that I cannot care for myself, or my husband anymore, and probably never will be able to."

For good reasons, plaintiffs Jody Sobczak and his wife, Deborah, oppose compulsory vaccinations as do Lyle Bloom and his wife, Julie (ECF 1-3, 1-4, 1-5, 1-6). Plaintiff Joseph Makowski works for a Huntsville employer that is requiring its employees to be vaccinated no later than December 8, 2021 (Ex. 3 attached hereto). Plaintiffs Michael Nelson and Joseph Leahy both live in Huntsville and work at the Marshall Space Flight Center, and they confront a vaccine mandate requiring

vaccination by November 22, 2021 (Ex. 4 attached hereto). Both Nelson or Leahy object to being vaccinated.

Dr. Scott Jensen has stated that "anyone under the age of 17 is at statistically zero risk of dying of Covid 19 infection." (ECF 1-1). Nonetheless, there is a present effort to vaccinate children as young as 5 years of age. Dr. Steven Roth works in a hospital's emergency room, and he has stated as follows:

> I have not seen a COVID-19 patient in many months, but I am seeing many patients come to the emergency department patients post-COVID-19 shot. All of these patients came in with COVID-like symptoms that occurred within 48 hours of the shot.
>
> All of these patients required hospital admission.
>
> **Several of these patients progressed to death. From the vaccine.** (ECF 1-9).

Dr. Angelina Farella (ECF 15-2), and Dr. Richard Urso (ECF 15-3) have read and they agree with the facts alleged in the initial complaint filed in this case (ECF 10) and the first motion for a preliminary injunction (ECF 15). Some of these facts with which they agree are the following (the below numbers correspond to the paragraph numbers in that amended complaint):

> 4. The Vaccines appear to be linked to a range of profoundly serious medical complications, among them myocarditis, miscarriage, irregular vaginal bleeding, clotting disorders, strokes, vascular damage and autoimmune disease.
>
> * * *
>
> 182. The SARS-CoV-2 has a spike protein on its surface. The spike protein is what allows the virus to infect other bodies. It is clear that the spike protein is

not a simple, passive structure. The spike protein is a "pathogenic protein" and a toxin that causes damage. The spike protein is itself biologically active, even without the virus. It is "fusogenic" and consequently binds more tightly to our cells, causing harm. If the purified spike protein is injected into the blood of research animals, it causes profound damage to their cardiovascular system, and crosses the blood-brain barrier to cause neurological damage.

183. The study reveals that unlike traditional vaccines, this spike protein enters the bloodstream and circulates throughout the body over several days post-vaccination. It accumulates in a number of tissues, such as the spleen, bone marrow, liver, adrenal glands and ovaries. It fuses with receptors on our blood platelets, and also with cells lining our blood vessels. It can cause platelets to clump leading to clotting, bleeding and heart inflammation. It can also cross the blood-brain barrier and cause brain damage. It can be transferred to infants through breast milk.

* * *

193. Salk Institute for Biological Studies researchers in collaboration with the University of San Diego, published in the journal *Circulation Research* that the spike proteins themselves damage vascular cells, causing strokes and many other vascular problems. All the vaccines are causing clotting disorders (coagulopathy) in all ages. The spike proteins are known to cause clotting that the body cannot fix, such as brain thrombosis and thrombocytopenia.

* * *

195. The spike proteins are perceived to be foreign by the human immune system, initiating an immune response to fight them. While that is the intended therapeutic principle, it is also the case that any cell expressing spike proteins becomes a target for destruction by our own immune system. This is an autoimmune disorder and can affect virtually any organ in the body. It is likely that some proportion of spike protein will become permanently fused to long-lived human proteins and this will prime the body for prolonged autoimmune diseases. Autoimmune diseases can take years to show symptoms and many scientists are alarmed at giving young people such a trigger for possible autoimmune disease.

* * *

> 204. The Vaccines induce the cells of the recipient to manufacture trillions of spike proteins for an undetermined amount of time with the pathology described above, whereas naturally occurring COVID-19 comes and goes. The spike protein is the same. The increased risk comes from reprogramming the cells to permanently create the spike protein at potentially high levels. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, a very strong immune response, including those which can damage their own cells and tissues, including by stimulating blood coagulation.
>
> * * *
>
> 208. Antibody Dependent Enhancement ("ADE") occurs when SARS-CoV-2 antibodies, created by a Vaccine, instead of protecting the vaccinated person, cause a more severe or lethal case of the COVID-19 disease when the person is later exposed to SARS-CoV-2 in the wild. The Vaccine *amplifies* the infection rather than *preventing* damage. It may only be seen after months or years of use in populations around the world.

On October 22, 2020, the FDA's Vaccines and Related Biological Products Advisory Committee conducted a meeting for various attendees to discuss sundry matters related to the COVID-19 pandemic. During this meeting, a slide presentation was given wherein one of slides disclosed the following possible "risks" of the vaccines:

> Guillain-Barré syndrome
> Acute disseminated encephalomyelitis
> Transverse myelitis
> Encephalitis/myelitis/encephalomyelitis/
> meningoencephalitis/meningitis/encepholapathy
> Convulsions/seizures
> Stroke
> Narcolepsy and cataplexy
> Anaphylaxis

Acute myocardial infarction
Myocarditis/pericarditis
Autoimmune disease
Deaths
Pregnancy and birth outcomes
Other acute demyelinating diseases
Non-anaphylactic allergic reactions
Thrombocytopenia
Disseminated intravascular coagulation
Venous thromboembolism
Arthritis and arthralgia/joint pain
Kawasaki disease
Multisystem Inflammatory Syndrome in Children
Vaccine enhanced disease

See Ex. 5 attached hereto.

However, a few months later when Pfizer, Moderna and Jansen published "Fact Sheets" where they were obligated to provide vaccine recipients specific information about the "benefits and risks" of each vaccine, these potential risks were not mentioned, but were carefully concealed. For example, in the "Fact Sheet" published by Pfizer, Inc., dated May 10, 2021, the risks" of its vaccine were described in the following manner (ECF 24-1, page 3):

> WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
>
> There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

• Difficulty breathing
• Swelling of your face and throat
• A fast heartbeat
• A bad rash all over your body
• Dizziness and weakness

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

• severe allergic reactions
• non-severe allergic reactions such as rash, itching, hives, or swelling of the face
• injection site pain
• tiredness
• headache
• muscle pain
• chills
• joint pain
• fever
• injection site swelling
• injection site redness
• nausea
• feeling unwell
• swollen lymph nodes (lymphadenopathy)
• diarrhea
• vomiting
• arm pain

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

In a "Fact Sheet" published by Janssen Biotech Inc., dated April 23, 2021, the "risks" of its vaccine were described in the following manner (ECF 24-10, pages 3-4):

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine

include:

• Injection site reactions: pain, redness of the skin and swelling.
• General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

• Difficulty breathing,
• Swelling of your face and throat,
• A fast heartbeat,
• A bad rash all over your body,
• Dizziness and weakness.

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks following vaccination. Most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

• Shortness of breath,
• Chest pain,
• Leg swelling,
• Persistent abdominal pain,
• Severe or persistent headaches or blurred vision,
• Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen

COVID-19 Vaccine is still being studied in clinical trials.

In the "Fact Sheet" published by Moderna, Inc., dated March 26, 2021, the "risks" of its vaccine were described in the following manner (ECF 24-6, page 3):

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported in a clinical trial with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

"Established in 1990, the Vaccine Adverse Event Reporting System (VAERS)

is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention." [3] But, data from VAERS that has been carefully concealed reveals a darker and more sinister result of the vaccines. Since vaccines were provided and administered to the American public at the start of this year, there have been, just for Medicare recipients, a total of 51,100 deaths, with many from Alabama. See Ex. 6 attached hereto.

It is logical to conclude that improvements in the vaccines were made after the vaccine manufacturers developed and tested them, and thus the current vaccines are better than the "test" vaccines. If there have been 51,100 deaths just from Medicare recipients (a subset of the American public) since the vaccine program started, surely the deadly nature of these vaccines must have been known to the vaccine manufacturers as well as the defendants.

[3] See: https://vaers.hhs.gov/about.html (last visited Nov. 19, 2021)

RELEVANT LEGAL BACKGROUND

I. Statutory Foundation.

As a result of the 2001 terrorist attacks, Congress determined that there was a need for a federal program to respond to any foreign attack using chemical, biological, radiological, or nuclear agents, and it thus enacted the "Project BioShield Act of 2004", Pub L. 108–276, 118 Stat. 835. Provisions of this act amended the Federal Food, Drug and Cosmetic Act by substantially re-writing 21 U.S.C. 360bbb–3 into its present form (118 Stat. at 853). Pursuant to this section, when the HHS Secretary determines that there is a "public health emergency, * * * that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad," he may implement the powers authorized by this section, which include permitting "EUAs" for approved vaccines to treat individuals affected by the health crisis.

The following year via the "Public Readiness and Emergency Preparedness Act", Pub L. 109–148, 119 Stat. 2818, Congress amended provisions of the Public Health Service Act by adding a new section to it, now codified at 42 U.S.C. § 247d–6d. This section provides immunity from suit for "covered persons" during a "covered countermeasure", which is a response to a declared national health crisis.

On Friday, October 18, 2019, at The Pierre Hotel in New York City, Event 201

was conducted, which was a global pandemic exercise.[4] This careful planning happened just a little less than two months before events in Wuhan, China, garnered worldwide attention. On December 31, 2019, "WHO's Country Office in the People's Republic of China picked up a media statement by the Wuhan Municipal Health Commission from their website on cases of 'viral pneumonia' in Wuhan, People's Republic of China."[5] By January 25, 2020, the "WHO Regional Director for Europe issued a public statement outlining the importance of being ready at the local and national levels for detecting cases, testing samples and clinical management."

In response, President Trump on January 31, 2020, issued his "Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Persons who Pose a Risk of Transmitting 2019 Novel Coronavirus,"[6] that interdicted international travel from China into the United States. As events developed, the perceived threat posed by COVID-19 appeared to be increasing, causing President Trump to thereafter issue his "Proclamation on Declaring a National Emergency Concerning the Novel

[4] See: https://www.centerforhealthsecurity.org/event201/about (last visited Nov. 19, 2021).

[5] See WHO Timeline of COVID events: https://www.who.int/news/item/29-06-2020-covidtimeline (last visited Nov. 19, 2021).

[6] See Proclamation 9984, 85 Fed.Reg. 6709 (Feb. 5, 2020).

Coronavirus Disease (COVID-19) Outbreak" on March 13, 2020.[7]

"On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV)." 85 Fed.Reg. 7316 (February 7, 2020). Thereafter, various vaccine manufacturers such as Pfizer, Inc., Johnson and Johnson, and Moderna commenced at "warp speed" research on vaccines to treat COVID-19, and these efforts were reaching fruition by early December, 2020.

On December 3, 2020 (85 Fed.Reg. 79190, Dec. 9, 2020), the HHS Secretary granted immunity for "covered countermeasures" to vaccine manufacturers ("covered persons") that he might thereafter authorize to produce and distribute a vaccine. On December 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine was granted EUA (86 Fed.Reg. 5200, Jan. 19, 2021). The Secretary found that

> "it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and

[7] Proclamation 9994, 85 Fed.Reg. 15338 (March 18, 2020).

older" (86 Fed.Reg. at 5203).

But, the EUA for this vaccine imposed various requirements on Pfizer, Inc., which included providing critical information about adverse reactions to the vaccine to VAERS:

> F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
> • Vaccine administration errors whether or not associated with an adverse event;
> • Serious adverse events (irrespective of attribution to vaccination);
> • Cases of Multisystem Inflammatory Syndrome in children and adults; and
> • Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.
> These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.[8]

A few days after the grant of EUA for the Pfizer vaccine, ModernaTX, Inc., was granted an EUA for its vaccine, Moderna COVID-19 Vaccine, on December 18, 2020 (86 Fed.Reg. 5211, Jan. 19, 2021). The Secretary made the essential findings that this vaccine "was believed to be effective" and that the "potential benefits of Moderna COVID-19 Vaccine outweigh the known and potential risks" (86 Fed.Reg. at 5212). Further, a duty was also imposed on ModernaTX, Inc., to make reports to VAERS similar to that for Pfizer (86 Fed.Reg. at 5216).

On February 27, 2021, Janssen Biotech, Inc., was granted an EUA for its vaccine, Janssen COVID-19 Vaccine (86 Fed.Reg. 28608, May 27, 2021). Again, the

[8] 86 Fed.Reg. at 5207.

FDA made the essential findings that this vaccine "was believed to be effective" and that the "potential benefits of Moderna COVID-19 Vaccine outweigh the known and potential risks" (86 Fed.Reg. at 28620). Finally, a duty was also imposed on Janssen Biotech, Inc., to make reports to VAERS similar to that for Pfizer (86 Fed.Reg. at 28624).

These "COVID-19 vaccines authorized or approved by the [FDA] effectively protect vaccinated individuals against severe illness and death from COVID-19" (86 Fed.Reg. 61402-03, Nov. 5, 2021).

II. The Vaccine Manufacturers.

In 1849, two German immigrants, Charles Pfizer and his cousin Charles F. Erhart formed a company that eventually became Pfizer, Inc., which currently is an American multinational pharmaceutical and biotechnology corporation with headquarters in New York City. Its annual revenues exceed that of small countries like New Zealand.

When developing vaccines, Pfizer has engaged in harmful conduct which has resulted in lawsuits. In 1996 in Nigeria, its vaccine experiments resulted in the death and other severe injuries to a number of Nigerian children. As a result, Pfizer was sued and the Second Circuit described Pfizer's injurious conduct in *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 169 (2d Cir. 2009):

[I]n April 1996, Pfizer, dispatched three of its American physicians to work

> with four Nigerian doctors to experiment with Trovan on children who were patients in Nigeria's Infectious Disease Hospital ("IDH") in Kano, Nigeria. Working in concert with Nigerian government officials, the team allegedly recruited two hundred sick children who sought treatment at the IDH and gave half of the children Trovan and the other half Ceftriaxone, an FDA-approved antibiotic the safety and efficacy of which was well-established. Appellants contend that Pfizer knew that Trovan had never previously been tested on children in the form being used and that animal tests showed that Trovan had life-threatening side effects, including joint disease, abnormal cartilage growth, liver damage, and a degenerative bone condition. Pfizer purportedly gave the children who were in the Ceftriaxone control group a deliberately low dose in order to misrepresent the effectiveness of Trovan in relation to Ceftriaxone. After approximately two weeks, Pfizer allegedly concluded the experiment and left without administering follow-up care. According to the appellants, the tests caused the deaths of eleven children, five of whom had taken Trovan and six of whom had taken the lowered dose of Ceftriaxone, and left many others blind, deaf, paralyzed, or brain-damaged.

This case was later settled.[9]

In 2002, Pharmacia & Upjohn Company, a Pfizer subsidiary, developed a drug named Bextra, and started vigorously promoting its sale to its sale force. The start of this sales program was described as follows in the sentencing memorandum of the AUSA who brought criminal charges against Pfizer:

> Bextra was officially launched at a national meeting for sales representatives in Atlanta, Georgia from April 9-12, 2002. During this meeting, the sales force was given a vivid message of how to promote Bextra for the "power" position. They were inundated with displays of music, light shows, acrobats and dancers. The marketing managers led the entire audience in thrusting their fists into the air (the marketing symbol of Bextra) and pounding them against their upraised hands in unison to symbolize the power of Bextra and to "Power Up" the sales

[9] See: https://www.law.com/almID/1202482854504/ (last visited Nov. 16, 2020).

> force. Ultimately, simulated large steel doors crash down on the stage, and the Bextra fist symbol crashed through the doors. The events from the launch demonstrates the sales frenzy that accompanied Bextra, as the company strove to make the drug reach "blockbuster" (billion dollar a year sales) status.

Condensing this sordid story, Pharmacia sales representatives promoted Bextra using false and misleading claims, eventually leading to civil actions being filed by the United States as well as federal criminal charges in several districts. These civil and criminal charges were ultimately settled by Pfizer, and the Department of Justice press release summarized that conclusion:

> American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.
>
> Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. * * * The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.[10]
>
> It is reported that since 2000, Pfizer has paid $4,660,896,333 in penalties.[11]

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[10] See: https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history (last visited Nov. 16, 2021).

[11] See: https://violationtracker.goodjobsfirst.org/prog.php?parent=pfizer&sort=asc (last visited Nov. 16, 2021).

Johnson & Johnson/Janssen Pharmaceuticals, Inc., have had similar problems. In April, 2010, the Department of Justice announced that two "Johnson & Johnson Subsidiaries [agreed] to Pay Over $81 Million to Resolve Allegations of Off-Label Promotion of Topamax Epilepsy Drug Approved by FDA Promoted for Psychiatric Uses".[12] In 2012, 37 State Attorneys General reached a similar settlement regarding the promotion and sale of the drug, Risperdal: "Janssen Pharmaceuticals has agreed to pay $181 million to settle claims brought against it by Oregon Attorney General Ellen F. Rosenblum and 36 other Attorneys General alleging that the drug company used unfair and deceptive practices in marketing Risperdal and three related anti-psychotic drugs." [13] In November, 2013, the Department of Justice announced that "Johnson & Johnson [agreed] to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations". [14] More recently to address its role in assisting the Opioid crisis that has recently plagued a number of States in this Union, the New York

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[12] See: https://www.justice.gov/opa/pr/two-johnson-johnson-subsidiaries-pay-over-81-million-resolve-allegations-label-promotion (last visited Nov. 16, 2021).

[13] See: https://www.doj.state.or.us/media-home/news-media-releases/oregon-attorney-general-and-36-others-reach-181-million-risperdal-settlement/ (last visited Nov. 16, 2021).

[14] See: https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations (last visited Nov. 16, 2021).

Attorney General announced a $230,000,000 settlement with the company.[15] The company has paid a total of $9,248,447,763 in penalties since 2000.[16]

Moderna, Inc., was formed in 2010 and has since been primarily devoted to research and development of vaccines.[17] The first product it has EVER distributed to the American public is its experimental COVID-19 vaccine which is available only because of its EUA approval. This vaccine is now being sold to a number of countries around the world, which obviously makes its stockholders happy.

SUMMARY OF ARGUMENT

Count VI of the amended complaint notes that President Biden's Executive Orders of September 9, 2021, are based on specifically identified federal laws related to the acquisition of goods and services by the federal government as well as laws related to the federal civil service. But, these laws are limited to these purposes, and cannot provide the essential statutory authority needed to impose vaccine mandates on private contractors as well as government employees. In short, President Biden's Orders are an attempt by him to exercise legislative powers that can only be exercised

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[15] See: https://ag.ny.gov/press-release/2021/attorney-general-james-reaches-230-million-settlement-treatment-and-prevention (last visited Nov. 16, 2021).

[16] See: https://violationtracker.goodjobsfirst.org/prog.php?parent=johnson-and-johnson (last visited Nov. 16, 2021).

[17] See: https://en.wikipedia.org/wiki/Moderna (last visited Nov. 16, 2021).

by Congress, if at all. Because these Orders are invalid and unlawful, the vaccine mandates based on them are void and unenforceable, and the plaintiffs are entitled to the requested preliminary injunction.

Count II of the amended complaint concerns the plaintiffs' fundamental constitutional right to "bodily integrity" which will be violated and abridged if the forthcoming vaccine mandates are enforced against the plaintiffs by their employers. The plaintiffs contend here that even if the defendants as well as the United States possessed the constitutional power and authority to impose vaccine mandates (which the plaintiffs deny), that authority cannot be used to transgress and breach this constitutional right. Just based on the assertion of this constitutional right, the plaintiffs are entitled to a preliminary injunction.

Count III of the amended complaint focuses on the EUAs themselves, which the plaintiffs contend are unlawful. Prior to the time of issuance of these EUAs to the 3 vaccine manufacturers, it was known to the defendants that the vaccines were very harmful, injurious and dangerous. However, this predictable harm to vaccine recipients was not disclosed by either the vaccine manufacturers or the defendants, who have repeatedly informed the American public that the vaccines are "safe and effective".

While the vaccine manufacturers and a wide variety of federal officials including the President and the other defendants constantly harp that the vaccines are

"safe and effective," there is evidence to the contrary. Most recently, VAERS data indicates that there have been more than 50,000 deaths from the vaccines just among Medicare recipients. From this simple fact it is easy to infer that the vaccines as first developed and tested were more dangerous than those being used today. And this inference leads to something more troubling: the vaccine manufacturers have engaged in misbranding, a fact known by the defendants.

SUCCESS ON THE MERITS

I. Count VI.

Count VI of the amended complaint asserts that EOs 14042 and 14043 issued by President Biden on September 9, 2021 have no statutory support and are thus unlawful. As shown below, the plaintiffs are correct in this regard and are entitled to relief based on this count alone.

A. The Constitutional Deficiencies of the United States.

Here in America, the police power is vested in the States and not the federal government. See *Wilkerson v. Rahrer*, 140 U.S. 545, 554 (1891) (the police power "is a power originally and always belonging to the States, not surrendered to them by the general government, nor directly restrained by the constitution of the United States, and essentially exclusive"); *Bohon's Assignee v. Brown*, 101 Ky. 354, 41 S.W. 273 (1897); *John Woods & Sons v. Carl*, 75 Ark. 328, 87 S.W. 621, 623 (1905); *Southern Express Co. v. Whittle*, 194 Ala. 406, 69 So.2d 652, 655 (1915); *Shealey v. Southern*

Ry. Co., 127 S.C. 15, 120 S.E. 561, 562 (1924) ("The police power under the American constitutional system has been left to the states. It has always belonged to them and was not surrendered by them to the general government, nor directly restrained by the constitution of the United States. * * * Congress has no general power to enact police regulations operative within the territorial limits of a state"); and *McInerney v. Ervin*, 46 So.2d 458, 463 (Fla. 1950).

The police power of the States forms "a portion of that immense mass of legislation which embraces everything within the territory of a State not surrendered to the General Government; all which can be most advantageously exercised by the States themselves. Inspection laws, quarantine laws, health laws of every description, as well as laws for regulating the internal commerce of a State, and those which respect turnpike roads, ferries, &c., are component parts of this mass." *Gibbons v. Ogden*, 22 U.S. 1, 203 (1824).

This police power encompasses the power of the states to regulate the practice of medicine, not the federal government or its officers, agents and employees. See *Linder v. United States*, 268 U.S. 5, 18 (1925) ("Obviously, direct control of medical practice in the states is beyond the power of the federal government"); *Lambert v. Yellowley*, 272 U.S. 581, 598 (1926)("It is important also to bear in mind that 'direct control of medical practice in the States is beyond the power of the Federal Government.' * * * Congress, therefore, cannot directly restrict the professional

judgment of the physician or interfere with its free exercise in the treatment of disease. Whatever power exists in that respect belongs to the states exclusively."); *Du Vall v. Board of Medical Examiners*, 49 Ariz. 329, 335, 66 P.2d 1026 (1937)("The Congress, under the federal Constitution, has power to levy a tax upon narcotics and their sale, but the states have not delegated to the United States the power to regulate such sales and to punish therefor, or to regulate the practice of medicine."); *Ghadiali v. Delaware State Medical Society*, 48 F.Supp. 789 (D.Del. 1943)(the practice of medicine is a State concern); *F.T.C. v. Simeon Management Corp.*, 391 F.Supp. 697 (N.D.Cal. 1975), affirmed at 532 F.2d 708 (9th Cir. 1976); *United States v. Evers*, 453 F.Supp. 1141, 1150 (M.D.Ala. 1978); *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002); and *Oregon v. Ashcroft*, 368 F.3d 1118, 1124 (9th Cir. 2004).

B. The unconstitutional exercise of legislative power by President Biden.

In EO 14042, President Biden claimed that the profound power he was exercising was authorized by the Federal Property and Administrative Services Act, 40 U.S.C. § 101, *et seq.,* as well as 3 U.S.C. § 301. By means of these laws, the President claimed that he could mandate that a medically injured young man engaged in sanitation work at a federal facility in Huntsville, Alabama, could be compelled to take a vaccine contrary to the instructions of that man's doctor.

In EO 14043, President Biden asserted that sections 3301, 3302, and 7301 of title 5, United States Code, which relate to the federal civil service and the hiring of

federal employees, gave him the authority to mandate the imposition of vaccines. According to President Biden, he can force two men working for NASA to be subjected to harmful vaccines notwithstanding their assertion of their fundamental constitutional right to bodily integrity as well as their religious objections.

The legal principle that a legislature cannot delegate the power to make law to an executive official has common law origins, to be very briefly addressed here. King Henry VIII issued a number of unpopular Proclamations during his reign in England, and subsequent monarchs similarly abused this privilege. Eventually with the *Case of Proclamations*, 77 ER 1352 (1611), Sir Edward Coke, Chief Justice of the King's Bench, was asked to decide the legality of one proclamation. Coke and his fellow judges declared that "the King by his proclamation or other ways cannot change any part of the common law, or statute law, or the customs of the realm* * * also the King cannot create any offence by his prohibition or proclamation, which was not an offence before, for that was to change the law, and to make an offence which was not * * * ergo, **that which cannot be punished without proclamation, cannot be punished with it."** *Id.* As such, he held that the challenged proclamation was "utterly against law and reason, and for that void." *Id*.

Based on this history, John Locke, one of the most influential of Enlightenment thinkers, wrote in his *Second Treatise of Civil Government*, Chap. XI (1690):

The legislative cannot transfer the power of making laws to any other hands.

> For it being but a delegated power from the people, they, who have it, cannot pass it over to others. * * * And when the people have said, We will submit to rules, and be govern'd by laws made by such men, and in such forms, no body else can say other men shall make laws for them; nor can the people be bound by any laws but such as are enacted by those, whom they have chosen, and authorised to make Laws for them. The power of the legislative being derived from the people by a positive voluntary grant and institution, can be no other, than what the positive grant conveyed, which being only to make laws, and not to make legislators, the legislative can have no power to transfer their authority of making laws, and place it in other hands.

Here in America, the "Federal Constitution and State Constitutions of this country divide the governmental power into three branches. * * * [I]n carrying out that constitutional division * * * **it is a breach of the National fundamental law if Congress gives up its legislative power and transfers it to the President, or to the Judicial branch, or if by law it attempts to invest itself or its members with either executive power or judicial power."** *J. W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 405-406 (1928). James Madison noted in Federalist No. 47 that delegating legislative power to an executive too often results in tragedy: "The accumulation of all powers, legislative, executive, and judiciary, in the same hands * * * may justly be pronounced the very definition of tyranny."[18]

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[18] It may very well be that Madison acquired this idea from Coke, who wrote: "Wherever law ends, tyranny begins, if the law be transgressed to another's harm; and whosoever in authority exceeds the power given him by the law, and makes use of the force he has under his command to compass that upon the subject which the law allows not, ceases in that to be a magistrate * * *." Section 202 of Chap. XVIII "Of Tyranny" in Book II of the Two Treatises of Government.

This problem of executive officials adopting "codes" or regulations to address and resolve health crises in their states has been the subject of several state cases. In *State v. Marana Plantations*, 75 Ariz. 111, 115, 252 P.2d 87 (1953), at issue were state health regulations applicable to agricultural labor camps. The Arizona Supreme Court concluded that these sanitary regulations were unconstitutional:

> We think that the attempt by the legislature to make it the duty of the board to "formulate general policies affecting the public health" and to give the board unrestrained power to regulate sanitation and sanitary practices and promote public health and prevent disability and mortality is a constitutional relinquishment of its legislative power and to such extent is violative of constitutional principles, and the so-called Sanitary Code applicable to agricultural labor camps is void.

See also *Schaezlein v. Cabaniss*, 135 Cal. 466, 471, 67 P. 755 (1902); and *Boreali v. Axelrod*, 71 N.Y.2d 1, 6, 517 N.E.2d 1350 (1987)("We hold that the Public Health Council overstepped the boundaries of its lawfully delegated authority when it promulgated a comprehensive code to govern tobacco smoking in areas that are open to the public.").[19]

"The Congress manifestly is not permitted to abdicate or to transfer to others the essential legislative functions with which it is thus vested." *Panama Refining*

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[19] Some older cases have invalidated cattle quarantines on the same basis. See *Reims v. State*, 17 Ala. App. 128, 82 So. 576 (1919); *Abbott v. State*, 106 Miss. 340, 63 So. 667 (1913); and *Ex parte Leslie*, 87 Tex. Crim. 476, 223 S.W. 227 (1920). Two interesting cases on different issues are *Long v. State*, 202 Ga. 235, 237, 42 S.E.2d 729 (1947); and *DePetrillo v. Coffey*, 118 R.I. 519, 376 A.2d 317 (1977).

Company v. Ryan, 293 U.S. 388, 421 (1935). It "cannot delegate legislative power to the President to exercise an unfettered discretion to make whatever laws he thinks may be needed or advisable for the rehabilitation and expansion of trade or industry." *Schechter Poultry Corp. v. United States*, 295 U.S. 495, 537-38 (1935). See also *Carter v. Carter Coal Co.*, 298 U.S. 238, 310–12 (1936), as well as *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952), which found President Truman's takeover of steel mills unconstitutional because he lacked statutory authority.

This constitutional principle that the chief executive of a state or our country cannot exercise legislative powers has arisen and been addressed during this supposed COVID pandemic crisis. In *Midwest Inst. of Health, PLLC v. Governor of Mich. (In re Certified Questions from the United States Dist. Court)*, 506 Mich. 332, 958 N.W.2d 1 (2020), that court found various actions of Michigan's governor unconstitutional ("it is one thing if a statute confers a great degree of discretion, i.e., power, over a narrow subject; it is quite another if that power can be brought to bear on something as 'immense' as an entire economy.").

Also last year, the Centers for Disease Control devised a moratorium on tenant evictions, but that agency action was held unconstitutional in *Tiger Lily, LLC v. United States Dept. of Housing and Urban Development*, 992 F.3d 518 (6th Cir. 2021). A D.C. district court held similarly in *Ala. Ass'n of Realtors v. U. S. Dept. of Health and Human Services*, No. 20-cv-3377 (DLF), 2021 U.S. Dist. LEXIS 85568

(D.D.C. May 5, 2021), and the Supreme Court upheld that decision in *Ala. Ass'n of Realtors v. United States Dept. of Health and Human Services*, No. 21A23, 2021 U.S. LEXIS 3679 (Aug. 26, 2021).

II. Count II.

Most states have existing laws generally defining the practice of medicine as encompassing the treatment or cure of a disease. For example, Ala. Code § 34-24-50 defines the practice of medicine to include "diagnos[ing], treat[ing], correct[ing], advis[ing] or prescrib[ing] for any human disease, * * * by any means or instrumentality". As shown *supra*, the federal government lacks the constitutional power to regulate the practice of medicine. However, via a number of EUAs issued during this supposed COVID pandemic, this is precisely what the federal government has attempted.

In the "Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 and Republication of the Declaration," 85 Fed.Reg. 79190 (Dec. 9, 2020), the HHS Secretary stated the following when once again extending tort protection to "Covered Persons":

> The amended Section VII adds that PREP Act liability protections also extend to Covered Persons for Recommended Activities that are related to any Covered Countermeasure that is:
> (a) Licensed, approved, cleared, or authorized by the Food and Drug Administration (FDA) (or that is permitted to be used under an Investigational

> New Drug Application or an Investigational Device Exemption) under the Federal Food, Drug, and Cosmetic (FD&C) Act or Public Health Service (PHS) Act to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom.[20]

This tort protection has not only been extended to the vaccine manufacturers, but also to any and all people, firms and corporations (including pharmacists) involved in any way with the administration of vaccines to vaccine recipients in the States. And all of this is funded by the Coronavirus Aid, Relief, and Economic Security Act or, CARES Act, which was passed by Congress on March 27, 2020. Public Law 116–136, 134 Stat. 281.

When this COVID pandemic started, one of the first industries to assert legal challenges to various restrictions imposed by state governments when they attempted to "flatten the curve" was the abortion industry. In the Spring of 2020, Dr. Scott Harris, Alabama's State Health Officer, imposed restrictions on abortionists, who were quick to sue. That case was resolved by a decision of the 11th Circuit in *Robinson v. Attorney General*, 957 F.3d 1171, 1178 (11th Cir. 2020), previously noted. What the 11th Circuit held there is worth repeating a second time: "'if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is, beyond all

[20] 85 Fed.Reg. at 79194.

question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of courts to so adjudge, and thereby give effect to the Constitution.'"

An abortion involves the extraction of a human being from a woman's body, and the courts provide protection to this constitutionally recognized procedure. Vaccination involves injecting a chemical into a human's body, and one must be very certain of the chemicals that are in that injection to avoid any adverse ramifications. From a constitutional perspective the difference is striking. In the instance of abortion, the courts have made clear that the imposition of laws that interfere with the right to kill a fetus are unconstitutional. Yet here the defendants seem to be proclaiming that they may mandate a procedure based on an experimental injection. Are we to believe that the fundamental right to control our bodies is to be recognized when it comes to efforts such as preventing abortion, but this fundamental right to control our bodies does not apply to efforts such as the injection of chemicals into our bodies?

This fundamental constitutional right to bodily integrity must be considered. In the words of the *Robinson* court, this is "a plain, palpable invasion of rights secured by the fundamental law, it is the duty of courts to so adjudge, and thereby give effect to the Constitution.'"

III. Count III.

"It is axiomatic that physicians are expected to do no harm. When a physician

breaches that duty and puts his own interests above those of his patients, great harm can occur. Though the regulation of the practice of medicine is delegated to the states, when a physician misuses medical devices and threatens public health, the physician may run afoul of the Federal Food, Drug, and Cosmetic Act". *United States v. Kaplan*, 836 F.3d 1199, 1204 (9th Cir. 2016). The same applies to vaccine manufacturers.

The federal laws regulating the manufacture, sale and distribution of vaccines are predicated on the constitutional power of Congress to regulate interstate commerce (21 U.S.C. § 331). Further, the crime of "misbranding" is the subject of 21 U.S.C. § 352(j), and it provides that a drug is misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

On October 22, 2020, the FDA possessed a list of probable harms of the 3 different vaccines that would be approved within the next few months, and that list included the utmost harm: death. Probably within a month of this FDA meeting, Pfizer, Johnson and Johnson, and Moderna submitted applications to it to get their vaccines EUA approved. Once these vaccines were approved, these companies published Fact Sheets which ignored these harms and failed to even mention them.

However, there now is evidence that there have been in excess of 50,000 deaths from these vaccines just among Medicare recipients. Thus, there has been

concealment of the harms of these vaccines, which constitutes "misbranding." See *Kordel v. United States*, 335 U.S. 345 (1948).

Pfizer and Johnson & Johnson are well aware of what constitutes misbranding because they both have been charged with violations of 21 U.S.C. § 352(j), and they plead guilty to those charges. Some years after these misbranding convictions, these companies submitted EUA applications to the FDA to obtain approval for their vaccines, as did Moderna. At the time these 3 applications were submitted, the FDA clearly knew of the probable harms of these vaccines because they were the subject of the October 22, 2020, seminar at the FDA. Since these vaccine manufacturers later published Facts Sheets which failed to reveal these harms, it may be inferred that the applications for EUA approval likewise omitted this vital information. Nonetheless, the FDA approved the EUA applications, and thus participated in concealing this extremely important information about the vaccine harms, all in violation of 21 U.S.C. § 352(j).

The defendants assert as a defense here that via 21 U.S.C. U.S.C. §360bbb–3 (i), the approval of the EUAs for these vaccines is subject to their absolute discretion, which prevents review of these EUAs in this case. However, here the FDA and the defendants abused their statutory discretion, which consequently permits review here. A federal court may "invalidate agency action not only if it conflicts with an agency's own statute, but also if it conflicts with another federal law." *Nextwave Personal*

Communications, Inc. v. FCC, 254 F.3d 130, 149 (D.C. Cir. 2001), aff'd, 537 U.S. 293, 300 (2003). Here, the FDA was subject to 21 U.S.C. § 352(j), yet violated it when it approved these vaccines.

The plaintiffs will succeed in their claim asserted in Count III.

IRREPARABLE INJURY

Within the last few weeks, OSHA has promulgated what is best characterized as its own COVID vaccination program (86 Fed.Reg. 61402, Nov. 5, 2021). Pursuant to the manner by which challenges are made to OSHA regulations, a number of states and companies affected by them filed petitions for review with the Fifth Circuit. On November 12, 2021, the Fifth Circuit enjoined OSHA's implementation of those rules pending further review. See *BST Holdings, LLC v. OSHA*, Case No. 21-60845. The rationale for the holding in this case involved due process principles; but the Fifth Circuit also found that implementation of that OSHA imposed vaccine program abridged fundamental constitutional rights, the violation of which "unquestionably constitutes irreparable harm." (Page 19 of order).

It is "the alleged violation of a constitutional right that triggers a finding of irreparable harm." *Jolly v. Coughlin*, 76 F.3d 468, 473 (2d Cir. 1996). See also *Mitchell v. Cuomo*, 748 F.2d 804, 806 (2d Cir. 1984)("'When an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary.'"); *Deerfield Med. Ctr. v. City of Deerfield Beach*, 661

F.2d 328, 338 (5th Cir. Unit B. 1981)("It is well settled that the loss of First Amendment freedoms for even minimal periods of time constitutes irreparable injury justifying the grant of a preliminary injunction."); *Johnson v. Bergland*, 586 F.2d 993, 995 (4th Cir. 1978)("Violations of first amendment rights constitute per se irreparable injury."); and *Citizens for a Better Environment v. City of Park Ridge*, 567 F.2d 689, 691 (7th Cir. 1975)("temporary deprivation of First Amendment rights constitutes irreparable harm in the context of a suit for an injunction.").

Here, its is perfectly clear that the fundamental constitutional right at issue is that of the plaintiffs' "bodily integrity". "[T]he 'liberty' protected by the Due Process Clause [of the Fourteenth Amendment] includes the right[] . . . to bodily integrity". *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). "Involuntarily subjecting nonconsenting individuals to foreign substances with no known therapeutic value — often under false pretenses and with deceptive practices hiding the nature of the interference — is a classic example of invading the core of the bodily integrity protection." *Guertin v. Michigan*, 912 F.3d 907, 921 (6th Cir. 2019). Forcing the plaintiffs to take a shot against their will obviously violates this fundamental constitutional right, and the plaintiffs have demonstrated irreparable harm.

INJURY TO THE UNITED STATES

The third factor needed to be shown when a party seeks an injunction relates to the harm, if any, that might be suffered by the party to be enjoined. But when an

injunction against a government is sought, this and the fourth factor are merged. See *Nken v. Holder*, 556 U.S. 418, 420 (2009) ("[t]he third and fourth factors, harm to the opposing party and the public interest, merge when the Government is the opposing party"); and *Gonzalez v. Governor of Georgia*, 978 F.3d 1266, 1271 (11th Cir. 2020).

THE PUBLIC INTEREST

As discussed *supra*, the vaccines currently being offered to the American public are harmful. But now on the eve of these dangerous shots becoming mandatory, the plaintiffs object, seeking to protect their fundamental constitutional right to bodily integrity. But to show entitlement to an injunction, they must persuade this court that it is in the public interest for this vaccine program to be shut down. The plaintiffs have clearly shown facts demonstrating that it is indeed in the public interest to do so.

Two of the vaccine manufacturers, Pfizer and Johnson and Johnson, have previously been prosecuted for the federal offense of misbranding. They have also paid what has been reported as the largest fines in the history of the United States (perhaps the world). In the aggregate, they have paid penalties in the billions since the year 2000. It is probably fair to state that it would be extremely difficult to find any other American company that has paid more.

While these companies are extremely profitable, they certainly will be more profitable as the direct result of this COVID pandemic. They have contracts with

countries around the world, as well as the United States, to produce these vaccines at a price for each shot between $18 and $19.[21] When you multiply this price per spot with the millions of shots they will produce, it is clear that the results of this pandemic will be billions in the bank accounts of the vaccine manufacturers.

But, there is also the troubling matter of violations of federal law, specifically that of misbranding. There is evidence indicating that as many as 50,000 Medicare recipients who took the shot have died as a result. This leads to the conclusion that it is very probable that the vaccines have always been this dangerous, especially when the manufacturers were developing and testing them. Why is this fact concealed?

This large number of adverse consequences of the vaccines, clearly known by the manufacturers, must certainly have been known by the defendants, the FDA, and other officers, employees and agents of the United States. Knowledge of these adverse consequences clearly demonstrates that the defendants, to one degree or another, looked the other way and ignored the violations of the law by the vaccine manufacturers.

"There is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). "[T]he

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[21] See: https://www.nytimes.com/2020/12/18/upshot/coronavirus-vaccines-prices-europe-united-states.html (last visited on Nov. 19, 2021)

public interest lies in a correct application of the federal constitutional and statutory provisions upon which the claimants have brought this claim". *Coalition to Defend Affirmative Action v. Granholm*, 473 F.3d 237, 252 (6th Cir. 2006).[22]

NOTE ABOUT PLAINTIFFS' STANDING

All counts in the amended complaint are predicated on 5 U.S.C. §702, which has its own unique subset of standing rules based on various decisional authorities. In *Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967), the Supreme Court identified the parties who have standing to institute suits against federal agencies to challenge their actions:

> "Where the legal issue presented is fit for judicial resolution, and where a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance, access to the courts under the Administrative Procedure Act and the Declaratory Judgment Act must be permitted, absent a statutory bar or some other unusual circumstance, neither of which appears here."

See also *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986)("Once the

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[22] See also *ACLU v. Alvarez*, 679 F.3d 583, 590 (7th Cir. 2012) ("[T]he public interest is not harmed by preliminarily enjoining the enforcement of a statute that is probably unconstitutional."); *Pursuing Am.'s Greatness v. F.E.C.*, 831 F.3d 500, 511 (D.C. Cir. 2016)("[E]nforcement of an unconstitutional law is always contrary to the public interest."); *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994) ("[I]t is always in the public interest to prevent the violation of a party's constitutional rights."); and *Planned Parenthood Ass'n v. City of Cincinnati*, 822 F.2d 1390, 1400 (6th Cir. 1987)("Finally, the last factor — whether the public interest is served by the injunction — is also met, since the public is certainly interested in the prevention of enforcement of ordinances which may be unconstitutional.").

agency publicly articulates an unequivocal position * * * and expects regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review."); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000)("If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes 'binding.'"); and *Union Pac. R.R. Co. v. Surface Transp. Bd.*, 358 F.3d 31, 35 (D.C. Cir. 2004)("For an order to be final, two conditions must be satisfied: the order must not be 'tentative' or 'interlocutory' in nature, and it must be an action in which 'rights or obligations have been determined' or from which 'legal consequences will flow.'"

In this case, the employers of the plaintiffs clearly believe that the challenged executive orders of President Biden are binding and mandatory, and that the EUAs are valid enough to warrant the imposition of vaccines on all employees. While it is is not the defendants who are actually instructing the plaintiffs to get the shot, the defendants actions and legal directives are the foundation of the employers' demands, and the defendants are not absolved of any responsibility. "[M]ere indirectness of

causation is no barrier to standing, and thus, an injury worked on one party by another through a third party intermediary may suffice." *National Wildlife Federation v. Hodel*, 839 F.2d 694, 705 (D.C. Cir. 1988).

RELIEF SOUGHT AND CONCLUSION

The plaintiffs assert that they have very valid claims set forth in Counts VI, II and III of their amended complaint and they have clearly shown that they are entitled to a preliminary injunction herein. They move the court for a preliminary injunction enjoining enforcement of EOs 14042 and 14043, and every rule, directive, and guidance based thereon.

Respectfully submitted this the 19th day of November, 2021.

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CERTIFICATE OF SERVICE

I hereby certify that on this date, November 19, 2021, I electronically transmitted this pleading to the Clerk of the Court using the CM/ECF system for filing, which will send notification of such filing to all counsel for the parties in this case.

/s/ *Lowell H. Becraft, Jr.*
Lowell H. Becraft, Jr.

Exhibit 1:

Executive Order 14042

Presidential Documents

Executive Order 14042 of September 9, 2021

Ensuring Adequate COVID Safety Protocols for Federal Contractors

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Property and Administrative Services Act, 40 U.S.C. 101 *et seq.,* and section 301 of title 3, United States Code, and in order to promote economy and efficiency in procurement by contracting with sources that provide adequate COVID–19 safeguards for their workforce, it is hereby ordered as follows:

Section 1. *Policy.* This order promotes economy and efficiency in Federal procurement by ensuring that the parties that contract with the Federal Government provide adequate COVID–19 safeguards to their workers performing on or in connection with a Federal Government contract or contract-like instrument as described in section 5(a) of this order. These safeguards will decrease the spread of COVID–19, which will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites where they are performing work for the Federal Government. Accordingly, ensuring that Federal contractors and subcontractors are adequately protected from COVID–19 will bolster economy and efficiency in Federal procurement.

Sec. 2. *Providing for Adequate COVID–19 Safety Protocols for Federal Contractors and Subcontractors.* (a) Executive departments and agencies, including independent establishments subject to the Federal Property and Administrative Services Act, 40 U.S.C. 102(4)(A) (agencies), shall, to the extent permitted by law, ensure that contracts and contract-like instruments (as described in section 5(a) of this order) include a clause that the contractor and any subcontractors (at any tier) shall incorporate into lower-tier subcontracts. This clause shall specify that the contractor or subcontractor shall, for the duration of the contract, comply with all guidance for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force (Task Force Guidance or Guidance), provided that the Director of the Office of Management and Budget (Director) approves the Task Force Guidance and determines that the Guidance, if adhered to by contractors or subcontractors, will promote economy and efficiency in Federal contracting. This clause shall apply to any workplace locations (as specified by the Task Force Guidance) in which an individual is working on or in connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order).

(b) By September 24, 2021, the Safer Federal Workforce Task Force (Task Force) shall, as part of its issuance of Task Force Guidance, provide definitions of relevant terms for contractors and subcontractors, explanations of protocols required of contractors and subcontractors to comply with workplace safety guidance, and any exceptions to Task Force Guidance that apply to contractor and subcontractor workplace locations and individuals in those locations working on or in connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order).

(c) Prior to the Task Force publishing new Guidance related to COVID–19 for contractor or subcontractor workplace locations, including the Guidance developed pursuant to subsection (b) of this section, the Director shall, as an exercise of the delegation of my authority under the Federal Property

and Administrative Services Act, *see* 3 U.S.C. 301, determine whether such Guidance will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors. Upon an affirmative determination by the Director, the Director's approval of the Guidance, and subsequent issuance of such Guidance by the Task Force, contractors and subcontractors working on or in connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order), shall adhere to the requirements of the newly published Guidance, in accordance with the clause described in subsection (a) of this section. The Director shall publish such determination in the *Federal Register*.

(d) Nothing in this order shall excuse noncompliance with any applicable State law or municipal ordinance establishing more protective safety protocols than those established under this order or with any more protective Federal law, regulation, or agency instructions for contractor or subcontractor employees working at a Federal building or a federally controlled workplace.

(e) For purposes of this order, the term ''contract or contract-like instrument'' shall have the meaning set forth in the Department of Labor's proposed rule, ''Increasing the Minimum Wage for Federal Contractors,'' 86 FR 38816, 38887 (July 22, 2021). If the Department of Labor issues a final rule relating to that proposed rule, that term shall have the meaning set forth in that final rule.

Sec. 3. *Regulations and Implementation.* (a) The Federal Acquisition Regulatory Council, to the extent permitted by law, shall amend the Federal Acquisition Regulation to provide for inclusion in Federal procurement solicitations and contracts subject to this order the clause described in section 2(a) of this order, and shall, by October 8, 2021, take initial steps to implement appropriate policy direction to acquisition offices for use of the clause by recommending that agencies exercise their authority under subpart 1.4 of the Federal Acquisition Regulation.

(b) By October 8, 2021, agencies shall take steps, to the extent permitted by law, to exercise any applicable authority to ensure that contracts and contract-like instruments as described in section 5(a) of this order that are not subject to the Federal Acquisition Regulation and that are entered into on or after October 15, 2021, consistent with the effective date of such agency action, include the clause described in section 2(a) of this order.

Sec. 4. *Severability.* If any provision of this order, or the application of any provision of this order to any person or circumstance, is held to be invalid, the remainder of this order and its application to any other person or circumstance shall not be affected thereby.

Sec. 5. *Applicability.* (a) This order shall apply to any new contract; new contract-like instrument; new solicitation for a contract or contract-like instrument; extension or renewal of an existing contract or contract-like instrument; and exercise of an option on an existing contract or contract-like instrument, if:

(i) it is a procurement contract or contract-like instrument for services, construction, or a leasehold interest in real property;

(ii) it is a contract or contract-like instrument for services covered by the Service Contract Act, 41 U.S.C. 6701 *et seq.;*

(iii) it is a contract or contract-like instrument for concessions, including any concessions contract excluded by Department of Labor regulations at 29 CFR 4.133(b); or

(iv) it is a contract or contract-like instrument entered into with the Federal Government in connection with Federal property or lands and related to offering services for Federal employees, their dependents, or the general public;

(b) This order shall not apply to:

(i) grants;

(ii) contracts, contract-like instruments, or agreements with Indian Tribes under the Indian Self-Determination and Education Assistance Act (Public Law 93–638), as amended;

(iii) contracts or subcontracts whose value is equal to or less than the simplified acquisition threshold, as that term is defined in section 2.101 of the Federal Acquisition Regulation;

(iv) employees who perform work outside the United States or its outlying areas, as those terms are defined in section 2.101 of the Federal Acquisition Regulation; or

(v) subcontracts solely for the provision of products.

Sec. 6. *Effective Date.* (a) Except as provided in subsection (b) of this section, this order is effective immediately and shall apply to new contracts; new contract-like instruments; new solicitations for contracts or contract-like instruments; extensions or renewals of existing contracts or contract-like instruments; and exercises of options on existing contracts or contract-like instruments, as described in section 5(a) of this order, where the relevant contract or contract-like instrument will be entered into, the relevant contract or contract-like instrument will be extended or renewed, or the relevant option will be exercised, on or after:

(i) October 15, 2021, consistent with the effective date for the action taken by the Federal Acquisition Regulatory Council pursuant to section 3(a) of this order; or

(ii) for contracts and contract-like instruments that are not subject to the Federal Acquisition Regulation and where an agency action is taken pursuant to section 3(b) of this order, October 15, 2021, consistent with the effective date for such action.

(b) As an exception to subsection (a) of this section, where agencies have issued a solicitation before the effective date for the relevant action taken pursuant to section 3 of this order and entered into a new contract or contract-like instrument resulting from such solicitation within 30 days of such effective date, such agencies are strongly encouraged to ensure that the safety protocols specified in section 2 of this order are applied in the new contract or contract-like instrument. But if that contract or contract-like instrument term is subsequently extended or renewed, or an option is subsequently exercised under that contract or contract-like instrument, the safety protocols specified in section 2 of this order shall apply to that extension, renewal, or option.

(c) For all existing contracts and contract-like instruments, solicitations issued between the date of this order and the effective dates set forth in this section, and contracts and contract-like instruments entered into between the date of this order and the effective dates set forth in this section, agencies are strongly encouraged, to the extent permitted by law, to ensure that the safety protocols required under those contracts and contract-like instruments are consistent with the requirements specified in section 2 of this order.

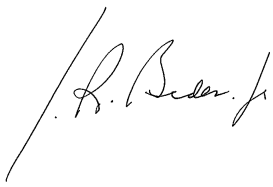
Sec. 7. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
September 9, 2021.

[FR Doc. 2021–19924
Filed 9–13–21; 8:45 am]
Billing code 3295–F1–P

Exhibit 2:

Executive Order 14043

Presidential Documents

Executive Order 14043 of September 9, 2021

Requiring Coronavirus Disease 2019 Vaccination for Federal Employees

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 3301, 3302, and 7301 of title 5, United States Code, it is hereby ordered as follows:

Section 1. *Policy.* It is the policy of my Administration to halt the spread of coronavirus disease 2019 (COVID–19), including the B.1.617.2 (Delta) variant, by relying on the best available data and science-based public health measures. The Delta variant, currently the predominant variant of the virus in the United States, is highly contagious and has led to a rapid rise in cases and hospitalizations. The nationwide public health emergency, first declared by the Secretary of Health and Human Services on January 31, 2020, remains in effect, as does the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) declared pursuant to the National Emergencies Act in Proclamation 9994 of March 13, 2020 (Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak). The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services has determined that the best way to slow the spread of COVID–19 and to prevent infection by the Delta variant or other variants is to be vaccinated.

COVID–19 vaccines are widely available in the United States. They protect people from getting infected and severely ill, and they significantly reduce the likelihood of hospitalization and death. As of the date of this order, one of the COVID–19 vaccines, the Pfizer-BioNTech COVID–19 Vaccine, also known as Comirnaty, has received approval from the Food and Drug Administration (FDA), and two others, the Moderna COVID–19 Vaccine and the Janssen COVID–19 Vaccine, have been authorized by the FDA for emergency use. The FDA has determined that all three vaccines meet its rigorous standards for safety, effectiveness, and manufacturing quality.

The health and safety of the Federal workforce, and the health and safety of members of the public with whom they interact, are foundational to the efficiency of the civil service. I have determined that ensuring the health and safety of the Federal workforce and the efficiency of the civil service requires immediate action to protect the Federal workforce and individuals interacting with the Federal workforce. It is essential that Federal employees take all available steps to protect themselves and avoid spreading COVID–19 to their co-workers and members of the public. The CDC has found that the best way to do so is to be vaccinated.

The Safer Federal Workforce Task Force (Task Force), established by Executive Order 13991 of January 20, 2021 (Protecting the Federal Workforce and Requiring Mask-Wearing), has issued important guidance to protect the Federal workforce and individuals interacting with the Federal workforce. Agencies have also taken important actions, including in some cases requiring COVID–19 vaccination for members of their workforce.

Accordingly, building on these actions, and in light of the public health guidance regarding the most effective and necessary defenses against COVID–19, I have determined that to promote the health and safety of the Federal workforce and the efficiency of the civil service, it is necessary to require COVID–19 vaccination for all Federal employees, subject to such exceptions as required by law.

Sec. 2. *Mandatory Coronavirus Disease 2019 Vaccination for Federal Employees.* Each agency shall implement, to the extent consistent with applicable law, a program to require COVID–19 vaccination for all of its Federal employees, with exceptions only as required by law. The Task Force shall issue guidance within 7 days of the date of this order on agency implementation of this requirement for all agencies covered by this order.

Sec. 3. *Definitions.* For the purposes of this order:

(a) The term ''agency'' means an Executive agency as defined in 5 U.S.C. 105 (excluding the Government Accountability Office).

(b) The term ''employee'' means an employee as defined in 5 U.S.C. 2105 (including an employee paid from nonappropriated funds as referenced in 5 U.S.C. 2105(c)).

Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

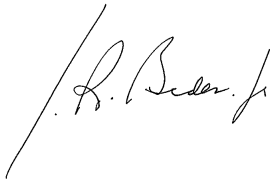
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.



THE WHITE HOUSE,
September 9, 2021.

[FR Doc. 2021–19927
Filed 9–13–21; 8:45 am]
Billing code 3295–F1–P

Exhibit 3:

Declaration of Joseph Makowski

Declaration of Joseph Makowski

State of Alabama)
County of Madison)

I, Joseph Makowski, declare under the penalties of perjury as follows:

I am Joseph Makowski, a plaintiff in this case, and I have personal knowledge of the facts stated herein.

I live in Madison City, Madison County, Alabama and work in Huntsville, Madison County, Alabama. I work for a company named Phoenix Industries located at 2939 Johnson Road. Phoenix is a great company that provides employment opportunities and support for individuals with disabilities, like me. I perform my custodial services work for the Government Services Division of Phoenix at the Von Braun Center located on Redstone Arsenal in Huntsville.

Dr. David Calderwood lives and works in Huntsville. He is one of the original members of plaintiff America's Frontline Doctors, and he is a plaintiff in this case. Because of my disability and medical history, I became one of his patients for the purpose of determining whether I should get a COVID vaccine. After consultation with him and after he reviewed my medical history, he determined that I should not receive any such vaccination because of the possible harm it likely could cause me.

My employer, in published information, informed me that I must receive a

COVID vaccine by December 8, 2021, if I am not granted a medical and/or religious exemption. The dates are currently fluid and dependent upon the guidance from the government customer. This requirement is imposed because of Executive Order 14042 issued by President Biden on September 9, 2021.

I, Joseph Makowski, declare under penalty of perjury, pursuant to 28 U.S.C. §1746, that the foregoing facts are true and correct.

Respectfully submitted this the 18th day of November, 2021.

Joseph Makowski

Joseph Makowski

FILED
2021 Nov-19 PM 11:28
U.S. DISTRICT COURT
N.D. OF ALABAMA

Exhibit 4:

Declaration of Mike Nelson

Declaration of Michael Nelson

State of Alabama)
County of Madison)

I, Michael Nelson, declare under the penalties of perjury as follows:

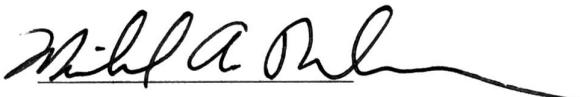
I am Michael Nelson, a plaintiff in this case, and I have personal knowledge of the facts stated herein.

I live and work in Huntsville, Madison County, Alabama and I work at Marshall Space Flight Center as Aerospace Engineer Team Lead in the Propulsion Department. I work with plaintiff Joseph Leahy who is also employed with NASA at MSFC in the Propulsion Department.

Pursuant to Executive Order 14043 issued by President Biden on September 9, 2021, I and Joseph Leahy must be fully vaccinated (defined by having had the at least the Johnson and Johnson vaccine for two weeks) by November 22, 2021. As of this time we have requested a religious exemption and approval of is pending.

I, Michael Nelson, declare under penalty of perjury, pursuant to 28 U.S.C. §1746, that the foregoing facts are true and correct.

Respectfully submitted this the 19th day of November, 2021.



Michael Nelson

Exhibit 5:

Exhibit Shown at FDA Meeting Oct. 22, 2020

FDA Safety Surveillance of COVID-19 Vaccines :

DRAFT Working list of possible adverse event outcomes

Subject to change

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

Ex. 6:

Data from Medicare System

Medicare Deaths - 0-14 Days Post-Vaccination

	# of Days Died after COVID Vaccine	% of Beneficiaries who Died	% of Beneficiaries who died (within 14 days)	Cumulative Frequency	Cumulative Percent
51,100 beneficiaries died within 14 days after the COVID-19 vaccine	0	935	1.83	935	1.83
	1	2,196	4.30	3,131	6.13
	2	2,715	5.31	5,948	11.44
	3	2,918	5.71	8,764	17.15
	4	3,104	6.07	11,968	23.23
	5	3,318	6.49	15,186	29.72
	6	3,402	6.66	18,588	36.38
	7	3,662	7.17	22,250	43.54
	8	3,870	7.23	25,943	50.77
	9	3,916	7.57	29,813	58.34
	10	3,870	7.66	33,729	66.01
	11	4,209	8.24	37,938	74.24
	12	4,314	8.44	42,252	82.68
	13	4,377	8.57	46,629	91.25
	14	4,471	8.75	51,100	100.00

Adverse Events 0-14 Days After Vaccine: Alabama

	Adverse Event	# of Beneficiaries who devloped symptom within 14 days of vaccination	% of Beneficiaries who developed symptom post-vaccination and then died at any point during 2021	% of Beneficiaries who developed this symptom post-vaccination and then died at any point during 2021
Alabama Adverse Events Reported	Acute Kidney Failure	831	237	28.52
	Anaphylaxis	19	1	5.56
	Cardiac Arrest	160	131	81.88
	Cerebovascular Event	382	63	16.49
	Covid-19	1895	256	13.58
	Emboism	472	90	19.07
	Encephalitis, Myeutis, Enchephalomyelitis, Meningitis or Encepholatpathy	24	5	20.83
	Guillain-Barre Syndrome	4	1	25.00
	Intravascular Coagulation	12	9	75.00
	Myo-Endo-Peri-Carditis	95	16	16.84
	Myocardial Infraction	655	117	17.86
	Narcolepsy / Cataplexy	13	1	7.69
	Plegia, Palsy or Paralysis	335	54	16.12
	Pneumonia	1069	295	27.62
	Respiratory Distress	256	113	44.14
	Respiratory Failure	745	290	37.58
	Respiratory Infection	803	68	8.47
	Respiratory Synctial Virus	3		
	Seizure or Convulsion	241	34	14.11
	Stroke or Cerebral Infraction	569	87	15.29
	Thrombocytopenia	640	89	13.91
	Thrombosis	418	71	16.99