IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

MOMS FOR AMERICA, JEFF JACKSON, MICHELLE UTTER, HENRIETTA SIMOES, ADELIO SIMOES, ELIZABETH BROWN, CODY HOWARD, ALLEN MARTIN, TAYLOR MARTIN, AND LA NEDIA ROOKER,

Plaintiffs,

vs.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION, HHS SECRETARY XAVIER BECERRA, in his official capacity, the UNITED STATES OF AMERICA, and PRESIDENT OF THE UNITED STATES JOSEPH R. BIDEN, in his official capacity.

Defendants.

Case No. _____

_____/

COMPLAINT FOR
DECLARATORY AND INJUNCTIVE RELIEF

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Plaintiffs, MOMS FOR AMERICA, JEFF JACKSON, MICHELLE UTTER, HENRIETTA SIMOES, ADELIO SIMOES, ELIZABETH BROWN, CODY HOWARD, ALLEN MARTIN, TAYLOR MARTIN, and LA NEDIA ROOKER (together "Plaintiffs"), bring this Complaint for declaratory and injunctive relief against the U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA in his official capacity as the Secretary of the Department of Health and Human Services, the UNITED STATES OF AMERICA, and JOSEPH R. BIDEN in his official capacity as the President of the United States (together "Defendants") and state as follows:

INTRODUCTION

"*Act in Haste, Repent at Leisure*"
-unknown

1. Fundamental to the concept of ordered liberty is the will and ability of the government to protect citizens from harming each other, and resolving conflicts in and between citizens when injuries occur. America's historical system, based on common law and its Constitutional government, normally resolves those conflicts, and remedies those injuries, by

adjudicating civil causes of action by and between citizens.

2. This case is about the government's failure to resolve conflicts involving Americans killed or grievously harmed while receiving health care during the COVID-19 pandemic.

3. The wellspring of failure is the unconstitutional Public Readiness and Emergency Preparedness Act of 2005 (the "PREP Act" of "Act"), its broad invocation by the Secretary of the Department of Health and Human Services during the COVID-19 pandemic and after, and the facial and as-applied-to-COVID-19 inadequacy of the compensation program provided under the PREP Act.

4. Congress passed the PREP Act in its 2006 Defense Appropriations package after then-President George Bush delivered a passionate speech about the nation's lack of preparedness for a potential pandemic. At the time of voting, lawmakers were assured the law provided only limited liability protection to manufacturers, any adverse serious physical injury that might be caused by a vaccine would be compensated, and that the program would not be funded until there was an emergency:

> Mr. DEAL of Georgia: Mr. Speaker, I rise in support of the provisions in

> this bill called the Public Readiness and Emergency Preparedness Act. This is absolutely critical legislation. It addresses parts of the important speech given by the President to address the threat of pandemic flu and other bioterror threats.
>
> The Health Subcommittee of the Energy and Commerce Committee has held several hearings on this important threat and the need to begin to have the manufacturing capacity to produce pandemic flu vaccine. Unfortunately, there is no business model that would have vaccine manufacturers take on the tremendous liability risks to produce such a vaccine. We must address this concern or we will have none. It's really that simple.
>
> **This legislation does not actually provide any liability protection**. What the legislation does is provide authority to the Secretary the ability to declare **limited liability protection**. The Secretary can use these declarations to make sure the vaccine gets developed and to make sure doctors are willing to give it when the time comes.
>
> These are, of course, hypothetical circumstances. So why are we passing this legislation? It's simple. We cannot afford not to take the important steps of making sure we can get and deliver a vaccine.
>
> We have also provided the outline of **a compensation fund to address any adverse serious physical injury that might be caused by a vaccine** itself. But again, this is a hypothetical. We don't have a vaccine yet.
>
> There is no pandemic flu yet. And no declaration of liability protection has been issued. **Those who argue we are deficient because we have not yet put money in the compensation fund don't get it.** You really can't do that until there is a reason to do so. If there is no pandemic flu, there will be no reason for a vaccine to be administered. Indeed, we can't really produce an effective flu vaccine until we have the specific pandemic strain. Right now there is no need for any compensation funding at all.

CONFERENCE REPORT ON H.R. 2863, DEPARTMENT OF DEFENSE APPROPRIATIONS ACT, 2006; Congressional Record Vol. 151, No. 164, at page H12264 (*emphasis supplied*).

5. In other words, the PREP Act was passed to solve a vaguely

defined "hypothetical" future problem, when side-effects by definition could not possibly be known, though the law might never be needed, without any funding, and with vague reassurances that "any adverse serious physical injury" would be compensated.

6. But rather than limited liability protection, the PREP Act provides parties causing injuries with the broadest liability protection imaginable. Within the scope of its extensive COVID-19 coverage, the PREP Act immunizes defendants from a staggering panoply of fundamental and historically enshrined common law causes of action like negligence, medical malpractice, gross negligence, products liability, wrongful death, and even intentional torts like assault and battery under a completely subjective risk/benefit analysis.

7. Most irrationally of all, the PREP Act set a breathtakingly short one-year statute of limitations *for injuries caused by unknown, unknowable, and non-existent vaccine products and technologies*. Even to receive program compensation, the Act requires causation to be proved based on *established science* for those same novel products and technologies. Most medical studies take years to conduct, be drafted, be peer-reviewed, and to be published. It

is irrational to believe that a person taking a covered countermeasure could possibly have access to published medical/scientific studies within the one-year statute of limitation.

8. Rather than compensating Americans injured by covered treatments like vaccines, the PREP Act perversely but predictably denies relief in 99% of cases, in a claims evaluation process stripped of even a pretense of due process. Indeed, the PREP Act unconstitutionally created an opaque, unappealable, quasi-judicial tribunal to adjudicate claims lacking even a fig leaf of due process and explicitly disclaimed judicial oversight.

9. Considering the PREP Act's nearly consequence-free incentive structure and the moral hazard it created, some pharmaceutical companies and multi-billion-dollar health care providers have been predictably and often recklessly indifferent to the safety and efficacy of the treatments they provided. Turning tort law on its head, the PREP Act dissolved any conceivable commercial incentive for providers to be reasonably prudent.

10. As alleged in this lawsuit, the Plaintiffs' suffering (as well as countless more like them) is incomprehensible to those whose lives have not been upended, ruined, or taken by emergency "treatments" administered

for the collective good based on an empty promise that the collective would compensate any damage wreaked in the haste of emergency response. In many cases, the Federal Government itself urged and even *mandated* Americans to receive these "treatments" — as a collective service to society.

11. Now that the dust has settled, and the emergency is over, where is society? Where is the government, now that it is time to collect the dead and bandage the wounded?

12. Instead of *supporting* the victims, the PREP Act actively stripped them of their common law claims, their constitutional due process, and access to any relief. The sick and their families are left alone in their homes—disabled and dying—to grapple fruitlessly with the PREP Act's futile and incomprehensible quasi-judicial scheme, administered by a Byzantine, anonymous, underfunded, and unsupervised administrative tribunal adjudicating life and death issues in secret.

13. Since the PREP Act was designed for an unknown and unknowable emergency, it is unsurprising that it is fatally flawed and unconstitutional. It cannot be fixed. It should be enjoined during the pendency of this action, and declared unconstitutional and void.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1343 because this action arises under Article III of the United States Constitution as well as the Fifth, Seventh, and Fourteenth Amendments to the United States Constitution.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(e)(1) because one or more Plaintiffs reside in this district, no real property is involved in the action, and a substantial part of the events or omissions giving rise to the claim occurred here.

PARTIES

A. Plaintiffs

16. Plaintiff Moms for America is a 501(c)(3) educational organization incorporated in Ohio, in 2004, to activate, empower and mobilize moms to promote and advance a culture of truth, family and freedom in homes and communities across America. The individual Plaintiffs are each active members of Moms for America and as such are provided education and support services by Moms for America. Medical freedom, protection from medical harm, and the capacity of the medically

injured to obtain relief for their injuries have been central issues for Moms for America beginning in 2020. Since that time, Moms for America has advanced these causes on the national level through advocacy on behalf of its members and society at large. For example, Moms for America has hosted scores of interviews and webinars and clinics to educate members and others regarding medical health, medical freedom, forced medical isolation, and medical harm; resisted mask and vaccine mandates and otherwise advocated for medical freedom and the medically injured—in particular where such issues involved children—through rallies, educational initiatives, legislative advocacy, communications campaigns, and hundreds of media appearances; organized a "Moms for Medical Freedom" initiative, bringing together moms across the country to share their stories and support each other where they had experienced violations of medical freedom, medical harm, forced medical isolation, and unaddressed medical injuries. As the COVID-19 pandemic progressed, Moms for America became increasingly aware of the infringements on the liberty of Americans being perpetrated in the name of medical science, as members contacted Moms for America's leadership with questions regarding the effects of various

governmental actions on themselves, their spouses, and their children. Moms for America began researching the issues and providing updates and educational material as well as facilitating connections among members with the aim of helping members navigate the complex confusing and everchanging raft of policies, rules and regulations regarding COVID-19. Through its efforts, Moms for America became aware of how challenging it was and is for the average American family to obtain the information they need to make informed medical decisions and to obtain the medical treatment that is best for them. Moms for America discovered that the COVID-19 response contained almost none of the concessions or modifications for pregnant mothers and young children typically provided by government actions, especially during times of crisis. When attempting to obtain answers to legitimate questions during the pandemic, Moms for America found the various government offices to be difficult, confusing and non-responsive. Moms for America understands and agrees completely with the individual Plaintiffs that compensation and recovery for injuries or death of a loved one under the PREP Act, or from the CICP, is futile and is horrified that medically injured Americans have been left without a real means of

recovery.

17. Plaintiff Jeff Jackson resides in the State of Mississippi.

18. Plaintiff Michelle Utter resides in the State of Florida.

19. Plaintiffs Henrietta and Adelio Simoes reside in the State of New York.

20. Plaintiff Elizabeth Brown resides in the State of New York.

21. Plaintiff Cody Howard resides in the State of Florida.

22. Plaintiffs Allen and Taylor Martin reside in the State of Oklahoma.

23. Plaintiff La Nedia ("Nedia") Rooker resides in the State of Alabama.

24. The individual Plaintiffs desire to bring common law and state law claims for, among other things, products liability, negligence, wrongful death, fraud, failure to warn, battery, and negligent and intentional infliction of emotional distress against manufacturers and administrators of the products that injured them or their deceased loved ones.

B. Defendants

25. Defendant U.S. Department of Health and Human Services

("HHS") is a cabinet-level executive branch department of the federal government.

26. Defendant U.S. Health Resources and Services Administration ("HRSA") is an Operating Division of HHS. HRSA administers the Countermeasures Injury Compensation Program.

27. Defendant Xavier Becerra is the 25th and current United States Secretary of Health and Human Services.

28. Defendant United States of America is the federal government of the United States.

29. Defendant Joseph R. Biden is the President of the United States of America.

STATEMENT OF FACTS

The PREP Act

30. The PREP Act[1] was passed in 2005 to assist the country's ability to respond to public health emergencies involving chemical, biological, radiological, and nuclear agents, including emerging infectious diseases.

[1] Public Readiness and Emergency preparedness Act of 2005, Pub L. No. 109-148, 42 U.S.C. §§ 247d-6d, 247d-6e (2005).

31. The PREP Act's core feature is the liability immunity it provides to certain "covered persons." Under the Act, the HHS Secretary (the "Secretary") may grant "covered persons" broad immunity from any injuries they cause to individuals through the design, manufacture, and/or use of "covered countermeasures," which are also defined by the Secretary. The Act's broad immunity is intended to encourage private providers to make new and untested remedies immediately available to citizens, rather than withholding such treatments from fear of liability for inevitable injuries.

32. The PREP Act's immunity shield arises whenever the HHS Secretary determines and declares that a disease, other health condition, or other threat to health "constitutes a public health emergency." § 42 USC 247d-6d(b)(1).

33. Upon issuance of the emergency declaration, the PREP Act preempts any other provision or legal rights under federal, state, or common law that are "different from, or . . . in conflict with, any requirement applicable under" the PREP Act. § 42 USC 247d-6d(b)(8). The PREP Act provides unprecedented broad legal immunity whenever the Secretary

issues an emergency declaration:

> . . . a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure. . .

§ 42 USC 247d-6d(a)(1).

34. The PREP Act requires the Secretary of HHS to specify in the emergency declaration: (1) the effective period for which immunity shall be available;[2] (2) the "category or categories of diseases, health conditions, or threats to health specified in the declaration";[3] (3) the "one or more" specific countermeasures with regard to which immunity would be available;[4] (4) the category or categories of "covered persons" who may receive liability protections; [5] what actions "covered persons" shall be immune from liability for engaging in with regard to "covered countermeasures" (*e.g.,* the covered countermeasures' manufacture, testing, development, distribution,

[2] § 42 USC 247d-6d(b)(2)(B)

[3] § 42 USC 247d-6d(b)(2)(A)

[4] § 42 USC 247d-6d(b)(1)

[5] § 42 USC 247d-6d(a)(1); § 42 USC 247d-6d(i)(2)

administration, use, etc.);[6] and the geographic area within which immunity will apply.[7]

35. The PREP Act thus theoretically allows the HHS Secretary to circumscribe the parameters of the liability immunity the PREP Act provides no greater than needed to induce private providers to make countermeasures available to address the declared emergency.

36. However, as a practical matter, within the scope of applicability defined by any specific emergency declaration, PREP Act immunity is vague, undefined, unknowable (until specified by the Secretary), and nearly absolute. A "[l]oss" as defined in the PREP Act—from which "covered persons" will be immune from liability—includes most any form of physical, mental, or emotional injury, property damage, and business interruption losses. § 42 USC 247d-6d(a)(2)(iv).

37. The sole statutory exception to PREP Act immunity is for "willful misconduct." According to the PREP Act, "willful misconduct" consists of an act or omission that is taken:

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[6] § 42 USC 247d-6d(b)(1)

[7] § 42 USC 247d-6d(b)(2)(D)

(i) Intentionally to achieve a wrongful purpose;

(ii) Knowingly without legal or factual justification; and

(iii) In disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

See § 42 USC 247d-6d(c)(1)(A)(i)-(iii).

38. The strikingly narrow terms of this category are foreign to familiar notions of tort law. According to this definition, a "covered person" could intentionally act with a wrongful purpose, in knowing violation of the law, and in disregard of a known or obvious risk, but would be immune from liability—even for death or disability—so long as it was not "highly probable" that the harm of the risk outweighed its benefit. Worse yet, the intentionality requirement shields even the most reckless behaviors. It is difficult to imagine any rational basis for protecting "covered persons" from liability for all but such a preposterously narrow realm of activity.

39. Even where a victim's "loss" *is* caused by "willful misconduct", the PREP Act imposes a host of procedural obstacles to relief that are not commonly encountered in America's civil justice system.

40. According to the terms of the PREP Act, a claim for "willful misconduct", is "an exclusive Federal cause of action against a covered person." § 42 USC 247d-6d(d)(1).

41. No plaintiff has *ever* brought a successful claim for "willful misconduct" under the Act, probably because "willful misconduct" is such an onerous standard and because the procedural obstacles are so formidable that it is virtually impossible to succeed on such a claim. The Act requires such claims:

(a) May only be brought in the case of "serious physical injury or wrongful death." § 42 USC 247d-6d(d)(2).

(b) Must be brought in the United States District Court for the District of Columbia. § 42 USC 247d-6d(e).

(c) Must be pled with particularity. § 42 USC 247d-6d(e)(3).

(d) Must be verified and accompanied by a physician's affidavit certifying that the plaintiff's serious physical injury or death was proximately caused by a covered countermeasure. § 42 USC 247d-6d(e)(4)(B), (C).

(e) Must be assigned to a three-judge panel for "consideration of motions to dismiss, motions for summary judgment, and matters related thereto," after which it will be assigned by the chief judge for further proceedings, including trial. § 42 USC 247d-6d(e)(5).

(f) Must allow for a defendant's interlocutory appeal to the United States District court for the District of Columbia Circuit for any order denying a motion to dismiss or a motion for summary judgment. § 42 USC 247d-6d(e)(10).

(g) Must prevent the plaintiff from conducting any discovery until after any motion to dismiss is ruled on and any interlocutory appeal of any denial of such motion is heard. § 42 USC 247d-6d(e)(6)(A)(i)-(iii).

(h) Must reduce any award for damage in the amount of any collateral source benefits. § 42 USC 247d-6d(e)(7).

(i) Must restrict noneconomic damages paid by any defendant to the proportional amount of the

responsibility that defendant bears for the harm to the plaintiff. § 42 USC 247d-6d(e)(8).

(j) May be brought only where a potential plaintiff has already "exhausted such remedies" as are available under the "Covered Countermeasure Process Fund" process at § 42 USC 247d-6e.

(k) May only be brought after the plaintiff has qualified for compensation from the Countermeasure Injury Compensation Program fund, and only if the potential plaintiff elects to reject compensation from the fund. § 42 USC 247d-6e(d)(5).

(l) May only be brought against a manufacturer or distributor if the Secretary or the Attorney General has initiated an enforcement action against such manufacturer or distributor or, if such enforcement action has been initiated, if the action has been terminated or finally resolved with a specified remedy. § 42 USC 247d-6d(c)(5).

The PREP Act As Applied to COVID-19

42. Previous HHS Secretary Alex M. Azar II declared an emergency regarding COVID-19 on March 17, 2020.[8] (the "Emergency Declaration").

43. The Emergency Declaration's invocation of the PREP Act's already nearly limitless immunity was, if possible, even more broad. The Emergency Declarations' geographical reach was nationwide;[9] its effective period ran/runs from the time of the effective date of the Emergency Declaration until October 1, 2024, with an additional 12-months of protection for manufacturers;[10] it defines "covered countermeasures"—so long as they have obtained certain regulatory approvals—as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2" including "drugs, biological products, or devices authorized for investigational or emergency use" under the PREP Act, the Federal Food,

[8] Effective as of February 2, 2020. *See* Notice of Declaration, 85 Fed. Reg. 15198 (March 17, 2020).

[9] Emergency Declaration, § XI

[10] *See* Emergency Declaration, §§ XII and XIII.

Drug, and Cosmetic Act, or the Public Health Services Act;[11] and it defines "covered persons" to the fullest extent possible under the PREP Act to include all manufacturers, distributors, program planners (*i.e.* public and private health care administrators) and qualified persons (*i.e.* any health care provider) meeting certain minimal qualifications.[12]

44. Because the PREP Act covers not only "countermeasures" themselves but also "losses" "related to" their "administration" and their "use", the PREP Act's liability shield covers nearly any action undertaken by a healthcare provider while treating COVID-19, regardless of how negligent, reckless, or even intentional. For example, it would protect a healthcare provider who intentionally administers a COVID-19 treatment in contravention of an express refusal by a patient.[13] § 42 USC 247d-6d(a)(1).

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[11] *See* Emergency Declaration, § VI; *see also* § 42 USC 247d-6d(b)(1); *and* § 42 USC 247d-6d(i)(1)

[12] *See* Emergency Declaration, §§ V; *see also* § 42 USC 247d-6d(i)(2) *and* § 42 USC 247d-6d(i)(6), (8).

[13] Such a violation of traditional American notions of bodily autonomy would not qualify as "willful misconduct" under the PREP Act unless it could be shown that the treating health care provider's actions imposed a "known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." § 42 USC 247d-6d(c)(1)(A)(iii).

45. Since the Emergency Declaration was issued, the Secretary has issued eleven amendments and seven guidances concerning the PREP Act, and the General Counsel of Health and Human Services has issued six advisory opinions interpreting the PREP Act. For the most part, these amendments, opinions, and guidances have either broadened the Emergency Declaration's scope, or have 'clarified' the Secretary's unexpressed understanding of the broad reach of the immunity it provides.

46. Thus, despite the PREP Act's tools that could have allowed the HHS Secretary to draw the liability shield more narrowly, the Emergency Declaration swept within its protections virtually the entire response of the United States healthcare system to COVID-19, in or out of hospitals, care homes, jails, schoolhouses, or anywhere else mitigation measures were deployed.

47. At the same time as the HHS Secretary was exercising the PREP Act's unprecedented power to bar victims' claims, other parts of the Federal Government were busily creating markets—massive on a scale never seen in human history—for government-preferred treatments for COVID-19. These markets were created by and through federal vaccine mandates, hospital

treatment protocols/care and treatment recommendations initiated/published by the National Institute of Health and the Center for Disease Control, and the reimbursement policies of the Centers for Medicare & Medicaid Services. The Emergency Declaration immunized from liability anyone connected with government-preferred treatments, regardless of risk, consequence, or preference.

48. Taken together, these policies of the Federal Government effectively nationalized and centralized the American health care response to COVID-19, dissolving the independent judgment of individual front-line healthcare providers for treating individual patients, and ensuring not only astronomical sales and record profits for the providers of "covered countermeasures," but also ensuring that those same makers enjoyed freedom from liability for the death or disability of unwitting Americans, even if the injuries resulted from gross violations of common law tort standards and public policy.

49. This centralized regime of bureaucratically-designed, flow-charted, one-size-fits-all, *liability-free* healthcare governed the design, manufacture, and administration of over a billion COVID-19 vaccine shots;

hundreds of millions of visits to health care providers; millions of hospitalizations; and unknown billions of incidents of the administration of medicines and devices falling within the nearly-unlimited definition of COVID-19 "countermeasures."

50. And it all played out against a backdrop of gross moral hazard, in which health care providers comported themselves in full knowledge of their tort liability immunity. The prospect of recourse through the civil justice system—and the discipline it normally imposes on healthcare providers—is so deeply ingrained into the assumptions of American patients, it can accurately be said that patient-victims who received COVID-19 related healthcare under the auspices of the Emergency Declaration had no idea to what they were agreeing.

51. The American legal system's traditional and historical understanding of the duties owed by providers of health care to patients was upended so completely and so radically that on March 17, 2020 — the date the Secretary issued the Emergency Declaration—Secretary Azar arguably became the most powerful man in the country. At least from a civil liability perspective, the Secretary held authority to issue something remarkably

similar to a "license to kill."

The CICP

52. Congress tried to balance the PREP Act's *taking* of injured Americans' causes of action with a countervailing right to compensation from the Countermeasures Injury Compensation Program (the "CICP"). The CICP was established by the PREP Act, is funded only by emergency appropriations, and is intended to provide "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." 42 U.S.C § 247d-6e(a).

53. Pursuant to the PREP Act, HHS and its component, the Health Resources and Services Administration ("HRSA"), promulgated regulations establishing and implementing the CICP. 42 C.F.R. Part 110. HRSA provides more information about the CICP on its web page.[14]

54. So far, so good. But compensation under the CICP was limited to serious physical injury or death "*directly* caused by the administration or

[14] HRSA.gov/cicp

use of a covered countermeasure" pursuant to an emergency declaration. 42 U.S.C. § 247d-6e(a), (b)(1). A determination as to such *direct* causation must be "based on compelling, reliable, valid, medical and scientific evidence." 42 U.S.C. § 247d-6e(b)(4). Such direct, compelling, reliable, valid, medical and scientific evidence related to a novel treatment or therapeutics is likely to be unavailable within the twelve-month statutory claim period.

55. Even under its own terms, the CICP's lack of due process unsettlingly evokes a Byzantine bureaucracy one might expect to find in a work of dystopian fiction. But it gets worse.

56. The process begins when an applicant files a Request Form with HRSA. 42 C.F.R. § 110.42(a). This Request Form must be filed "within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury." *Id.* This one-year timeline applies despite the fact that the PREP Act, a public health emergency statute, by its nature immunizes many novel treatments for which harms have not yet been conclusively discovered or identified.

57. Next, applicants must submit copious medical evidence to

HRSA.[15] 42 C.F.R. § 110.50(a). If the Secretary weighs the provided medical evidence and determines it is insufficient, he will notify the applicant, and the applicant "will be given 60 calendar days from the date of the Secretary's notification to submit sufficient documentation." 42 C.F.R. § 110.71.

58. At this point, the CICP's quasi-judicial process dissolves from view and becomes entirely passive and opaque to the applicant. The quasi-judicial process by which CICP decision-makers rule on whether serious physical injury or death were "directly caused by the administration or use

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[15] Specifically:

- All medical records documenting medical visits, procedures, consultations, and test results that occurred on or after the date of administration or use of the covered countermeasure;
- All hospital records, including the admission history and physical examination, the discharge summary, all physician subspecialty consultation reports, all physician and nursing progress notes, and all test results that occurred on or after the date of administration or use of the covered countermeasure; and
- All medical records for one year prior to administration or use of the covered countermeasure as necessary to indicate an injured countermeasure recipient's pre-existing medical history.

See 42 C.F.R. § 110.50(a).

of a covered countermeasure,"[16] and are therefore compensable, are invisible and unknowable to the applicant and the public, except at the highest levels of generality.

59. The anonymous staff of the CICP who weigh the evidence and adjudicate an applicant's request are in effect both the judge and the advocate for the opposing party in a trial conducted without the applicant present to advocate for themselves, cross-examine witnesses, object to the use of hearsay, discover the government's contrary evidence, challenge conflicts of interest, or make any rebuttal. While citizens have a year to bring claims, no enforceable time limit is imposed on the government to issue its ruling.

60. The HRSA brings its own experts, evidence, studies, consultants, and advisors — in other words, its evidence and witnesses — into the decision-making process. But injured applicants cannot cross-examine or even confront HRSA's witnesses or challenge its evidence. Applicants cannot impeach HRSA's experts for bias. Applicants cannot review any

[16] 42 U.S.C. § 247d-6e(a), (b)(1).

expert reports or opinions or explore the scientific basis for any such opinions. Not only does the applicant have no right to discovery, but the applicant doesn't even know what discovery might be needed.

61. Applicants are invited to submit, along with their medical records, any evidence and expert opinions (in written form) that the applicant believes is relevant to their case. 42 C.F.R. § 110.50(b). But without knowing who and what opposes them and on what basis, it is like inviting a blindfolded boxer to punch in any direction and as hard as he wants.

62. The CICP purports to provide a right to appeal. It is illusory. If the Secretary rules an applicant ineligible for CICP compensation, the applicant may seek reconsideration within 60 days, from *the HRSA* — the same entity that just ruled against the applicant. 42 C.F.R. § 110.90. No additional documentation or evidence may be submitted as part of the reconsideration process. *Id.* at § 110.90(a).

63. And that is that. No further administrative review is available. No legal review is available. No judicial review is available. Applicants are statutorily foreclosed from availing themselves of any review of any kind. 42 U.S.C. § 247d-6e(b)(5)(C).

64. Where a lucky applicant *is* found eligible for CICP benefits, the applicant must then provide *additional* documentation to establish benefit amounts. 42 C.F.R. § 110.60-63. Categories of allowed benefits include payment or reimbursement for necessary medical services; lost employment income; and death benefits. 42 C.F.R. § 110.2. Again, the process is opaque and passive, and the applicant must wait for HRSA to reach its determination.

65. Compensation for lost employment income is capped at $50,000 a year,[17] but even this overstates what may be recovered since benefits must be reduced by any amounts received from third-party payers. 42 C.F.R. § 110.80-84. More importantly, benefits are *de facto* limited by the fact that the Secretary of HHS has no authority to generate funds to pay benefits but is limited to such amounts as are designated by Congress as an emergency appropriation. 42 U.S.C. § 247d-6e(a).

Commander Grimes' Congressional Testimony

66. On February 15, 2024, Commander George Reed Grimes testified

[17] 42 C.F.R. § 110.81(c).

before the House of Representatives Select Subcommittee on the Coronavirus Pandemic.[18] The following alleged facts were obtained from his written testimony provided to the Subcommittee.

67. The CICP began operating in 2010.

68. Commander Grimes became the Director of Injury Compensation Programs in 2021, including the CICP and the Vaccine Injury Compensation Program (VICP).

69. When the COVID-19 PREP Act declaration was issued in 2020, the CICP had no direct appropriation and only four staff members.

70. In 2020, the CICP resolved zero claims per month.

71. Approximately 14,000 claims have been filed with the CICP since the beginning of the pandemic.

72. Congress did not authorize any budget for the CICP until 2022, when Commander Grimes became its director.

73. Congress has made no permanent appropriation for the CICP

[18] The written portion of Commander Grimes' testimony is available online at: https://oversight.house.gov/wp-content/uploads/2024/02/HRSA_SSCP-Testimony-for-02.15.2024-Hearing.pdf (last accessed April 3, 2024).

budget, which is funded through emergency allocations.

74. The FY 2024 Budget proposes $15 million to operate the CICP.

75. Under Commander Grimes' directorship, the CICP's staff has increased to 35 people, and in 2023, its resolution rate increased to about 90 claims per month.

76. To be eligible for compensation, the CICP must determine that a covered countermeasure like the COVID-19 vaccines proximately caused the covered injury and was not just temporally associated with receipt or use of the countermeasure.

77. The CICP's determinations can only be made after evaluating "compelling, reliable, valid, medical, and scientific evidence."

78. If, after weighing the evidence and determining causation, the CICP finds compensation is due, it must apply a statutory framework to the claimant's evidence of injury to calculate the amount.

79. The CICP acts as a quasi-judicial tribunal, weighing evidence, taking testimony, applying legal principles, and making final determinations. In fact, the word "evidence" — used in its legal context — appeared seven times in Commander Grimes' eight-page testimony.

80. Applying those nearly insurmountable standards, the CICP has denied over 99% of considered claims related to COVID-19.

81. Attorney's fees, punitive damages, and pain and suffering are ineligible for reimbursement under the CICP framework, effectively eliminating applicants' right to counsel.

The Vaccine Injury Compensation Program

82. The CICP's poorly designed and unfunded framework compares unfavorably with the similarly named Vaccine Injury Compensation Program (the "VICP"), which is also a formal judicial process established as part of the 1986 National Childhood Vaccine Injury Act and serves as an alternative to the traditional tort system.

83. Injuries caused by COVID-19 vaccines are not eligible for compensation under the VICP, only under the CICP.

84. The VICP does not suffer from the CICP's unfunded character. The VICP is funded through an annual appropriation based on a Trust Fund that itself is funded by an excise tax on scheduled vaccines.

85. Any person who believes they were injured by a scheduled vaccine must first file a claim with the VICP.

86. The VICP process is faster, easier, and less costly than traditional court lawsuits.

87. VICP claims are filed in the U.S. Court of Federal Claims, where a special master (a judge who specializes in VICP cases) makes the decisions in a formal proceeding including substantial elements of due process.

88. Claimants need not prove the vaccine was defective, manufactured improperly, or that there was any negligence; they need only to show causation by the vaccine.

89. The VICP program maintains a table listing specific injuries or conditions that are presumed to be caused by vaccines if they temporally occur within a certain timeframe after vaccination. But claimants may also prove their injury is novel and not previously recognized in academic literature.

90. If the special master rules in favor of the VICP claimant, compensation includes medical and legal expenses, including attorney's fees, loss of future earning capacity, and up to $250,000.00 for pain and suffering (but not punitive damages). A death benefit is also available in fatal cases.

91. Claimants may accept or reject the VICP award. Accepting VICP compensation means the claimant may not sue the vaccine manufacturer or the healthcare provider who administered the vaccine in a civil case.

92. But an injured claimant can reject the VICP compensation award and then pursue a normal civil lawsuit against the vaccine manufacturer or the healthcare provider who administered the vaccine (including seeking punitive damages).

93. Or, if the claimant disagrees with the special master's decision, they may appeal the decision to the judge of the U.S. Court of Federal Claims. Further appeals can be made to the U.S. Court of Appeals for the Federal Circuit and, ultimately, to the U.S. Supreme Court.

94. A record is made of all VICP proceedings.

95. The Supreme Court has noted that the VICP accomplishes the twin beneficial goals of design-defect torts: (1) prompting the development of improved vaccine designs, and (2) providing compensation for inflicted injuries.[19]

[19] *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 238–39 (2011).

96. Practically and by its design, the CICP fails to accomplish either of these beneficial goals of design-defect torts.

97. The VICP has a generous compensation scheme,[20] but the CICP does not.

98. The VICP provides many means of improving vaccine design,[21] but the CICP does not.

99. The VICP requires vaccine manufacturers and healthcare providers to report adverse side effects,[22] but the CICP does not.

100. The VICP provides for monitoring of vaccine safety,[23] but the CICP does not.

101. The VICP sets up a structural *quid pro quo* where vaccine manufacturers fund from their sales an informal, efficient compensation program for vaccine injuries, and in exchange they avoid costly tort

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[20] *Id.*

[21] *Id.* (the NCVIA "directs the Secretary of Health and Human Services to promote the development of childhood vaccines that result in fewer and less serious adverse reactions. It establishes a National Vaccine Program, whose director is to achieve optimal prevention of human infectious diseases ... and to achieve optimal prevention against adverse reactions," cleaned up, ellipses in original).

[22] *Id.*

[23] *Id.*

litigation and the occasional disproportionate jury verdict.[24]

102. The CICP has no structural *quid pro quo* between protected citizens (e.g., vaccine manufacturers) and injured citizens.

103. Unlike the VICP, the CICP has no built-in funding mechanism.

104. The Supreme Court has previously expressed doubt that Congress would ever quietly pre-empt products-liability claims without providing a federal substitute,[25] but that is precisely the CICP's effect.

105. The CICP program features none of the VICP's due process, efficiency, funding, beneficial effects, safeguards, right to appeal, right to jury trial, award of attorney's fees, or any of the VICP's other carefully considered and carefully designed elements.

106. In other words, the VICP's design and effect illustrate the CICP's unconstitutional design and effect.

The CICP Buckles Under COVID-19

107. In practice, the CICP is even worse than its sounds.

108. According to records made available by HRSA, 12,854 COVID-

[24] *Id.*

[25] *Id.* at 240.

19 CICP claims have been filed in the four years since the Emergency Declaration *but only 11 have been compensated.*[26] Of the rest, the vast majority, 10,640, are "in review" or "pending review."[27] An actual decision has been reached on 2,214 requests and almost every decision—2,174—has been a denial.[28] In all, the CICP's judges have found eligibility for compensation only for 40 requests, and, as mentioned above, compensation has been paid to only 11 victims.[29] The maximum compensation awarded to any one of these 11 victims was $8,961.00 (not a typographical error).[30] The average compensation for these 11 compensated victims was only $3,743.18.[31]

109. It is important to recall the awesome scope of the PREP Act's immunity and thus, presumably, the correspondingly broad scope that the CICP's compensation scheme should be required to cover.

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[26] Countermeasure Injury Compensation Program (CICP) Data, HRSA, (March 18, 2024), https://www.hrsa.gov/cicp/cicp-data (last accessed March 20, 2024).

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Table 4. CICP Claims Compensated (Fiscal Years 2010-2023),* HRSA, https://www.hrsa.gove/cicp/cicp-data/table-4 (last accessed March 20, 2024).

[31] *Id.*

110. The PREP Act is not limited to the vaccine injured. It blankets countless injured or dead patient-victims who suffered—in the language of the PREP Act—"loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." § 42 USC 247d-6d(a)(1). The PREP Act's immunity thus applies to nearly every one of the hundreds of millions of Americans who were seen, hospitalized, medicated, sedated, intubated, and vaccinated or provided other prophylactic treatment for COVID-19, negating any claims they may have for *inter alia*, negligence, gross negligence, medical malpractice, products liability, wrongful death and, in some cases, even intentional torts such as assault and battery. This liability moratorium began on February 2, 2020, and *continues to this day*.

111. Considering that the treatment of COVID-19 was the central preoccupation of the American health care system for no less than several years, and that treatments were provided subject to the moral hazard of zero liability, colorable claims might number in the hundreds of thousands if not millions. Against this number, the mere 12,854 claims the CICP reports having received is perhaps the single most demonstrable piece of evidence

of the program's utter futility and moral bankruptcy.

112. It is not lost on injured Americans that, as their lives were ruined and their loved ones killed, the healthcare industry—PREPped against liability for any wrongdoing—generated hundreds of billions of dollars protecting Americans from COVID-19.[32] Many injured Americans, hopelessly adrift in an ocean of unaccountability and without financial support for uncountably expensive chronic medical care, understandably view the PREP Act and its CICP as a betrayal by their country.

113. The CICP is perversely underfunded, with the HRSA allocating a mere $5 million and $7 million for its administration in 2022 and 2023

[32] To take a single example, in the years 2021-2023, Pfizer and Modern reportedly enjoyed revenue from their COVID-19 vaccines of $110.2 Billion and $42.8 Billion, respectively. https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2021/performance/; https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2022/performance/; https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2023/; https://www.pharmaceutical-technology.com/news/moderna-reports-revenue-2021/; https://www.fiercepharma.com/pharma/moderna-covid-vax-scarfed-sales-184b-2022-company-says; https://www.reuters.com/business/healthcare-pharmaceuticals/modernas-2023-prelim-covid-vaccine-sales-meet-target-2024-01-08/ (last accessed March 24, 2024).

respectively.[33] Less than ten percent of these funds go to compensation, with over 90% used to administer the program itself.[34] The cost of administering the program so greatly exceeds the amount paid to injured applicants that, if the CICP were a private charity, it would appear fraudulent. Considering the central role of the CICP in America's overall COVID-19 policy (*i.e.* compensating those who have been harmed by America's response to COVID-19 and its many federal mandates) the CICP is, for all intents and purposes, *unfunded*. To properly perform a job of the magnitude the CICP has been mandated to perform, the CICP probably requires billions of dollars.

114. Given its unfunded and uncertain status, it is not surprising that the CICP only decided claims at an approximate rate of about 90 a month in 2023.[35] Nor is it surprising that the Secretary of HHS has failed to perform his duty to create a CICP COVID-19 injury table that would greatly expedite

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[33] *FY 2023 Operating Plan,* HRSA, https://www.hrsa.gov/about/budget/operating-plan (last accessed March 20, 2024).

[34] *See* J. Zhao, et al, *Reforming the Countermeasures Injury Compensation Program for COVID-19 and Beyond: An Economic Perspective*, Duke J. of Law & Biosciences, p. 2 (2022)

[35] *See*https://oversight.house.gov/wp-content/uploads/2024/02/HRSA_SSCP-Testimony-for-02.15.2024-Hearing.pdf (last accessed April 3, 2024).

the speed and certainty of CICP decisions and compensation. 42 U.S.C. § 247d-6e(b)(5)(A).

115. Since the CICP remarkably purports to immunize *itself* from liability — in the form of judicial oversight or even common-law mandamus relief — the Plaintiffs cannot seek relief from the courts when their claims are lost, delayed, or denied.[36]

116. Among victim advocacy groups and attorneys practicing in the complementary Vaccine Injury Compensation Program, the CICP is perceived as a waste of time; in other words, the CICP claims process is an exercise in futility. At this point, it seems the only people who bother filing a CICP claim are those who need to make a record of due diligence, or those who are acting for other personal purposes (such as meeting some emotional need).

117. As designed, the CICP does not survive rational basis review.

118. The CICP's unconstitutional design cannot be remedied by

[36] 42 U.S. Code § 247d–6d(7) ("No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection").

severing the offending parts of the statute.

The Plaintiffs' Common-Law Claims and CICP Filings

Facts Common to All Plaintiffs

119. The Plaintiffs have obtained medical opinions from qualified healthcare professionals causally linking the injuries to the COVID-19 vaccines.

120. If the PREP Act did not bar their common law claims, access to court, and their right to a fair jury trial, the Plaintiffs have and would bring common law claims against various parties.

121. The Plaintiffs' common law claims include, but are not limited to: battery, fraud in the inducement, fraud, conspiracy, products liability, negligence, malpractice, and wrongful death.

122. Many, if not all of Plaintiffs' common law claims would be subject to federal jurisdiction via diversity of the parties. For one, all the parties are jurisdictionally diverse from the companies that designed the injection products, and all their damages exceed the jurisdictional threshold of $75,000.00.

123. Whether or not they submitted a CICP claim, all Plaintiffs believe

the CICP claims process to be futile.

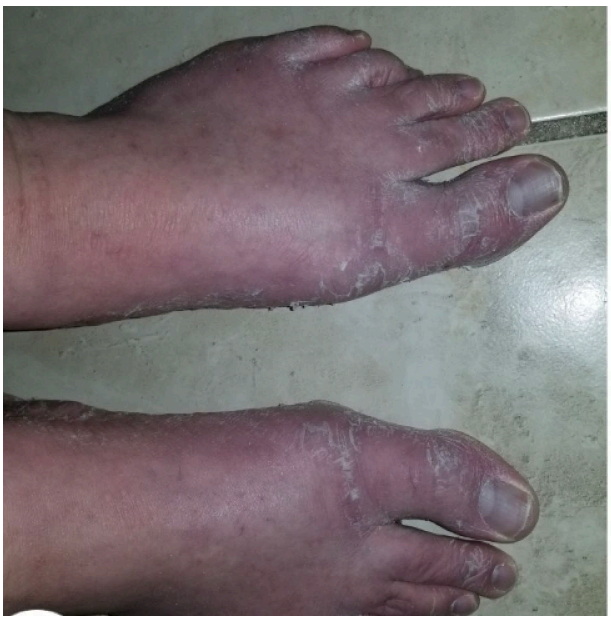
124. The Plaintiffs have substantial evidence establishing their injuries were proximately caused by a covered countermeasure.

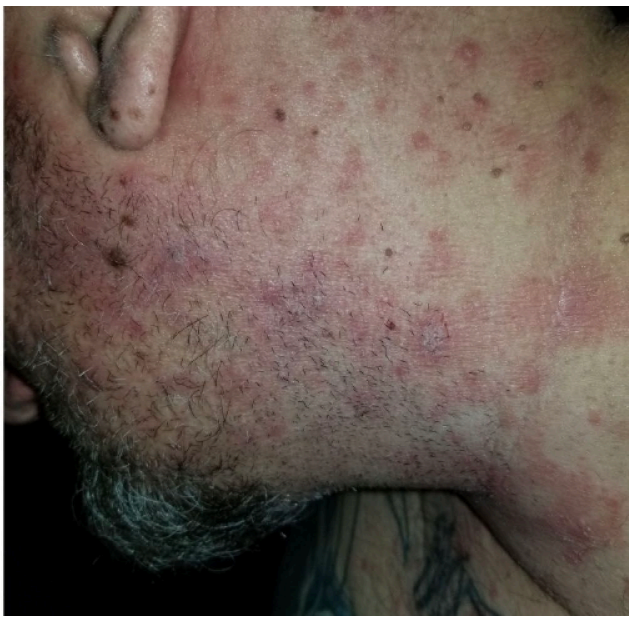
125. Of the Plaintiffs who submitted CICP claims, none have received any meaningful response.

126. Although several Plaintiffs have submitted paperwork to preserve their claims, none consent to the jurisdiction of the CICP tribunal.

Jeff Jackson

127. **Plaintiff Jeff Jackson** is 49 years old. He lives in Lucedale, Mississippi.





128. He took two Moderna shots in the late summer/early fall of 2021. Before receiving his shots, Jeff was extremely active. He worked as a cell phone tower technician, routinely climbing from 150 to 400 feet up cell phone towers where he worked for 12-hour shifts, suspended from a harness. After work he usually went to the gym to exercise. On weekends, he commonly took on additional work hanging dry wall.

129. Jeff's parents are in their 70's. They have no one but Jeff to care for them. Jeff did not particularly want to be vaccinated, but many people in Jeff's small-town community urged him to receive the shots to protect others, particularly his parents. The tragic irony is that now that the COVID-19 vaccinations have ravaged Jeff's body, he cannot even care for himself, much less his parents.

130. Jeff took his first shot on August 2, 2021, and his second on September 28, 2021. On the day of his second shot, he had taken his mother to Walmart to go grocery shopping, stopping at the in-store pharmacy for his vaccination while he was there.

131. They arrived back at his mother's home about 20 minutes later. He was unloading the groceries from the car when he started feeling hot.

His mother was startled to see the back of his arm, neck, and shoulder turning pink and purple down to the point of the shot. The place on his shoulder where the shot went in was burning hot, and when Jeff removed the band aid over the site to have a closer look, blood squirted out.

132. He called the pharmacist who had given him the shot, and she assured him that this maroon discoloration was a normal, temporary response that would soon go away. She suggested the rash was probably "Moderna Arm", which she explained was a common condition experienced by recipients of the Moderna COVID-19 vaccine in which the injection site becomes red and swollen.

133. Jeff went to sleep. When he woke the next morning, he had what felt like a terrible case of the flu. Within five days his skin began to peel off, a condition that got worse until he was shedding his own skin as if he had a severe sunburn. The condition covered his whole body, including his face. It was painful, involving lesions and pustules on his armpits and inner thighs and scabs all over his body. At the same time, his entire body discolored into various shades of pink and purple.

134. The year that followed was a nightmare. Jeff felt like a monster,

because he frightened people with his appearance. Any room he was in had to be cleaned after he left, because he left behind such a large volume of shedded skin. He dreaded going to the grocery store to buy food, because children would react badly on seeing him and would even sometimes cry.

135. When he first went to the emergency room to receive treatment, the treating physician was shocked by Jeff's appearance, and evaluated Jeff from the far side of the treatment room. He sent Jeff home from the ER with useless antibiotics.

136. Jeff quickly became homebound. He stopped seeing his children and grandchildren, concerned that he would frighten them with his appearance and that his condition could somehow be transmissible to them.

137. Since conventional medicine could not even diagnose him, Jeff experimented with various salves and tried using ultraviolet light to treat his skin condition. His peeling has now come partially under control, and his skin has largely returned to its natural color. He continues to suffer from a rash, which fluctuates in severity, on the back of his head, upper arms, and upper back. His skin has become baby-smooth and paper thin, easily tearing open if he stretches his body the wrong way. But, for the time being at least,

he is not visibly shedding skin, and he can go out in public without causing people to recoil on sight.

138. Jeff has been diagnosed with lichenoid dermatitis and plaque psoriasis. Alongside his skin disorder, Jeff developed joint problems after receiving the shots, and he has been diagnosed with psoriatic arthritis. He has great difficulty walking, and he has terrible pain in his legs and back, sometimes keeping him in bed for entire days at a time. He also suffers from weakness and numbness in his legs, and sometimes while standing he will collapse to the ground, because his legs suddenly give out, losing all strength and sensation.

139. Jeff's teeth have become brittle, breaking apart under pressure. He has developed temporomandibular joint dysfunction, causing him jaw pain and bleeding gums. He recently received dentures to replace his crumbling teeth, a procedure that involved peeling back his gums and inserting screws into the bone to anchor the dentures.

140. Jeff occasionally blacks out, coming to without any idea what has happened to him.

141. Jeff cannot work and is trying his best to live on $1,300.00 a

month from Social Security payments. He is grateful that he now has been able to secure Medicaid health care coverage because it means he has more resources to receive regular health care treatments for his conditions.

142. Even beyond the physical and financial consequences Jeff experienced from his vaccine injury, the greatest suffering of all has been emotional, as Jeff has lost his community of friends and has largely been cut off from his family.

143. Jeff submitted a CICP claim to HRSA in early 2022, and the CICP administrators confirmed receipt of his claim on March 18, 2022. But that was the last he has ever heard about his claim. In September of 2022, he called the HRSA and spoke with a CICP representative who explained that the program was experiencing backlogs and that they would get to Jeff's claim as soon as they could. Jeff has since called on several other occasions to check on the status of his claim but, at this point, Jeff is unable to get the CICP administrators to return his calls.

Michelle Utter

144. **Plaintiff Michelle Utter** is 54 years old. At the time of her vaccination, she was working at the surgical nursing unit at Advent Health

in Daytona, Florida.

145. Advent Health mandated that she receive the COVID-19 vaccine. Had Michelle refused, her employment would have been terminated.

146. Before Advent Health's vaccine mandate, Michelle was in fantastic shape and perfect health. She was training for a Spartan Race, which is an organized, long-distance race over an obstacle course. She ran three to six miles a day and participated in CrossFit training.

Before


After, while receiving IVIG infusions

147. Michelle took her first shot on December 22, 2020, and fell sick for two weeks. She had inflammation throughout her body, restless leg

syndrome, and flu-like symptoms.

148. When it came time for her to take a second dose, she was hesitant, based on her experience with the first shot. However, the pharmacist at Advent Health scheduled to administer her shot assured her she would be fine, as did several of her other colleagues. Eventually, she relented.

149. Immediately Michelle realized she had made a tragic mistake. Moments after her second dose, she felt deeply fatigued and weak. She just wanted to go home and go to sleep.

150. She walked outside the hospital, where her condition got worse. She sat down on the curb of the hospital parking lot. Her legs started aching and her body felt like it was on fire inside. She felt invisible pins sticking through the skin of her legs.

151. She managed to get up and made it to her car, driving herself home. Her symptoms got worse. Her limbs became inflamed and swollen. She walked into her house with great difficulty. It was still first thing in the morning, but still she laid down and fell asleep.

152. She woke up 24 hours later. Her entire body was badly swollen,

and she felt like heavy weights were pressing down on her hips. She could not move her hands at the wrists because of how swollen her arms were.

153. Michelle tried to climb out of bed but collapsed on the floor. For a time, she lay on the floor crying, and then she crawled and drug herself to the bathroom, standing up by slowly pulling herself up on the bathroom counter. Her legs felt like they weighed 100 pounds each.

154. What began that day as an acute vaccine reaction has evolved into a state of chronic suffering. Michelle was diagnosed with chronic inflammatory demyelinating polyneuropathy ("CIDP"). CIDP is a neurological disorder characterized by progressive weakness and impaired sensory function in the legs and arms. CIDP is caused by damage to the myelin sheath, the protective covering that surrounds nerve fibers, due to an autoimmune response.

155. Michelle suffers from constant chest pain, a stabbing sensation in her legs, tinnitus, heart palpitations, tremors, vascular issues, micro clotting in her blood, and Mast Cell Activation Syndrome. Walking is difficult, painful, and exhausting.

156. Since July 2021, she has received monthly infusions of

intravenous immunoglobulin ("IVIG"), a biological agent used to manage immunodeficiency and other conditions. The IVIG sessions last six hours, during which time she has an intravenous injection in her arm. Because of all the damage from the extended infusion sessions, she now has trouble using her right arm.

157. In late 2023, healthcare professionals at her IVIG lab observed that her blood was becoming abnormally thick and dark. This condition arose from micro-clotting in her blood, for which she now sees a specialist in Alabama.

158. For some unknown reason, tests show that her body still produces the COVID-19 spike protein, a vaccine artifact.

159. While the IVIG infusions are painful, they are the only thing that has given her even partial relief from her symptoms. She can now usually ascend and descend the stairs to her second story apartment with great difficulty, as well as enter and exit her car with much effort. Prior to the IVIG injection, however, Michelle had to ascend the stairs to her apartment by sitting on each stair and lifting herself to the next, one by one. And getting into her car was such a time-consuming and painful task that she stopped

driving completely.

160. Earlier this year, Michelle's IVIG treatments stopped because she lost the insurance coverage that had been provided by her previous employer.

161. Michelle does not take pain medications, for fear of addiction.

162. Michelle's three sons are all in the Navy. Shortly after she took her second shot, her middle son took a 7-month leave of absence from his station in Japan and moved in with Michelle to take care of her. She has no insurance, and she is seeking social security disability benefits so that she will have some income. She has burned through much of her savings and may soon be evicted from her apartment.

163. One of the hardest things for Michelle is the toll her condition has taken on her personal relationships. She lives in a small town where she grew up, and when people see her now they look at her and treat her differently.

164. Before her vaccine injury, Michelle was active in CrossFit, Spartan Races, martial arts, and she was always at the gym. In her own words, "you couldn't stop me."

165. One of her favorite things to do was exercise with her sons. She had helped each of them to train before they had gone off to Navy boot camp, and it was one of the most important ways she related to her boys.

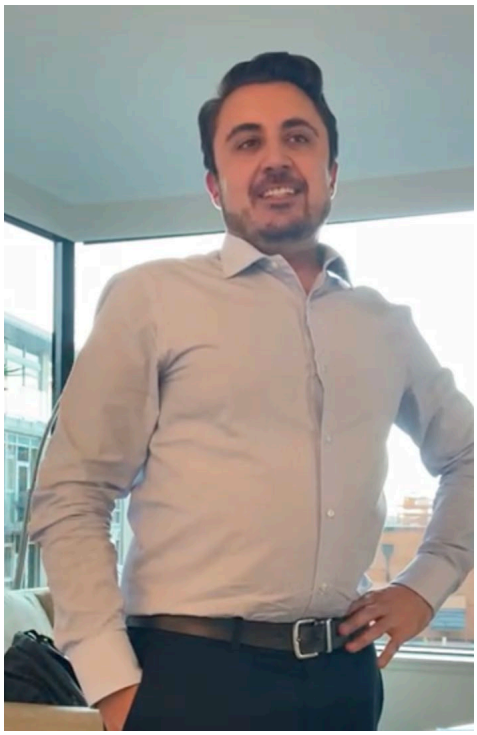
166. Once, after her injury, while one of her sons was visiting, he had forgotten about her condition and asked if she wanted to go to the gym with him to work out together. And then he remembered that she was no longer able to do that. In Michelle's words, "[i]t's hard when you have one of your sons look at you and you're mom, but you're not mom. I lost that connection with them."

167. Michelle's CICP application was received on October 27, 2021, per her phone call to the program confirming its receipt. In March of 2023, she received a FedEx package from CICP administrators notifying her that her case had gone into review and requesting additional health records. She did her best to provide what had been requested. For a long time, she did not hear anything, though she called monthly to confirm her case was still being reviewed. She had no idea who was looking at her records or the basis on which they would make their decision. In February of this year, she received a letter from the CICP denying her claim.

168. Originally, Michelle believed that the CICP would provide her the support she needed to pay for her health care and deal with her loss of work. Now that she has spoken to others who have applied to the CICP, she knows of the CICP's long wait times, astronomical rejection rate, and inconsequential payouts. She now believes receiving any meaningful support from the CICP is unrealistic. She has started to lose everything she owns because of mounting medical bills, and she has no further recourse for her injuries.

Henrietta and Adelio Simoes (Victor)

169. **Plaintiffs Henrietta Simoes and Adelio Simoes** were the parents of Victor Castillo Simoes. Victor passed away on May 6, 2021, at 3:15 a.m. in an emergency room in Seattle, Washington. He was 34 years old.



Victor on the eve of his death

170. Victor received his only COVID-19 vaccination shot on April 20, 2021. Victor was young and healthy at that time.

171. Prior to his death, Victor was a talented young man with most of his life ahead of him. He had earned a BA from Boston College and an MBA from the Kellogg School of Management at Northwestern University.

172. His family and many friends fondly recall his generous and helpful nature. While in college, though he had very little money, he started and funded a yearly scholarship for students at his former high school. The 2021 check for that year's scholarship had just been received by the school in

the weeks before he passed. After his undergraduate studies and while employed full-time at JP Morgan, he volunteered as the CFO of a charitable organization focused on helping disadvantaged children improve their reading skills, recruiting some of his friends to help with the tutoring.

173. Upon graduation from business school, he helped launch two startups involved in developing medical products – one to treat breast cancer and the other for orthopedic applications.

174. In August 2020, Victor accepted an executive-level position with Amazon, and on the night he passed, he was temporarily in Seattle, where the company is based.

175. Victor had spent the evening of the night he died at dinner with his girlfriend to celebrate a promotion she had received that day. He began to feel poorly after they returned home. He thought maybe he had eaten something at the restaurant that had made him sick, and he went to bed.

176. He woke his girlfriend in the middle of the night. He had already dressed and had called an ambulance to go to the hospital. He had chest pain, jaw numbness, and his heart was racing. Readings on his Apple Watch after his death show that his heartbeat exceeded 190 beats per minute.

Victor went downstairs to meet the paramedics, telling his girlfriend that he would contact her from the hospital.

177. She followed him downstairs, and when she arrived, the paramedics had sat Victor down on a street-side bench to take his blood pressure and vital signs. Victor introduced his girlfriend to the paramedics, then immediately experienced a seizure and passed out.

178. The paramedics unsuccessfully attempted to revive Victor and then rushed him to the hospital emergency room. Further efforts to revive him in the ambulance and at the emergency room were also unsuccessful. Victor passed away that night, dying from a thoracic rupture to his aorta.

179. His parents were devastated. Aside from his recent vaccination, nothing in Victor's medical and family history provided any explanation for his sudden aortic dissection. The autopsy, too, failed to identify a cause.

180. A histological pathology report found that Victor suffered from myocarditis and pericarditis (both inflammatory reactions), had never had COVID 19, and found spike protein in his aorta (which could only be the result of the COVID-19 vaccine).

181. Victor had been very close to his family, and he had regularly

traveled home to visit his parents, siblings, and grandparents, who all live close to each other on Long Island. Victor's two younger siblings looked up to him as a mentor. He was their go-to person on many issues young people face, including when they needed career guidance. The night of his death, Victor and his girlfriend had discussed their wedding and their future together. He and his siblings, who were also planning families, had often discussed and looked forward to raising their children together.

182. The day before his death, Victor spoke to his parents, brother, and several of his friends by the telephone. He was in great spirits and excited about the future. As Henrietta describes it, "I felt like he never left home. He loved us and we loved him. This has destroyed us."

183. Henrietta still goes to sleep crying and wakes up crying every morning because she must face the day without Victor in the world. And Adelio visits Victor's grave every day, rain or shine. Theirs is a surreal existence. They still cannot process that their son is gone.

184. Prior to his vaccination, Victor was fearful he would catch COVID-19 and then transmit it to his elderly grandparents. He decided to be vaccinated, believing it would help protect his grandparents and other

vulnerable loved ones from COVID-19.

185. Henrietta and Adelio familiarized themselves with the CICP and concluded the novel nature of the vaccine meant that much was still unknown about its risks; that the one-year time-period within which to file a claim was simply too short; and that the medical proof they needed would not become available within such a short window of time. Indeed, it took them well over two years to obtain it. They also understood the bureaucratic and opaque nature of the CICP, and they were not emotionally and psychologically prepared to grapple with a faceless bureaucracy over, at most, a pittance in payment, nor suffer the indignity of having unknown arbiters adjudicate the legitimacy of Victor's claim at a time when many of the vaccine's adverse reactions were still not publicly known.

Elizabeth Brown (Daniel)

186. **Plaintiff Elizabeth Brown** was married to Daniel Brown. Their relationship began at age 19 and spanned 11 years before their marriage in 1993. Residing in Long Island, they shared their home and life with their three beautiful children. Their journey together extended over 39 years before it was painfully and prematurely ripped away. Elizabeth lost her

husband and their children lost their father when Daniel died on October 30, 2021, from complications due to a COVID-19 vaccine shot.

187. Elizabeth ("Liz") and Daniel had each received two vaccine shots in April of 2021. They trusted official government statements that the COVID-19 vaccine shots were safe and effective, and they believed side effects from the shots were minimal and rare.

188. For Liz, observable side effects from the shots were minimal. Tragically, Daniel was not as fortunate.

189. Four to five days after his second shot, Daniel started to experience night sweats several times every night, accompanied by a high fever. Daniel also experienced swollen lymph nodes and swelling in his abdomen and spleen. He was soon admitted to the hospital, where his doctors suspected Lymphoma. He took a battery of tests, including biopsies of his lymph nodes, four spinal taps, CAT scans, PET scans, and others, but all of them came back negative for Lymphoma or cancer.

190. Over the next 66 days, Daniel remained in the hospital, but continued to decline. His doctors were baffled. They could not diagnose his condition or do anything to treat his symptoms. Liz was confronted with the terrible helplessness of knowing she was watching her husband die.

191. Liz felt that Daniel was falling through the cracks of the large healthcare system in which he was hospitalized, and it tore her and her children apart. She compiled detailed daily notes of his treatment to improve coordination of care and to provide resources for exploring alternative potential diagnoses, since the theories pursued by his physicians thus far had been incorrect.

192. Finally, Daniel was seen by a specialist physician and academic,

who diagnosed him with hemophagocytic lymphohistiocystosis ("HLH"), a life-threatening, hyper-inflammatory disorder that she believed was caused by the COVID-19 shots Daniel had received. This physician would later publish a case study in the BMJ medical journal concerning Daniel's case along with another patient she had treated with a similar response to the vaccine.

193. She changed Daniel's treatment regimen, putting him on a heavy regimen of steroids and etoposide treatments. Some of his blood work temporarily improved, and he was released from the hospital.

194. After discharge, Daniel returned to his home with Liz and his children. He remained there for approximately six weeks, attending weekly appointments with the specialist. But even after returning home, it was clear something was wrong. As Liz describes it, "he was here, but it wasn't him. . . his body had been so badly ravaged."

195. Daniel never tested positive for COVID-19, but for some reason, his COVID-19 antibody levels were high, exceeding the maximum level on available tests. Week after week, those levels stubbornly refused to drop. According to his doctor, it was as if his body kept making more and more

antibodies to COVID-19 for no reason at all.

196. As the weeks passed, Daniel felt worse and worse. After about six weeks out of the hospital—near the end of September 2021—Daniel was attending a doctor's visit when he suddenly lost the ability to speak and collapsed. He was rushed to the hospital and intubated. He would never return to his home again.

197. After re-admission to the hospital, Daniel's blood tests showed his platelets were falling, requiring daily blood transfusions. Liz and the rest of Daniel's family worried that the new blood Daniel was receiving contained COVID-19 antibodies that could be harming him further. Daniel's oldest son was a match for Daniel's blood type, and he volunteered to donate his blood since he had not been vaccinated.

198. Daniel died two days before his son could give blood to try to save him. He passed away on October 30, 2021, at 60 years old. Liz recalls that in all, Daniel was in the hospital for 96 days and that she was there with him every single day.

199. At the time of his vaccination, Daniel was only several months from his planned retirement from GEICO, where he had spent his career. He

was excited about the future and, in his retirement years, he planned to join his brother and his younger son in running a lighting business.

200. Daniel loved being active outside, and he loved being around people. He would drop whatever he was doing to help family, neighbors, friends, and strangers. He never pursued acknowledgements or accolades, preferring instead to fly under the radar. And he was larger than life. Liz remembers that when she was out with him in their local community, they were always running into people who knew Daniel somehow or other. He waved to just about everyone and they waved back. Everyone seemed to know and love him.

201. Liz and Daniel's three children were advised not to receive COVID-19 shots because of the risk that their bodies would respond to the shots as Daniel's had. In their view, their father saved their lives, because they only avoided the COVID-19 shots because of what their father suffered because of taking the vaccine.

202. Liz says that not a day goes by that she does not hurt for the loss of her husband. In her own words, his premature death was wrong because "the only one that can call you home is God." Daniel was the love of Liz's

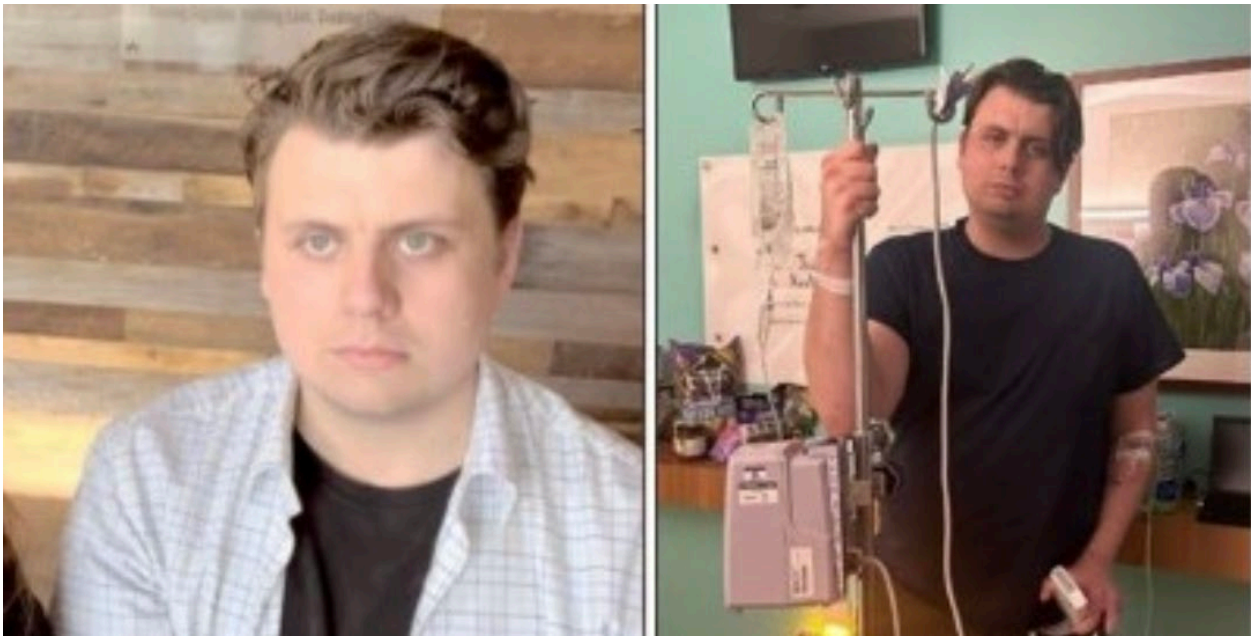
life, and she now finds it hard to live since she's lost her heart.

203. Liz contemplated filing a CICP claim. It seemed cruel to her that she would have to spend the first year after the devastating loss of her husband imploring a faceless bureaucracy to acknowledge that Daniel had died from a vaccine injury. Liz was aware the CICP process lacked transparency, did not allow for meaningful legal representation, had a shocking denial of claims rate, and had an average pay out insufficient even to cover a month's expenses.

204. She did not file a CICP claim because it would have been futile.

Cody Howard

205. **Plaintiff Cody Howard** is 24 years old. He is currently a college student, and he still hopes to eventually be an English professor/teacher and to be an author.



206. At the end of July 2021, Cody received his second COVID-19 vaccination shot. Within a week, a rash appeared on both his arms, and then his feet, spreading to other areas of his body. He then developed pain in his right leg, increasing slowly at first until, by the end of September, he was having trouble walking.

207. One evening around that time, Cody woke up in the middle of the night coughing up blood. He was rushed to the hospital where he was diagnosed with a pulmonary embolism. Both of his lungs were bleeding, most severely on the right. He also had a leaking heart valve and an inflamed left ventricle.

208. According to the physician that saw him, Cody had suffered a

catastrophic reaction to the vaccine. A hematologist ultimately diagnosed him with antiphospholipid syndrome ("APS"), an immune disorder resulting in the production of antibodies that attack the body's tissues, causing blot clots to form in the arteries and veins. According to his doctor, if Cody had not been exercising strenuously five days a week before getting sick, he almost certainly would not have survived that first trip to the hospital.

209. Cody was released from the hospital, but his health has remained critically precarious. He has remained largely confined to a bed since October 2023, because he cannot walk more than 50 feet at a time, and he needs assistance moving around. When he walks, he uses his cane, suffering regular falls. For distances of more than 50 feet, he is forced to use a wheelchair or scooter. If he is not treated with powerful steroids or immunosuppressants and blood thinners, he gasps for air like a fish out of water, and his lips, toes, and fingers turn blue. He has been in and out of the hospital ever since his pulmonary embolism, and he has been diagnosed with a host of other conditions, including the recent discovery of a partial thrombosis of the brain in the vein that allows deoxygenated blood to leave

his brain. This condition was caused by Cody's APS blood clotting disorder. Cody was also diagnosed with a large frontal lobe stroke and narrowing of the veins (stenosis) in the left side of his brain, also caused by his APS blood clotting disorder.

210. In case his brain thrombosis worsens or additional blood clots occur, Cody has signed powers of attorney to his parents, so that they can manage his affairs if he is mentally incapacitated.

211. To survive with "high risk" or "triple positive" APS (the variety of APS from which Cody suffers), Cody must take medicines to reduce the risk of stroke and blood clots. A common problem for patients suffering from "high risk" or "triple positive" APS is that their bodies stop responding to clot-preventing medicines, a phenomenon referred to as "failing". Eliquis originally worked for Cody, but his body ultimately failed Eliquis. His body has also failed Warfarin so it, too, no longer works to help prevent Cody from developing blood clots. His current medicine has now largely stopped working as well, though he continues to take it for any benefit that it can provide. He has been referred for use of a cancer drug off label, in an attempt to treat his APS, but he does not know whether and for how long it will

work, or whether he will be able to find a replacement if his body fails this new medicine too.

212. In addition to blood clotting, and the related need to take blood thinners to live, APS can also cause excessive bleeding due to the possibility of recurring thrombocytopenia (bleeding complication), such that every day Cody must check his gums, nose, and the whites of his eyes for signs of bleeding to ensure his blood has not become life-threateningly thin.

213. When Cody became sick, his family was planning to move to Arizona, where his father had taken a new job. They had already sold their Florida home and purchased a new one in Arizona.

214. But Cody's vaccine injury upended everything. As his mother Heather says, "we had to drop everything and save Cody's life".

215. Cody's father gave up his job in Arizona, and the family sold their new Arizona home at a large financial loss. The medical bills are mounting, and Cody's family is struggling to stay out of debt.

216. Of course, Cody has paid the highest price of all. He has lost the ability to care for himself independently, and he has lost most of his friends. Because of his limited mobility, multiple hospitalizations, and chronic

fatigue, he has been unable to maintain most of his relationships, leaving him without a community when he needs it most.

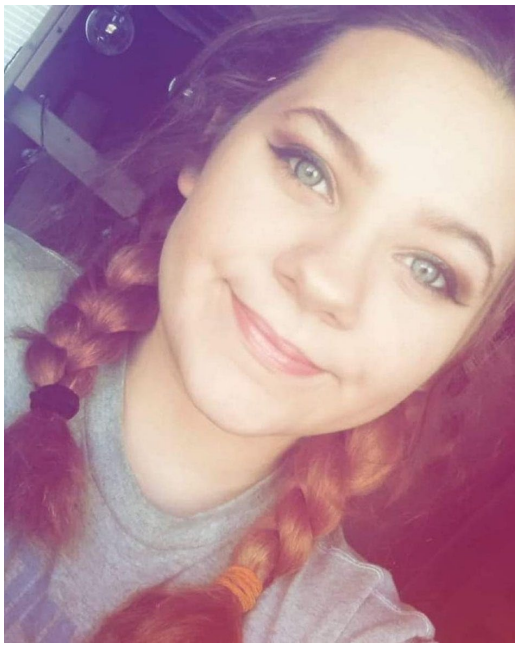
217. Because Cody's health remains uncertain, his and his family's future remains uncertain as well. For now, they are simply fighting to keep him alive.

218. Cody did not file a claim with the CICP because by the time he and his family learned of its existence, the one-year statute of limitation under the CICP had nearly run, and Cody and his family were consumed with treating his medical condition which, itself, was not yet fully diagnosed. Even if he and his family had had the time and resources to file with the CICP, they likely would not have because of its obvious futility: in particular, they cite the long wait times, inadequate compensation offered to successful applicants, unclear compensation parameters, and the unclear qualifications of the decision-makers.

Allen and Taylor Martin (Trista)

219. **Plaintiff Allen Martin**, and his wife, **Taylor Martin**, were the parents of Trista Martin. Trista passed away suddenly on November 9, 2022, 12 days after she is believed to have received her second COVID-19

vaccination shot. Trista was 18 years old.



220. Trista took her first shot on July 20th, 2022. When Trista received her first shot, her doctor conducted a physical and ordered a complete blood panel that showed Trista was in excellent health except for a slight Vitamin D deficiency. Shortly thereafter, she started showing symptoms, sleeping more and periodically reporting her vision going black when she stood up. She mentioned experiencing nausea after eating, and lost weight. But Trista, who rarely complained, did not seem concerned about these issues, and so Allen and Taylor did not worry much about them either.

221. On October 28, 2022, Trista returned to the same doctor who had

given her the first vaccine shot—Dr. Athena Mason. The medical records from that day's visit are incomplete and unintelligible, and Dr. Mason remains stubbornly uncooperative, so Allen and Taylor cannot say with certainty that Trista received her second shot that day. But that is the most likely explanation for her return to Dr. Mason's office.

222. It was an exciting time in Trista's life, because she had recently turned 18 and had been promoted to assistant manager at her restaurant job. She loved children, and her goal was to become a child psychologist or a social worker and to adopt foster children. After she died, Allen and Taylor found under Trista's bed a "bucket list" she had put together. It contained 66 things she wanted to do in her life, including turning 18 (so that she could give blood), becoming a mother, and adopting a teenage foster child, since teenage foster children were so often overlooked.

223. On the night before her death on November 9, 2022, Trista and her stepsister, who was also her best friend, had spent the night at the home of a mutual friend watching movies.

224. When she woke in the morning around 8:30 a.m., Trista reported that her body ached all over and that she was having trouble breathing.

According to her friend and her stepsister, Trista appeared unstable on her feet. Trista lay back down to see if she would start to feel better.

225. Ten minutes later, Trista's stepsister and friend went in to check on her. Trista was unresponsive and they could not wake her up. They called Taylor, who was only minutes away at the time. Taylor rushed over to find that Trista was not breathing. While waiting for the ambulance, Taylor conducted CPR on her daughter, following instructions from the 911 operator.

226. Allen first became aware of what had happened when Taylor called. She told him it was about Trista, that it was an emergency, and that he needed to get to the hospital.

227. The hospital, Saint Francis, is an enormous, sprawling facility with over 1,100 beds. But as soon as Allen entered the emergency room, a desk nurse approached him and asked simply, "are you dad?"

228. The nurse took him to Trista. She was connected to various tubes and machines. Her skin was gray, and her eyes were partially open. The first thing Allen thought when he saw Trista was that she was gone.

229. Hospital staff continued to work on Trista throughout the long

day, but at 5:05 p.m. pronounced Trista dead. Her doctors could not explain it. Trista's toxicology reports were clean, she had no preexisting conditions, and she had no known congenital defects.

230. Trista's autopsy returned a cause of death of "undetermined." She had suffered pulmonary embolisms and a heart attack, her veins had thickened, and her bowel was so inflamed that a portion of it had begun to necrotize.

231. After Trista's death, Allen and Taylor began gathering the records they would need to file a claim with the CICP.

232. They had no idea the challenges they would confront simply trying to obtain records of Trista's recent medical history.

233. Allen and Taylor first requested Dr. Athena Mason's office provide them Trista's medical records on March 7, 2023, via certified letter. Originally, they were told someone was gathering the records, and that Allen should come to the office to sign a HIPPA release, which he did. However, Dr. Mason's office soon began to drag its feet, and when Allen called to follow up on April 17th and April 28th, he was told that they were still in the process of gathering the materials and that the records should be

ready very soon. When he called again on May 15th, the receptionist informed him that a company called CIOX maintained the office's records, and that to obtain Trista's records, he would need to contact CIOX. She also told him to stop calling the office directly.

234. That same day Allen left a phone message with CIOX and submitted an electronic request for records via their website. Eleven days later, Allen and Taylor received a packet from CIOX containing records from when Trista was 5 years old, partial records from Trista's treatment at Saint Francis Hospital, and a single, nearly blank page from Dr. Mason's office. Although Allen and Taylor's independent records confirmed that Trista had been vaccinated at Dr. Mason's office on July 20, 2022, documentation of the July 20, 2022, visit was nowhere to be found in the records they had received.

235. On June 21, 2023, Allen and Taylor filed a complaint with the Oklahoma Board of Osteopathic Examiners regarding Dr. Mason's failure to provide them Trista's medical records. The Chief Investigator called Allen and Taylor to inform them that Trista was never in Dr. Mason's office on July 20, 2022. When Allen and Taylor protested that they had Trista's vaccine card signed by Dr. Mason dated July 20, 2022, the Chief Investigator told

them that was not sufficient proof, and that "doctors do not lie and do not hide records."

236. The next day, Allen and Taylor sent the Chief Investigator their insurance company billing records showing indisputably that Dr. Mason's office had billed for a visit by Trista on July 20, 2022. Dr. Mason lied.

237. The following day, Dr. Mason's office finally relented and provided Allen and Taylor the medical records of their deceased daughter.

238. Disappointingly, the records were still incomplete, and the handwriting on what records were provided is largely in unintelligible script. No informed consent form regarding the COVID-19 shot appears anywhere in the records Allen and Taylor were provided.

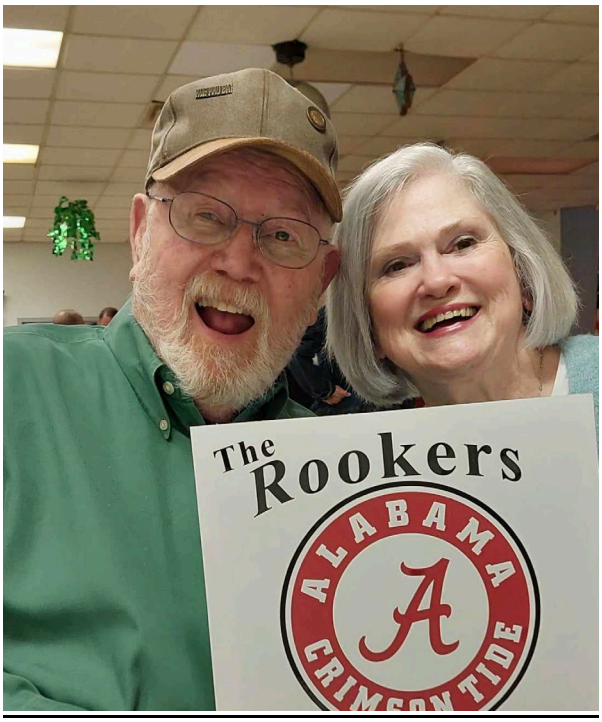
239. The Martins nearly did not file a CICP claim at all because they had been told by so many other people that the CICP was a sham, and that filing was pointless. However, they decided to try, and their CICP claim was delivered on October 10, 2023, as confirmed by U.S. Postal Service (the "USPS") records. Allen called HRSA to follow up on February 26, 2024, and he was told that no claim number existed for Trista and that no claim package had ever been received from the Martins. Allen and Taylor filed a

second time, again confirming delivery of their claim package through USPS records, this time on February 29, 2024. Allen called HRSA again in March, when he was again informed that no claim package had ever been received. In April, he called again, and was informed that the application finally had been received and was in the queue for review.

240. Allen, Taylor, and Trista's siblings are heartbroken. They were so proud of Trista and loved her so much. Tragically, so many items on Trista's "bucket list" will forever remain incomplete. Allen and Taylor are trying to move on with their lives in loving memory of Trista, working to pay off the funeral bills and saving money to purchase the pedestal that will decorate Trista's graveside.

La Nedia Rooker (Larry)

241. **Plaintiff La Nedia ("Nedia") Rooker,** Lawrence ("Larry") Rooker's widow. Larry died from an injury caused by a covered countermeasure on January 19, 2024.



242. Nedia and Larry had both decided to be vaccinated in 2021 at the urging of their physicians. They were both over seventy at the time, and their doctors insisted that receiving the COVID-19 shot was a matter of life and death for them.

243. Trusting their doctors' assurances that the COVID-19 shots were safe and effective, they received two rounds of shots and then, in December of 2021, an additional booster. About three months later, Larry started to, as Nedia put it, "zone out." The first time she recalls this happening, they were together in their car, and Larry was driving. He suddenly stopped responding to her, staring blankly straight ahead. She was able to get the

car to the roadside, but when she got out of the car to take his place as the driver, he suddenly pushed the accelerator, nearly running her over.

244. Nedia would later learn that Larry was having a seizure, the first of many. In the following months, he began to have tremors and then to collapse regularly, losing consciousness for no reason at all.

245. By late 2022, he was having to be regularly hospitalized. At around this time, he attended his 12-year-old granddaughter's barrel racing competition. While there, he lost the ability to walk as a result of an extended seizure that continued until he could be taken to the hospital.

246. Larry's doctor concluded that his brain was bleeding and diagnosed him with cerebral amyloid angiopathy caused by the COVID-19 vaccine. Cerebral amyloid angiopathy is a rare condition involving the build-up of proteins on the walls of the arteries in the brain. It results in brain bleeding and dementia.

247. As 2022 became 2023, Larry's condition continued to decline. He developed severe memory problems, losing recollection of entire days. He took to mumbling to himself, and lost his sense of place, asking where he was. He became docile, following the suggestions and directions of Nedia

and his caretaker like a child. As Nedia describes it, "he was there, but he was not there. . . It's like I had become his mother."

248. Nedia wanted to put Larry into an assisted care facility in 2023, because she did not have the resources to properly care for him. But there was no money for that, and Nedia cared for Larry as best she could in their home.

249. Nedia remembers Larry as bright, knowledgeable, and well read. It broke Nedia's heart to see him decline. She recalls that he regularly bought her gifts and "never in 25 years of marriage had he forgotten my anniversary." As 2023 passed, however, Larry started forgetting important dates and, by the end, he often did not even recognize Nedia. "I have not heard I love you in a year," she recalled in late 2023.

250. Prior to retirement, Larry had had a long and adventurous career. He did two tours in Vietnam serving as the Crew Chief on Huey helicopters flying many dangerous missions. He owned several restaurants at various times, worked in the county tax assessor's office, and spent 12 years in a voluntary position with the local Sheriff's Department working on cold cases.

251. In their retirement, Nedia and Larry loved spending time with their children and grandchildren. They also loved reading history, travelling together to historical sites, and combing antique shops for interesting new finds. But as time passed, these activities became impossible.

252. Larry passed at home in Hospice care. Nedia was with him when he died. Larry had often spoken about how moved he had been at his own father's funeral by the playing of the song "Danny Boy", and Nedia held him and hummed the tune to him in the moments before he passed. After he died, Nedia held him for six hours to say goodbye. Larry is buried in Montevallo National Cemetery. Nedia arranged a small military funeral for him at which "Danny Boy" was played.

253. After Larry passed away, Nedia filed a CICP claim. She was distressed and angered by the short time frame provided for filing and the complicated forms that needed to be completed. She engaged a lawyer to help her file her claim, even though legal fees under the CICP are not reimbursed. As Nedia described it, the process was excessive to the point of being overwhelming. She enlisted the help of a friend with expertise in information technology to help her complete the online claim form. After a

loss like this one, she said "you are doing really well to pay your bills and care for your family" much less to complete a CICP application. On March 22, 2024, Nedia received confirmation that her application was received and assigned a corresponding claim number. Nothing has happened since. Nedia holds out virtually no hope of receiving any meaningful compensation from the CICP.

COUNT I

VIOLATION OF SEPARATION OF POWERS

254. Plaintiffs reincorporate paragraphs 1 through 253 above.

255. The PREP Act purports to eliminate all judicial oversight of its functions and the courts' jurisdiction over federal officials implementing it:

> **(7) JUDICIAL REVIEW**
> No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.

42 U.S. Code § 247d–6d(7).

256. The Constitution of the United States creates a three-branch federal structure to provide essential checks and balances between the branches.

257. The PREP Act attempts to improperly immunize the Legislative Branch from judicial oversight.

258. The PREP Act purports to give the CICP authority to adjudicate legal disputes, make judicial or quasi-judicial decisions, and carry out adjudicative processes such as taking testimony, weighing evidence, applying legal principles, and making determinations affecting the rights, duties, or interests of parties.

259. The PREP Act effectively collapses a citizen's state and common law claims into a single "claim" to be adjudicated by the CICP.

260. In establishing the CICP adjudicatory process, the PREP Act attempts to create an unfunded, poorly-conceived Article I tribunal.

261. The PREP Act oversteps powers typically reserved for the judiciary under Article III, not least by immunizing itself from judicial oversight.

262. By collapsing all other traditional claims into a single administrative claim against the government, the PREP Act purports to give the CICP virtually unlimited jurisdiction, broadly usurping the role of the Judiciary Branch.

263. Despite being outside the traditional judicial structure, the PREP Act's CICP tribunal must nevertheless provide aggrieved citizens with due process, fairness, and transparency.

264. The CICP does not provide due process, fairness, or transparency.

265. The CICP lacks safeguards ensuring independence, impartiality, and protection from undue influence. The PREP Act establishes no standards for professional conduct of the person or persons adjudicating CICP claims.

266. The CICP tribunal's decisions are not subject to review by any Article III court.

267. The CICP tribunal purports to adjudicate claims without consent of the parties. The CICP's "take it or leave it" approach forces parties to use the process or go away empty handed.

268. By creating an Article I tribunal, Congress cannot improperly deprive parties of their constitutional right to have their case heard by an Article III court for matters that fall traditionally under the judicial power defined in Article III.

269. The PREP Act effectively deprives parties of their constitutionally protected ability to have their private rights cases adjudicated by Article III courts.

270. The PREP Act substantively deprives parties of core Article III judicial power protections.

271. The CICP's subject matter, lack of consent provisions, claims preclusion, lack of appellate review, and its overall tribunal scheme improperly usurps the judicial power that must remain vested in Article III courts under the Constitution.

272. The PREP Act's CICP is an unconstitutional tribunal violating the constitutionally-defined separation of powers.

273. Declaratory relief is needed to resolve this controversy.

COUNT II

FIFTH AMENDMENT – PROCEDURAL DUE PROCESS VIOLATION

(Facially and As-applied)

274. Plaintiffs herein reincorporate paragraphs 1 through 253 above.

275. The Prep Act and the CICP implicate the following liberty or property interests of Plaintiffs:

a. Their interest in the category of common law rights encompassing the rights to bring common law tort claims for products liability, medical malpractice, and battery;

b. Their interest in the category of common law rights encompassing the rights to seek tort remedies for grievous bodily harm caused by another member of society;

c. Their interest in common law causes of action or other means of redress that allow citizens to be made whole for damages to their body and bodily autonomy; and

d. Their interest in being made whole under the CICP.

276. The risk of erroneous deprivation of these liberty or property interests is high as to the interests identified at paragraph 275(a)-(c) because the PREP Act, facially and as-applied, eliminates these interests, leaving Plaintiffs only an exclusively federal cause of action that can only be brought to the extent Plaintiffs' losses were caused by actions that fall within the definition of "willful misconduct" and can overcome the procedural hurdles for "willful misconduct" claims under the PREP Act.

277. The risk of erroneous deprivation of the liberty or property

interest identified at paragraph 275(a)-(c) is high, facially, because of its procedural inadequacies including the PREP Act's denial of Plaintiffs' right to confront witnesses in civil proceedings.

278. The risk of erroneous deprivation of the liberty or property interest identified at paragraph 275(d) is high, as-applied to COVID-19, because the CICP is unfunded and demonstrably cannot or will not make applicants whole for injuries that qualify under the terms of the CICP.

279. The government has no interest in impairing the liberty or property interests identified at 275(a)-(c) because removing such impairments would impose no burden on the government, but rather on private wrongdoers.

280. The government has no interest in impairing the liberty or property interests identified at paragraph 275(d) because maintaining such impairments results in a broad loss of public trust in the United States government and in the American health care sector's ability to perform its function, particularly in times of crisis.

281. Therefore, the PREP Act deprives Plaintiffs of their rights to procedural due process under the Fifth Amendment, both facially and as

applied.

282. Further, and separately, the PREP Act is unconstitutionally vague on its face because it fails to give affected citizens clear notice of what conduct is immunized from liability, what treatments or therapeutics are covered, what claims are precluded, or what injuries will be compensated. The Act allows the HHS Secretary to unilaterally define, on an arbitrary and chimeric basis, the "covered persons" and "covered countermeasures" to which liability immunity will extend.

283. Until and unless the Secretary issues a declaration, the scope of immunity under the PREP Act is undefined and unknowable to any "covered person." Even once a declaration is made, the Secretary retains authority to amend it, making the scope of immunity a constantly moving target.

284. Because the PREP Act allows the Secretary to define retrospectively and unilaterally the persons and therapeutics to which immunity will apply, "covered persons" lack fair notice of what conduct the Act will ultimately immunize from liability, what it will cover, what common law claims will be abolished, and who will be covered. This invites

arbitrary enforcement.

285. The PREP Act's vagueness leaves affected citizens, including the Plaintiffs, without clear guidance as to their potential rights, depriving them of due process under the Fifth Amendment.

286. Therefore, the PREP Act is void for vagueness under the Fifth Amendment's Due Process Clause.

287. Declaratory relief is needed to resolve this controversy.

COUNT III

FIFTH AMENDMENT – SUBSTANTIVE DUE PROCESS VIOLATION

(Facial and As-applied)

288. Plaintiffs reincorporate paragraphs 1 through 253 above.

289. The PREP Act has abolished certain categories of common-law rights in a sweeping way without a showing of compelling necessity or provision of a reasonable alternative remedy.

290. Among other constitutionally invalid categories of common law rights the PREP Act facially allows for the abolition of and, as-applied to COVID-19, did in fact abolish are:

a. the category of common law rights encompassing the

rights to bring common law tort claims for products liability, negligence, fraud, medical malpractice, and battery;

b. the category of common law rights encompassing the rights to seek tort remedies for grievous bodily harm caused by another member of society; and

c. the category of common law causes of action that allow citizens to be made whole for damages to their body and bodily autonomy.

291. The PREP Act also abolished constitutional rights encompassing the unqualified rights to live an undiminished physical life, to maintain bodily sanctity, to be free from bodily harm, and to life.

292. The government cannot make a compelling showing of necessity for abolishing these rights, because it cannot show that the COVID-19 treatments provided to Americans because of such abolitions were superior to the COVID-19 treatments they would have received without such abolitions.

293. The government has not provided a reasonable alternative

remedy for these abolitions because the CICP is procedurally infirm, unfunded, and demonstrably cannot or will not make applicants whole for injuries that qualify under the terms of the CICP.

294. Therefore, the PREP Act deprives Plaintiffs of their right to substantive due process under the Fifth Amendment both facially and as applied.

295. Declaratory relief is needed to resolve this controversy.

COUNT IV

FIFTH AMENDMENT – SUBSTANTIVE DUE PROCESS VIOLATION

(As-applied)

296. Plaintiffs reincorporate paragraphs 1 through 253 above.

297. The PREP Act, as applied to COVID-19, burdens the Plaintiffs' fundamental rights, specifically, their rights to bring common law causes of action for products liability, medical malpractice, negligence, fraud, and battery; their rights to seek tort remedies for grievous bodily harm caused by another member of society; their rights be made whole for damages to their body and bodily autonomy; and their fundamental rights to live an undiminished physical life, to maintain bodily sanctity, to be free from bodily harm, and to life.

298. These rights are deeply rooted in our nation's history and implicit in the concept of ordered liberty.

299. The provisions of the PREP Act that burden these fundamental rights do not further a compelling governmental interest, and even to the extent they do, they are not narrowly tailored to achieve that interest.

300. The only thing incentivized by the scope of immunity in the PREP Act is recklessly or knowingly bringing to market countermeasures that were either known to be unsafe or for which the safety was unknown.

301. Government mandates, public pressure campaigns, and government protocols caused broad use of "countermeasures" regardless of—and in some cases despite—their utility. Under such circumstances, the only economic incentive was for producers and manufacturers to bring products to market quickly, regardless of their safety and efficacy.

302. Meaningful regulatory hurdles to countermeasure approval were removed during the pandemic, such that there was no legitimate basis to believe that new, insufficiently tested products would do more good than harm.

303. The government does not have a compelling governmental

interest in providing liability protection for healthcare products and devices that are not more likely to help Americans than to harm them.

304. The government does not even have a rational basis to provide liability protection for healthcare products and devices that are not known to be more likely to help Americans than to harm them and, therefore, the immunities from liability contained in the PREP Act are not rationally related to a permissible government objective.

305. Therefore, the PREP Act deprives Plaintiffs of their right to substantive due process under the Fifth Amendment, as applied.

306. Declaratory relief is needed to resolve this controversy.

COUNT V

SEVENTH AMENDMENT
VIOLATION OF RIGHT TO JURY TRIAL

307. Plaintiffs reincorporate paragraphs 1 through 253 above.

308. The causes of action Plaintiffs would seek to bring in the absence of the PREP Act are "suits at common law" for the purposes of the Seventh Amendment to the U.S. Constitution, that would be brought in federal courts under diversity jurisdiction.

309. Plaintiffs are thus constitutionally entitled to jury trials for the

common law causes of action they would seek to bring in the absence of the PREP Act, and the PREP Act unconstitutionally deprives them of this entitlement.

310. Therefore, the PREP Act deprives Plaintiffs of their Seventh Amendment right to trial by jury.

311. Declaratory relief is needed to resolve this controversy.

COUNT VI

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

312. Plaintiffs reincorporate paragraphs 1 through 253 above.

313. The Administrative Procedure Act ("APA") provides that a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

314. The Secretary of Health and Human Services' actions in implementing the PREP Act, including but not limited to the issuance of the Emergency Declaration and subsequent amendments, constitute final agency actions subject to judicial review under the APA.

315. The Secretary's actions in implementing the PREP Act are

arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law for the following reasons:

a. The Secretary failed to provide a reasoned explanation for the broad scope of liability immunity granted under the Emergency Declaration;

b. The Secretary failed to consider important aspects of the problem, including the potential for harm to individuals receiving covered countermeasures and the lack of adequate compensation through the CICP;

c. The Secretary's actions are not rationally connected to the facts found and the choices made, particularly with respect to the breadth of immunity granted and the limited compensation available through the CICP;

d. The Secretary failed to respond to significant comments and concerns raised by stakeholders regarding the implementation of the PREP Act; and

e. The Secretary's actions exceed the statutory authority granted under the PREP Act by interpreting the Act's

provisions in an overly broad manner.

316. The Secretary's actions have caused Plaintiffs to suffer legal wrong and to be adversely affected and aggrieved within the meaning of the APA. 5 U.S.C. § 702.

317. Plaintiffs have no other adequate remedy at law to address these violations of the APA.

318. Therefore, the Secretary's actions in implementing the PREP Act should be held unlawful and set aside under the APA.

319. Declaratory and injunctive relief is needed to resolve this controversy and prevent further harm to Plaintiffs and others similarly situated.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request this Court enter judgment in Plaintiffs' favor and:

A) Enjoin the PREP Act;

B) Enjoin the Secretary from taking any further actions to implement the PREP Act in a manner inconsistent with the APA;

C) Declare that the PREP Act is unconstitutional for the reasons

described herein;

D) Declare that the Secretary's actions in implementing the PREP Act violate the APA;

E) Set aside and vacate the Secretary's Emergency Declaration and subsequent amendments;

F) Declare that Plaintiffs may proceed with their common-law claims in state or federal venues, as appropriate;

G) Toll or extend the statutes of limitations of the Plaintiffs' common-law claims by holding that their causes of action accrued on the date of the judgment;

H) Award attorney's fees and costs pursuant to 28 U.S.C. § 2412 and any other applicable authority;

and order any further relief this Court deems fair and just.

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Dated this 25th day of June, 2024.

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