No. 21-1511

IN THE

Supreme Court of the United States

JOY GARNER, individually and on behalf of THE CONTROL GROUP, et al.,
Petitioners,

v.

JOSEPH R. BIDEN, JR., in his official capacity as PRESIDENT OF THE UNITED STATES OF AMERICA,
Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Ninth Circuit

MOTION FOR LEAVE TO FILE *AMICUS* BRIEF
and
BRIEF OF *AMICUS CURIAE*
INSTITUTE FOR HEALTH RESEARCH
IN SUPPORT OF PETITIONERS

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APPENDIX

MOTION FOR LEAVE TO FILE BRIEF OF *AMICUS CURIAE*

Institute for Health Research ("*Amicus*") moves the Court for leave to file an *amicus* brief in support of Petitioners' request for a writ of certiorari to the Ninth Circuit. As grounds therefor, *Amicus* shows as follows:

In the district court as well as court of appeals, Respondent Joseph Biden, President of the United States, was represented by Philip A. Scarborough, AUSA in the Office of the United States Attorney for the Eastern District of California. On June 22, 2022, undersigned counsel contacted Mr. Scarborough by email requesting his permission to file herein an *amicus* brief on behalf of Petitioners Joy Garner et al. Mr. Scarborough replied that he did not represent Respondent and that Respondent was represented by the Solicitor General.

On June 22, 2022, counsel sent emails to the Solicitor General, and attached a letter requesting written permission to file the instant brief. No response has been received.

This *amicus* motion is unopposed by Petitioners Garner et al, who have supplied written permission to file this *amicus* brief.[1] The Solicitor General's Office was afforded 10 days' advance notice and has neither objected nor responded.

In support of this motion, *Amicus* asserts that the district court's dismissal of the case failed to recognize the President's direct responsibility for the national vaccine program that is crippling the nation, and the President's abdication of his responsibility to carry out the laws concerning misbranding of drugs in commerce. *Amicus* requests that this motion to file

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[1] See *amicus* brief for movant's interest, pursuant to Rule 37.5.

the attached *amicus* brief be granted.

No counsel for a party authored this *amicus* submission, and no person other than *Amicus*, its members, or its counsel made a monetary contribution to fund this motion or brief.

Respectfully submitted,

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INTEREST OF *AMICUS CURIAE*[1]

The Institute for Health Research is an exempt nongovernmental organization located in the States of New Jersey and Texas, and its Officers and Trustees are Ralph Fucetola, J.D., and Rima E. Laibow, M.D. This Institute advocates for natural solutions to human health problems, as opposed to the use of vaccines, pharmaceutical drugs and other unnatural interventions. The Institute seeks to help the public to prevent disease and strengthen immunity and health through providing information covering studies, protocols, and information on dietary supplements and other natural products.

Compelled vaccination through governmental force represents the exact scenario that the Institute for Health Research seeks to discourage and prevent, in the interest of the bodily integrity of all individuals. Further, the existence of a "control group" of unvaccinated persons is a national treasure, and indispensible to demonstrating the efficacy of natural solutions, in contrast to vaccines, in preventing and mitigating disease.

Finally, as all people everywhere, the Institute has a keen interest in preventing the use of misbranded drugs which could cause genocide.

This *amicus* brief is submitted in support of the Petitioners Joy Garner, individually and on behalf of The Control Group *et al.*

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[1] It is hereby certified that the parties received notice of the intention to file this brief at least 10 days prior to the filing of it; that Petitioners have extended written permission to file this brief; that no counsel for a party or a party to this case authored this brief in whole or in part; and that no person other than the *amicus curiae*, and its friends, made a monetary contribution to its preparation or submission.

SUMMARY OF ARGUMENT

To test both the safety and efficacy of drugs in development requires the existence of a "control" group and an "experimental" group. The former is administered a placebo while the latter is administered the drug being studied. When the test is completed, the difference in the health of participants in both groups is compared to determine the safety and efficacy of the drug.

Petitioners, acting as a control group, filed for declaratory and preliminary injunctive relief in district court, in order to uphold informed refusal in the face of the intention of the President of the United States to mandate administration of vaccines which allegedly prevent individuals from greatly suffering from COVID-19. Finding a lack of standing, the district court dismissed Petitioners' complaint with prejudice. *If* Petitioners appear to have "jumped the gun," however, they were certainly prescient: the President has instituted the very program they sought declaratory judgment against with his pronouncement on September 9, 2021 of a nationwide vaccine mandate, directed at millions of employees working for numerous employers, using "gene therapies" that are increasingly being revealed as unsafe and ineffective.[2]

These vaccine mandates demonstrate that the President has at least ignored his duties as mandated by the United States Constitution. The "Take Care Clause" of the Constitution provides in

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[2] "This nation * * * has no right to expect that it will always have wise and humane rulers, sincerely attached to the principles of the Constitution. Wicked men, ambitious of power, with hatred of liberty and contempt of law, may fill the place once occupied by Washington and Lincoln." *Ex parte Milligan*, 71 U.S. 2, 125 (1866).

Art. 2, §3 that "he shall take Care that the Laws be faithfully executed," and to accomplish this obligation, Art. 2, §2 authorizes him to "require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices." If federal laws compel officials in the executive branch to perform certain acts, "the obligations imposed on the President to see the laws faithfully executed" denies the "power to forbid their execution." *Kendall v. United States ex rel. Stokes*, 37 U.S. 524, 525 (1838). After all, the President "must abide by statutory mandates and prohibitions." *In re Aiken County*, 725 F.3d 255, 259 (D.C. Cir. 2013).

One federal law that the President must enforce makes the interstate shipment of misbranded drugs a crime. See 21 U.S.C. §352. In October 2020, before the current vaccines for COVID-19 "treatments" were approved, the President's Executive Officers, particularly those in the Department of Health and Human Services (HHS) as well as the Food and Drug Administration (FDA), were aware of predictable adverse consequences these vaccines would cause. Nonetheless, the President's Officers approved these vaccines in late 2020 and early 2021, and they have been distributed nationwide ever since. Now, abundant evidence exists demonstrating that these vaccines are indeed misbranded, causing harm to many Americans. Rather than actually being vaccines, they are really harmful "gene therapies," a matter obviously known to the President's Officers.

The theory and objective of the Garner complaint was to prevent the Garner Plaintiffs from being compelled to take these vaccines to which they objected, and the President had the constitutional authority to protect them as well as a duty to do so which could be enforced in a federal court. The crime

of "misbranding" is the subject of 21 U.S.C. § 352(j), and it provides that a drug or vaccine 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." The President could have inquired into this matter by soliciting "the Opinion, in writing, of the principal Officer[s]" of the HHS and FDA (as well as CDC), and learned that these vaccines were in fact "misbranded." Indeed, the Garner complaint made this point very clearly and obviously. Upon learning these facts, the President had several very reasonable courses of action: he could have ordered that the Plaintiffs could not be compelled to take the vaccines, or he could have mandated that every potential vaccine recipient be informed that taking such vaccine was "voluntary," which incidentally is required by 21 U.S.C. §360bbb-3(e).

But more bluntly, he should take care to entirely *stop* administration of these vaccines because they are misbranded. The President is our country's chief law enforcement officer, yet his Officers, having information that the vaccines are misbranded, obviously refuse to pursue the matter. Certainly, the President can direct his U.S. Attorneys to institute criminal proceedings against the guilty parties as well as prevent distribution and administration of the suspect vaccines. The President has failed to take any of the actions noted above, and the district court could have ordered him to do so, the obvious result of which would have granted the relief the Plaintiffs sought.

ARGUMENT

I.
The vaccine manufacturers

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

When developing vaccines, Pfizer has engaged in harmful conduct. In 1996 in Nigeria, its vaccine experiments resulted in death and other severe injuries to a number of Nigerian children. 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.[3,4]

In 2002, Pharmacia & Upjohn Company, a Pfizer subsidiary, developed a drug named Bextra, and started vigorously promoting its sale. The start of this sales program was described as follows in the sentencing memorandum of the Assistant U.S. Attorney 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

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[3] Internet links referenced in footnotes herein were last visited on July 5, 2022.

[4] *See* https://www.law.com/almID/1202482854504/.

> 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 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.[55]

Condensing this sordid story, Pharmacia sales representatives promoted Bextra using false and misleading claims, eventually leading to civil actions 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 a Department of Justice press release summarized the 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

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[5] [sic] *See* http://s3.amazonaws.com/fcmd/documents/documents/000/001/835/original/pfizer-bextra-settlement_sentence.pdf?1423021741

> 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.[6] [emphasis added]

It is reported that since 2000, Pfizer has paid $10,193,896,333 in penalties.[7]

Johnson & Johnson (J&J)/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."[8] 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

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[6] *See* https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history

[7] *See* https://violationtracker.goodjobsfirst.org/prog.php?parent=pfizer&sort=asc

[8] *See* https://www.justice.gov/opa/pr/two-johnson-johnson-subsidiaries-pay-over-81-million-resolve-allegations-label-promotion

drugs."[9] 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."[10] More recently, to address its role in assisting the opioid crisis that has recently plagued a number of States, the New York Attorney General announced a $230,000,000 settlement with the company.[11] The company has paid a total of $14,760,947,763 in penalties since 2000.[12]

Moderna, Inc., was formed in 2010 and has since been primarily devoted to research and development of vaccines.[13] The first product it has ***ever*** distributed to the American public is its experimental COVID-19 vaccine, which is available under its "Emergency Use Authorization" (EUA) under 21 U.S.C. §360bbb-3.[14]

II.
Development of the EUA COVID vaccines

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

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[9] See https://www.doj.state.or.us/media-home/news-media-releases/oregon-attorney-general-and-36-others-reach-181-million-ris perdal-settlement/

[10] *See* https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations

[11] See https://ag.ny.gov/press-release/2021/attorney-general-james-reaches-230-million-settlement-treatment-and-prevention

[12] See https://violationtracker.goodjobsfirst.org/prog.php?parent=johnson-and-johnson

[13] *See* https://en.wikipedia.org/wiki/Moderna

[14] Moderna's "Spikevax" and Pfizer's "Comirnaty" have been approved, but are not on the market, nor available to the public. Only the EUA versions of these injections are available.

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 (FD&C Act) by substantially rewriting 21 U.S.C. §360bbb–3 into its present form (118 Stat. at 853). Pursuant to this section, when the HHS Secretary determines 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.

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."[15] 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 issued the "Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Persons who Pose a Risk of Transmitting 2019 Novel Coronavirus"[16] on January 31, 2020, interdicting travel from China into the United States. When the perceived threat posed by COVID-19 appeared to be increasing, President Trump issued the "Proclamation on Declaring a

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[15] *See* WHO Timeline of COVID events: https://www.who.int/news/item/29-06-2020-covidtimeline

[16] Proclamation 9984, 85 Fed. Reg. 6709 (February 5, 2020).

National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak" on March 13, 2020.[17]

On February 4, 2020, the HHS Secretary determined, pursuant to section 564 of the FD&C Act, that:

> [T]here 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 research at "warp speed" on vaccines to treat COVID-19, and these efforts reached fruition by early December 2020.

On December 3, 2020, the HHS Secretary granted immunity for "covered countermeasures" to vaccine manufacturers ("covered persons") that he might thereafter authorize to produce and distribute vaccines.[18] On December 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine was granted EUA.[19] The Secretary found that:

> [I]t 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

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[17] Proclamation 9994, 85 Fed.Reg. 15338 (March 18, 2020).
[18] 85 Fed.Reg. 79190 (Dec. 9, 2020).
[19] 86 Fed.Reg. 5200 (Jan. 19, 2021).

> 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 older.

86 Fed.Reg. at 5203.

But the EUA grant imposed various requirements on Pfizer, which included providing critical information about adverse reactions to the injections to the Vaccine Adverse Events Reporting System (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.

86 Fed.Reg. at 5207.

A few days after the grant of EUA for the Pfizer vaccine, Moderna, Inc., was granted an EUA for its vaccine, Moderna COVID-19 Vaccine, on December 18, 2020.[20] The Secretary made the essential findings

[20] 86 Fed.Reg. 5211, Jan. 19, 2021.

that "it was reasonable to believe the [vaccine] may be effective" and that the "potential benefits of Moderna COVID-19 Vaccine ... outweigh its known and potential risks," 86 Fed.Reg. at 5212. Further, a duty was also imposed on Moderna to make reports to VAERS similar to those for Pfizer. *Id.*, at 5216.

On February 27, 2021, Janssen Biotech, Inc., was granted an EUA for its vaccine, Janssen COVID-19 Vaccine.[21] Again, the FDA made the essential findings that "it was reasonable to believe the [vaccine] may be effective" and that the "potential benefits of the Janssen COVID-19 Vaccine ... outweigh its known and potential risks." *Id.*, at 28620. Finally, a duty was also imposed on Janssen Biotech to make reports to VAERS similar to those for Pfizer. *Id.*, at 28624.

Pursuant to their reporting and disclosure requirements mandated in the above noted EUAs, these vaccine manufacturers have been publishing fact sheets setting forth the benefits and risks of their vaccines. Fact sheets published by Pfizer[22] dated May 10, 2021,[23] by Janssen Biotech dated April 23, 2021,[24] and by Moderna dated March 26, 2021[25] all provide the mandated statements of these

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[21] 86 Fed.Reg. 28619, May 27, 2021.

[22] *See Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009); *Showers v. Pfizer, Inc. (In re Pfizer Inc. Sec. Litig.)*, 819 F.3d 642 (2d Cir. 2016), which discuss Pfizer's past misrepresentations in fact sheets.

[23] *See* https://cdn5-ss13.sharpschool.com/UserFiles/Servers/Server_29596892/File/News/Pfizer%20Covid%20Vaccine%20Fact%20Sheet%20Patients%20May%2010%202021%20English%20(4).pdf

[24] *See* https://omh.ny.gov/omhweb/o-lov-covid19-vaccine/janssen-cv-19-fact-sheet.pdf

[25] *See* https://chapa-de.org/wp-content/uploads/2021/04/COVID-19-Vaccine-Moderna-Englishv2.pdf

"benefits and risks," which included statements regarding the risk of severe allergic reaction:

> WHAT ARE THE RISKS OF THE [Moderna, Pfizer, or Janssen] COVID-19 VACCINE?
>
> There is a remote chance that the ... 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 ... 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

Pfizer's fact sheet reported further side effects as follows:

> 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.

Janssen's fact sheet reported further side effects as follows:

> 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.
>
> ...
>
> 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.

Moderna's fact sheet reported further side effects as follows:

> 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.

It must be noted that a number of serious health problems or even ***death*** were not mentioned in these facts sheets, which federal law mandates be made available to vaccine recipients. See 21 U.S.C. §360bbb-3(e).

III.
COVID vaccines are criminally misbranded drugs

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). 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." *See Kordel v. United States*, 335 U.S. 345 (1948).

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 the following "risks" of the contemplated vaccines were indicated:

> 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 [26] [emphasis added]

Clearly, the above noted risks involved in the vaccination of large numbers of people were contemplated and expected months before the three vaccine manufacturers published their fact sheets.

The HHS Director of the National Vaccine Program is mandated by 42 U.S.C. § 300aa-2(a)(7)

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[26] See p. 17 of https://www.fda.gov/media/143557 /download

and § 300aa-3 to set up a plan to "monitor[] ... adverse effects of vaccines and immunization activities." That responsibility has been carried out through the Vaccine Adverse Events Reporting System (VAERS), co-managed by the CDC and the FDA since 1990.

In 2011, Harvard Pilgrim Health Care, Inc. conducted a study of the VAERS reporting system for the Agency for Healthcare Research and Quality (HHS), and concluded that "fewer than 1% of vaccine adverse events are reported."[27]

Despite the severe limitation of a low reporting rate for adverse events, VAERS still supplies early warning of crippling side effects and deaths from COVID-19 vaccines, especially when compared to the relative safety of all other vaccines reported upon heretofore. For example, 86 percent of *all* deaths ever reported in proximity to vaccination for over 32 years in the State and U.S. Territories alone have followed injection with the three COVID-19 EUA vaccines (16,106 death events out of a total of 18,763 ever reported).[28] It can reasonably be stated that nearly all deaths ever reported occurred since the COVID vaccines were rolled out 18 months ago, and this only represents reports processed and released to the public by the CDC to date.[29]

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[27] See p. 6 of https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

[28] Vaccine Adverse Event Reporting System (VAERS) 1990-06/24/2022, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Jul 5, 2022. Deaths, permanent disability, and spontaneous abortion were searched and filtered by vaccine type, for all reporting years, covering the U.S. and Territories. The July 5, 2022 query results for reported events related to deaths are saved at https://wonder. cdc.gov/controller/saved/D8/D297F897

[29] The processing of received reports is a black box as far as the

Similarly, 60 percent of all *permanent* disabilities ever reported (over 32 years) followed COVID-19 vaccines (16,331 out of a total of 27,312).[30] Spontaneous abortion (miscarriage) reported after COVID-19 vaccination comprises 74 percent of all such abortions ever reported (1,563 out of 2,108). The next highest reported abortion rate following vaccination is for HPV (e.g., Gardisil), at 13 percent of all such abortions reported, representing a period of 15 years' administration. None of the COVID-19 vaccine fact sheets to date reflect this high risk of fetal death or miscarriage.[31]

The prediction of the FDA, *see supra*, of three heart-related events to follow COVID-19 vaccination — myocarditis, pericarditis, and acute myocardial infarction — is borne out by a search of VAERS limited to those symptoms. Ninety-eight percent of all such heart-related events are reported following these deadly vaccines (5,864 out of 5,968 ever reported).[32] The FDA has published revised Moderna and Pfizer-BioNTech fact sheets to include myocarditis and pericarditis in the "side effects that have been reported,"[33] but *not* to include strokes or blood clots. And yet 98 percent of all stroke and blood clot-related events have also been reported as following the COVID-19 vaccines (13,706 out of 14,042 ever reported).[34] The Janssen fact sheet now

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public is concerned, but many observers have pointed out that it appears that VAERS is likely at least six months behind in releasing those reports to the public.

[30] *See* https://wonder.cdc.gov/controller/saved/D8/D297F900

[31] *See* https://wonder.cdc.gov/controller/saved/D8/D297F902

[32] *See* https://wonder.cdc.gov/controller/saved/D8/D297F904

[33] *See*, *e.g.* https://www.fda.gov/media/144414/download (published September 22, 2021).

[34] *See* https://wonder.cdc.gov/controller/saved/D8/D297F906

reflects blood clot risks and Gullain Barré Syndrome, but not heart risks.[35]

The above facts demonstrate that these vaccines are "misbranded." Before these manufacturers even applied for EUA approval of their vaccines, information published by the FDA indicated that death (among other serious injuries) was a realistic possible outcome of these vaccines. However, after these vaccines received EUA approval, these predictable injuries were not even mentioned in the facts sheets authored by the manufacturers. Instead, they pretended that the vaccines would only cause mild, insignificant injuries, if anything. This constitutes "misbranding" in violation of 21 U.S.C. § 352. See *Kordel, supra*.

Counsel for *Amicus* represents a number of plaintiffs in a civil action filed in the U.S. District Court for the Northern District of Alabama, styled *America's Frontline Doctors v. Becerra*, Case No. 2:21-cv-00702-CLM, and proof of some of the adverse consequences of the COVID-19 vaccines has been submitted in that case. Witness "Jane Doe" submitted a declaration stating that, based on her review of government computer data to which she had access, as many as 45,000 deaths had been caused by the vaccines by early July, 2021. *Id.*, ECF Doc. 15-4. Dr. Henry Ealy analyzed data posted on the VAERS website, which showed that during 2021, VAERS reported 21,382 deaths from these vaccines, of which 6,445 occurred within 48 hours of receiving the EUA vaccinations. He concluded that the real statistics posted on the VAERS website under-reported the adverse consequences of these vaccines "by a factor of 5 to 20 times." *Id.*, ECF Doc. 43-5.

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[35] *See* https://www.fda.gov/media/146305/download (published August 27, 2021).

Additionally, a declaration based on information provided by several whistleblowers who "are U.S. Army medical officers" with access to the Department of Defense Medical Epidemiological Database showed that the U.S. military collects medical information regarding many diseases of enlisted personnel, and that computer data revealed shocking multiple increases in the incidences of these diseases that can only be attributed to administration of the vaccines. *Id.,* ECF Doc. 47.

Misbranding is a serious federal crime, and it is happening in reference to the administration of these COVID-19 vaccines. These are crimes prosecuted by U.S. Attorneys, and two of the manufacturers of these vaccines (Pfizer and J&J) have previously been prosecuted for these crimes. The facts related to these crimes are clearly known by public "Officers" subordinate to the President, and the President could perform his constitutional obligation and "require the Opinion, in writing, of the[se] * * * Officer[s] in *** the[se] executive Departments" to learn about this crime. He could then "take Care that the [misbranding] Laws be faithfully executed," which is a remedy within the scope of that sought by the Garner Plaintiffs in their complaint. Taking this route, however, may pose problems regarding executive privilege. See *Cheney v. United States District Court*, 542 U.S. 367 (2004).

But a different route is available. Pursuant to 21 U.S.C. §360bbb-3(i), EUA approval of a "biologic" is committed to the "discretion" of the HHS Secretary, which arguably would preclude judicial review of these agency actions that approved these vaccines. See *Heckler v. Chaney*, 470 U.S. 821 (1985). However, when an agency or one of the President's Officers violates the law, that Officer has "abused his discretion," which permits judicial challenge to that

agency action. See *FCC v. Nextwave Personal Communications, Inc.*, 537 U.S. 293, 300 (2003) ("The Administrative Procedure Act requires federal courts to set aside federal agency action that is 'not in accordance with law,' 5 U. S. C. §706(2)(A) – which means, of course, any law, and not merely those laws that the agency itself is charged with administering.")

Here, there have been very serious "abuses of discretion." As noted *supra*, a federal law, 21 U.S.C. § 352(j), provides that a drug ("biologic") 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." Before the three COVID-19 vaccines were given EUA approval, the FDA, in a seminar for its own employees, noted that death and other exceptionally serious injuries were anticipated from administration of these vaccines. When the manufacturers submitted their EUA applications, no serious adverse consequences were noted. These manufacturers have even had the support of the President when he stated last September that the vaccines were "safe and effective." Now, evidence is piling up that shows these vaccines are "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." For federal officials to continue allowing use of these misbranded vaccines is a grave "abuse of discretion."

The Garner complaint sought to prevent Petitioners and members of their group from being forced to be vaccinated. As noted above, a legal theory clearly exists to extend to them the relief they seek because these vaccines are indeed misbranded and federal Officers have consequently abused their discretion by permitting their use.

Moreover, Petitioners also possessed "standing" to make their complaint. It is certain that it is the President who set into motion the activity of several federal agencies as well as state counterparts to impose vaccination requirements on Petitioners. Decisions of a number of courts on this point "show that mere 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). See also *America's Community Bankers v. FDIC,* 200 F.3d 822, 827-28 (D.C. Cir. 2000) ("an agency does not have to be the direct actor in the injurious conduct, but that indirect causation through authorization is sufficient to fulfill the causation requirement for Article III standing."); *Consumer Federation of America v. F.C.C.,* 348 F.3d 1009, 1012 (D.C. Cir. 2003) ("When an agency order permits a third-party to engage in conduct that allegedly injures a person, the person has satisfied the causation aspect of the standing analysis."); *Motor & Equip. Mfrs. Ass'n v. Nichols,* 142 F.3d 449, 457-58 (D.C. Cir. 1998) (one has standing to challenge government action based on the independent conduct of third parties where the evidence demonstrates that the challenged action "resulted in an almost unanimous decision" by those third parties to take action that harmed another); *Telephone and Data Systems, Inc. v. FCC,* 19 F.3d 42, 47 (D.C. Cir. 1994).

Standing also exists when parties are the clear object of some law or regulation threatened to be enforced against them. This Court had no problem regarding standing when it decided on June 24 the case of *Dobbs v. Jackson Women's Health Organization*, which involved a lawsuit filed the day after enactment of a Mississippi law impacting

abortion clinics and their practices. Abortionists being subjected to closure of their clinics because of COVID-19 "lockdowns" imposed by Alabama's Governor had standing to challenge the same in *Robinson v. Attorney General*, 957 F.3d 1171, 1177 (11th Cir. 2020).[25] Here, Petitioners assert that they too are the objects of federal and state imposed mandates requiring their vaccination, thus they certainly had standing to file their suit.

President Biden himself announced plans to force all *private* employers (with 100 or more employees) to mandate these new vaccines for their employees nationwide, and to fully discriminate against any who refuse.[36]

Neither the President nor any federal agency may implement a nationwide vaccine program and compel Americans who object thereto to receive a vaccine (which is really a "gene therapy"). It is certain that Petitioner Garner and others who fall within this unvaccinated class have standing to prevent being compelled to be vaccinated by the executive branch, whether that force is applied directly or indirectly.

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[25] Former Alabama Supreme Court Justice Roy Moore placed a Ten Commandments monument in the lobby of Alabama's Supreme Court building, and lawyers who entered the building but avoided passing by the monument had standing to complain about its placement there. See *Glassroth v. Moore*, 335 F.3d 1282, 1292 (11th Cir. 2003).

[36] *See* www.cnbc.com/2021/09/09/biden-to-detail-new-six-pronged-plan-to-increase-us-covid-vaccination-rates-fight-virus.html

CONCLUSION

The Petition for a Writ of *Certiorari* should be granted.

Respectfully submitted,

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APPENDIX

CONSTITUTIONAL PROVISIONS

Article II, Section 2

The President shall be Commander in Chief of the Army and Navy of the United States, and of the Militia of the several States, when called into the actual Service of the United States; he may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices, and he shall have Power to grant Reprieves and Pardons for Offences against the United States, except in Cases of Impeachment.

He shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur; and he shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

The President shall have Power to fill up all Vacancies that may happen during the Recess of the Senate, by granting Commissions which shall expire at the End of their next Session.

Article II, Section 3

He shall from time to time give to the Congress Information of the State of the Union, and recommend to their Consideration such Measures as he shall judge necessary and expedient; he may, on extraordinary Occasions, convene both Houses, or either of them, and in Case of Disagreement between them, with Respect to the Time of Adjournment, he may adjourn them to such Time as he shall think proper; he shall receive Ambassadors and other public Ministers; he shall take Care that the Laws be faithfully executed, and shall Commission all the Officers of the United States.

STATUTES (pertinent portions)

21 U.S.C. § 352(j)

A drug or device shall be deemed to be misbranded-

(j) **Health-endangering when used as prescribed**
If 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.