UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

JESSICA SMITH; JOEL WALLSKOG, M.D.; THEODORE CABANISS, on behalf of his minor son, T.C.; and ELIZABETH THIELE, M.D., Ph.D.,

Plaintiffs,

v.

UNITED STATES OF AMERICA; JOSEPH R. BIDEN, JR., in his official capacity as President of the United States of America; UNITED STATES HEALTH RESOURCES AND SERVICES ADMINISTRATION; CAROLE JOHNSON, in her official capacity as Administrator of United States Health Resources and Services Administration; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; and JOHN DOES 1-3,

Defendants.

Case No. 4:24-cv-00334

VERIFIED COMPLAINT FOR DECLARATORY RELIEF

INTRODUCTION

1. This case presents the tragedy of a cross-section of ordinary Americans who suffer from devastating and debilitating injuries that started within days of receiving a COVID-19 vaccine. While drugmakers reap billions of dollars in profits behind the impenetrable shield of legal immunity, Plaintiffs and their families are left without any reasonable recourse from the federal government for their shattered lives, mounting medical bills, ongoing testing and treatment, and in some cases, permanent disabilities and death. The Court should be aware that for every story told in this case, there are thousands upon thousands more, equally heartbreaking and unjust.

2. Plaintiffs desire to bring common law and state law claims for, *inter alia*, negligence, intentional infliction of emotional distress ("**IIED**"), and products liability against the manufacturers and administrators of the products that injured them.[1]

3. But instead of being able to sue the vaccine manufacturers for their injuries in a court of law, Plaintiffs have been forced by federal statute—the Public Readiness and Emergency Preparedness Act of 2005 ("**PREP Act**")[2]—into the Countermeasures Injury Compensation

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[1] In June 2022, Plaintiff Theodore Cabaniss filed a pro se lawsuit against Pfizer on his minor vaccine injured son T.C.'s behalf in the United States District Court for the Southern District of California. The district court ultimately dismissed Ted's claim for lack of subject matter jurisdiction, holding that the PREP Act immunized Pfizer from the claims asserted in the complaint. *T.C. v. Pfizer, Inc.*, No. 22-cv-01242-WQH-AHG, 2022 WL 17578871, at *1–2 (S.D. Cal. Nov. 9, 2022). The decision was recently affirmed by the Ninth Circuit Court of Appeals. *Cabaniss v. Pfizer, Inc.*, No. 23-55297, 2024 WL 511872 (9th Cir. Feb. 9, 2024). With respect to the other Plaintiffs, it is Plaintiffs' expectation that, pursuant to the instant litigation, the statutes of limitation on these claims will be tolled. These individuals have not initiated these suits by bringing common law and state claims because, as evidenced by Plaintiff Theodore Cabaniss's suit, doing so would be futile pursuant to the PREP Act and Plaintiffs need not engage in futile behavior to garner standing. *See J.R. v. Austin Indep. Sch. Dist.*, 574 F. Supp. 3d 428, 435 (W.D. Tex. 2021). It is also anticipated that the federal courts would have diversity jurisdiction over these claims if and when Plaintiffs are able to bring them.

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

Program ("**CICP**"). The CICP is akin to a black hole into which injured individuals submit a request for benefits, wait an indeterminate amount of time for a decision, and are then denied (if they receive any decision at all). There is no access to judicial review, and the affected are left to cope with both their physical injuries and the resulting financial, emotional, and mental injuries.

4. Plaintiff Jessica Smith's world has been turned upside down since suffering numerous injuries—including severe dysautonomia and tinnitus—from receiving the Pfizer COVID-19 vaccine in September 2021. Despite having been diagnosed as vaccine-injured, Jessica has never heard back from CICP in the two years since she applied for compensation. In the meantime, Jessica was forced to leave her job, has accrued massive medical expenses, and struggles to work more than a part-time schedule.

5. Plaintiff Joel Wallskog, M.D. likewise suffered serious injuries—including transverse myelitis—after receiving a Moderna COVID-19 vaccine. As a result, Dr. Wallskog is unable to continue his once thriving practice as an orthopedic surgeon. Despite having significant medical documentation evidencing that his injury was caused by the vaccine and receiving a determination of full disability from his employer's insurance, Dr. Wallskog's CICP application was curtly denied and his request for reconsideration has remained pending for over a year.

6. Plaintiff Ted Cabaniss's son, T.C., was a thriving, ten-year-old, straight-A student with a black belt in Tae Kwon Do until he received the Pfizer COVID-19 vaccine and experienced a cascade of debilitating injuries. T.C. has been diagnosed with a permanent blood disorder that requires intensive, invasive, and expensive treatments. Although a request for benefits was submitted to CICP on T.C.'s behalf over 18 months ago, CICP has yet to provide any response.

7. Plaintiff Elizabeth Thiele, M.D., Ph.D. was a Professor of Medicine at Harvard Medical School and a practicing pediatric neurologist with a thriving practice who now has a

COVID-19 vaccine related shoulder injury and psoriasis with arthropathy resulting in persistent pain that makes it nearly impossible to treat her young patients with her previous enthusiasm.

8. Despite their grievous injuries and the catastrophic effects on their lives, the only relief afforded to these Americans—who were told they "did the right thing" by getting a COVID-19 vaccine—is theoretical limited compensation under CICP. That is because the federal law that created the CICP immunizes vaccine manufacturers from financial liability.[3] In exchange for their ability to sue, CICP is supposed to compensate those who are injured by "covered countermeasures" like the COVID-19 vaccine.[4] The purported purpose of CICP is to "provid[e] **timely, uniform, and adequate compensation** to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure."[5]

9. As detailed herein, though, CICP is a Potemkin village—an elaborate façade

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[3] The only exception is for "willful misconduct." But if a willful misconduct claim could be brought by the U.S. government under the Public Health Service Act or the Food, Drug, and Cosmetic Act, then a plaintiff cannot bring that claim unless the government does so first. For other willful misconduct claims, a plaintiff must satisfy an extremely high burden of proof, especially against a vaccine manufacturer. Notably, willful misconduct first requires that the plaintiff seek compensation through the CICP and so the program is inescapable. If a plaintiff's request is granted, he or she cannot sue for willful misconduct if he or she elects to receive that compensation. If the plaintiff chooses instead to file a lawsuit, injured persons may sue only in the U.S. District Court for the District of Columbia. Such lawsuits must meet heightened standards for pleading and discovery and are subject to procedural provisions generally favorable to defendants. Injured persons must prove willful misconduct by clear and convincing evidence (a higher standard than in a typical civil case), and recovery for noneconomic damages such as pain and suffering is limited. A plaintiff must show that a defendant acted: (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. Willful misconduct claims are also subject to limits on discovery and non-economic damages. 42 U.S.C. §§ 247d-6d(c)(1)(A), (c)(3), (e)(1), (e)(6), and (e)(8).

[4] CICP covers numerous "countermeasures," a category which includes more than COVID-19 vaccines. For purposes of the instant action, the only countermeasures applicable to Plaintiffs are COVID-19 vaccines.

[5] 42 U.S.C. § 247d-6e(a) (emphasis added).

designed to hide an undesirable reality. Proceedings in the kangaroo court of the CICP ignore recognized standards of law and justice, are grossly unfair, and come to a predetermined conclusion, leaving injured Americans with no avenue of relief.

10. As a critical reminder: taxpayer funds were used to develop, test, purchase, distribute, and promote the COVID-19 vaccines. The federal government also mandated the vaccine through every avenue it could (and sometimes went beyond that until corrected by the judicial branch) and publicly encouraged mandates by state and local governments, private employers, and schools.

11. The government consistently tested legal limits in a stated effort to protect Americans from COVID-19. Indeed, Justice Gorsuch noted that during the COVID-19 pandemic era, Americans experienced "the greatest intrusions on civil liberties in the peacetime history of this country." *Arizona v. Mayorkas*, 143 S. Ct. 1312, 1314 (2023) (Gorsuch, J., concurring). Executive officials issued emergency decrees that shuttered businesses, schools, and churches; surveilled cities to enforce compliance with social distancing requirements under threat of criminal penalties; and divided cities and neighborhoods into color-coded zones that could be changed when challenged in the courtroom. *Id.* at 1314–15 (citing ten instances of intrusions on civil liberties). The government painted the vaccine as the only way out of this crushing regime of restrictions on individual and civil rights that it imposed.

12. Now, having taken away Plaintiffs' ability to obtain recompense from the manufacturers and/or administrators of the products that severely injured them (through the PREP Act), the government refuses to compensate those who heeded the call and suffered the most severe vaccine injuries. And, in doing so, the government denies those Americans even the most basic of due process measures.

13. CICP—at least as it functions now—is fundamentally inconsistent with Congress' intent. CICP claims are consistently lost, ignored, denied, or caught up in the years-long purgatory of government bureaucracy. The compensation, if any, is neither timely nor adequate. Perhaps the decisions are uniform, but only in the sense that claims uniformly get lost in a black hole for years or are uniformly denied.

14. Congress could remedy the defects in CICP by amending the PREP Act so that it satisfied Americans' constitutional rights and accomplished the stated objective of providing timely, uniform, and adequate compensation to Plaintiffs and other individuals harmed by the COVID-19 vaccine. At present, though, the legislative scheme fails to provide the most basic protections required under the U.S. Constitution.

15. As it stands, vaccine-injured individuals are left without the following basic legal and constitutional protections:

A. the name, title, and educational credentials of the individuals who are deciding COVID-19 vaccine injury claims;
B. confirmation that such decision-makers have no conflicts of interest or a process to challenge any particular decision-maker for conflicts of interest;
C. the identity of any expert witnesses or consultants used by the government in making determinations;
D. a reasonable opportunity to question witnesses, including experts, or review evidence used against claimants;
E. a reasonable opportunity to question or obtain discovery from such experts, including producing copies of any expert reports;
F. the opportunity to present expert witnesses on their behalf;
G. a reasonable opportunity to obtain discovery, including discovery from companies that manufactured or distributed the COVID-19 vaccines that harmed them;
H. copies of any records or documents used to decide COVID-19 vaccine injury claims;
I. notice to claimants and a reasonable opportunity to be heard before any decision;
J. reasonable recovery for all damages suffered, including related to medical treatment, loss of income or earning potential, death, and/or pain, suffering, and emotional distress;
K. the availability of attorneys' fees and costs (as long as the claim was submitted in good faith and with a reasonable basis);
L. right to an appeal/judicial review of a COVID-19 vaccine injury decision in a court

of law; and/or

M. a written record of any hearings or proceedings for judicial review.

16. The immunity to liability provisions within the PREP Act and the CICP are inextricably intertwined. As such, the overarching rationale for providing liability protection to vaccine manufacturers under the PREP Act—that an **alternative and adequate remedy** for those injured by a COVID-19 vaccine exists—evaporates if the alternative and adequate remedy provided by Congress is itself unconstitutional. This eviscerates the PREP Act's immunity protections for vaccine manufacturers as there is no constitutional alternative provided to vaccine-injured citizens.

17. Plaintiffs respectfully request that the Court enter an order (i) declaring that those provisions of the PREP Act pertaining to CICP, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, are unconstitutional and (ii) enjoining the federal government, pursuant to the Fifth Amendment to the U.S. Constitution, from enforcing those provisions of the PREP Act that provide liability protection.

JURISDICTION AND VENUE

18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1343. This action arises under the Fifth and Seventh Amendments to the United States Constitution.

19. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e)(1)(C) and 28 U.S.C. § 1391(b)(2) because at least one Plaintiff resides in this district and because a substantial part of the events or omissions giving rise to this action occurred in this judicial district. Specifically, this action involves CICP's deprivation of substantive and procedural due process, and deprivation of the Seventh Amendment right to a jury trial. Plaintiffs Wallskog and Smith currently reside in this District and Division and continue to endure medical impairments and

suffer irreparable harms due to Defendants' actions.

PARTIES

A. Plaintiffs

20. Plaintiff Jessica Smith is a citizen and domiciliary of the State of Texas, residing in Haslet, TX. Jessica Smith and her family have lived in Texas for approximately a year and a half and continue to suffer ongoing constitutional violations and irreparable harm while residing in this District.

21. Plaintiff Joel Wallskog, M.D. is a citizen and domiciliary of the State of Texas, residing in Lakeside, TX. Dr. Wallskog purchased a home in Texas in June 2023 and has resided in Texas since October 2023. He continues to suffer ongoing constitutional violations and irreparable harm while residing in this District. He previously resided in Wisconsin.

22. Plaintiff Theodore Cabaniss and his minor son, T.C., are and at all relevant times have been citizens and domiciliaries of the State of California, residing in Vista, CA.

23. Plaintiff Elizabeth Thiele, M.D., Ph.D. is a citizen and domiciliary of the Commonwealth of Massachusetts, residing in Newton, MA. Dr. Thiele has resided in the Commonwealth of Massachusetts for many years.

B. Defendants

24. Defendant United States Department of Health and Human Services ("**HHS**") is a cabinet-level executive branch department within the United States Federal Government. Defendant Xavier Becerra is the agency head of HHS and is sued in his official capacity. Defendant United States of America is the governing entity that operates and oversees HHS and HRSA. Defendant Joseph R. Biden, Jr. is President of the United States of America and is sued in his official capacity.

25. Defendant United States Health Resources and Services Administration ("**HRSA**") is an Operating Division of HHS. HRSA administers CICP, at issue in this suit. Defendant Carole Johnson is Administrator of HRSA and is sued in her official capacity.

26. Defendant John Does 1-3 (collectively, "**John Does**") are individuals charged with supervising, managing, directing, or operating CICP. As set forth below, various Plaintiffs have requested identification of John Does, but CICP, HHS, and/or HRSA have not disclosed their identities to date.

STATEMENT OF FACTS

A. Jessica Smith

27. Jessica Smith is thirty-five years old and lives in Haslet, Texas with her husband and twin ten-year-old daughters.

28. Before receiving the Pfizer COVID-19 vaccine, Jessica was generally healthy. Although she had lived with anxiety in the past, she was off medication for over a year and thriving before receiving the vaccine.

29. Everything changed on September 3, 2021, when Jessica received the first dose of the Pfizer COVID-19 vaccine.

30. Approximately one week later, Jessica began experiencing a feeling of severe internal vibrations and struggled to keep her balance. She was unable to eat or sleep and constantly felt freezing cold.

31. Jessica went from being an active mother and wife to not being able to get out of bed. She describes her experience this way:

> *I could no longer keep my balance, had pain throughout my entire body, got extreme fatigue from minor activities. I lost the ability to regulate body temperature, no matter what I did I was shivering. At the beginning I lost my ability to eat, I could put food in my mouth*

> *but couldn't get myself to swallow it, I lost almost 30 pounds in 30 days. By the end of the first month I was beginning to lose hope life would ever become livable. I thought I knew what anxiety was, but I was wrong. For a month straight I was in a constant state of fight or flight. Unlike normal anxiety that waxes and wanes, it was constant and debilitating. Sleep had become so intermittent and hard to achieve I would lay up at night and just cry. The tinnitus was so loud that even when my mind would calm, the screaming in my ears was preventing any rest from happening. My children watched me have seizures and go from active and fun to not being able to function.*

32. As her world crumbled around her, Jessica began struggling with thoughts of suicide. She wondered if her family would be better off without her.

33. Jessica made several trips to the emergency room after receiving the vaccine. Eventually, in October 2021, Jessica's physician determined that she was vaccine-injured and diagnosed her with dysautonomia from damage to her autonomic nervous system (the portion of the nervous system operating involuntary physiologic processes such as digestion, heart rate, blood pressure, respiration, and sleep).

34. Jessica was referred to a cardiologist for further evaluation of her dysautonomia. During her initial consultation in March 2022, Jessica's cardiologist explained that he had seen hundreds of patients, most of whom were young women, with the same diagnosis since the COVID-19 vaccine rollout. Jessica's dysautonomia diagnosis was confirmed through a tilt table test on March 28, 2022.

35. Jessica's family was also significantly impacted financially by her vaccine injury. After initially taking an unpaid leave of absence due to the vaccine injury in September 2021, Jessica was eventually forced to resign from her job. She did not return to work until July 1, 2022. In her most recent position, Jessica worked at her daughters' school assisting in the lunchroom until she was recently forced to resign from this job as well due to her ongoing health issues. When

her health permits, Jessica now works part-time making food deliveries.

36. Jessica's husband also lost his job in November 2021 because he had taken so many days off work to care for her. He was out of work for nine months providing care for Jessica. The Smiths had to borrow over $18,000 from family to help make ends meet during this time.

37. Jessica and her family moved to Texas from Oklahoma in mid-July 2022, so that her husband could find work.

38. Jessica's life has been forever altered by the COVID-19 vaccine. She continues to work with her physician to find treatment and get in a position where she can work full-time.

39. Although she has some good days, they are often followed by days when she is stuck in bed and unable to manage her symptoms.

40. She struggles to maintain a part-time job to help dig out of the family's financial hole.

41. Less than a year after receiving the COVID-19 shot, Jessica submitted a Request for Benefits form online to apply for compensation from CICP.

42. Jessica received no communication from CICP after submitting her claim, nor has CICP ever acknowledged her claim or sought more information. Over two years later, Jessica continues to wait for a decision.

B. Joel Wallskog, M.D.

43. For almost twenty years, Dr. Wallskog practiced as an orthopedic surgeon in Wisconsin.

44. During his professional career, Dr. Wallskog developed a large orthopedic practice focused on joint replacement. On average, Dr. Wallskog had over 5,000 patient visits and performed over 800 procedures annually. He loved his work and had a passion for it.

45. On December 30, 2020, Dr. Wallskog received his first Moderna COVID-19 shot.

46. By approximately January 7, 2021, Dr. Wallskog was experiencing numbness in his feet. Shocks ran down his spine, with a sensation that felt like pins and needles radiating through his feet. Dr. Wallskog received a cervical MRI, which could not provide any explanation for his condition. Subsequent MRIs, including an MRI of his thoracic spine, would reveal a demyelinated lesion at the T8/T9 level.

47. Days later, while sitting with a patient during a consultation, Dr. Wallskog found that he was not able to stand and, instead, fell backwards against a wall. At that point, Dr. Wallskog knew he was seriously injured.

48. Dr. Wallskog visited a neurologist who diagnosed him with transverse myelitis (inflammation of the spinal cord that extends horizontally across the vertebrae).

49. Dr. Wallskog took two weeks off work to rest and, when he returned, he performed surgeries on two shortened days. When Dr. Wallskog continued to feel terrible and his entire lower body remained numb, it became increasingly clear to him that he could no longer pursue his life's work as an orthopedic surgeon.

50. After Dr. Wallskog learned that the AstraZeneca vaccine was delayed in Europe due to cases of transverse myelitis,[6] he began to question whether his injuries were related to the COVID-19 vaccine.

51. On January 19, 2021, at Dr. Wallskog's request, his employer submitted a report to the federal Vaccine Adverse Event Reporting System ("**VAERS**"). A true and accurate copy of

[6] *See* Adam Feuerstein, *Covid-19 Vaccine Trial Participant Had Serious Neurological Symptoms, But Could Be Discharged Today, Astrazeneca CEO Says*, STAT (Sept. 9, 2020), https://www.statnews.com/2020/09/09/astrazeneca-covid19-vaccine-trial-hold-patient-report.

VAERS Report ID#0956311 is attached as **Exhibit 1**.

52. VAERS is co-managed by the United States Centers for Disease Control ("**CDC**") and the Food and Drug Administration ("**FDA**").[7] The CDC's website states that:

> [COVID-19] vaccines are monitored by VAERS and several other vaccine safety monitoring systems as part of the most intensive vaccine safety monitoring effort in U.S. history. This continuous, robust safety monitoring helps keep COVID-19 vaccines safe and helps ensure the benefits of vaccination continue to outweigh any risks.[8]

53. Hearing nothing following his VAERS report, Dr. Wallskog contacted CDC. Initially, a CDC physician, Dr. Reina Turcios-Ruiz, acknowledged that "[t]ransverse myelitis is an adverse event of special interest to CDC." A true and accurate copy of Dr. Turcios-Ruiz's email to Dr. Wallskog, dated February 10, 2021, is attached as **Exhibit 2**.

54. However, in subsequent communications with CDC physician Dr. Julianne Gee, CDC advised Dr. Wallskog that his condition was "non-serious" under federal law:

> Your report in VAERS is listed as "non-serious". Per federal law, reports are routinely defined as "serious" if one of the following outcomes occurs: death, hospitalization or prolongation of existing hospitalization, life-threatening illness, permanent disability, or congenital deformity. The initial report to VAERS did not indicate one of these outcomes, and thus was classified as "non-serious". One complication of this definition is that an adverse event can have a severe clinical presentation, but not be considered serious.

A true and accurate copy of Dr. Wallskog's communication with CDC, dated February 20–22, 2021, is attached as **Exhibit 3**.

55. Although Dr. Wallskog faced the possibility of never practicing medicine again,

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[7] *See* https://vaers.hhs.gov/about.html.

[8] *See* https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html.

his vaccine injury was apparently not serious enough to warrant further investigation by CDC. Dr. Wallskog received no further communications from CDC. He was never contacted by FDA or any other public health agency.

56. Dr. Wallskog's employer also contacted Moderna and was told that Dr. Wallskog should submit a Vaccine Adverse Event Reporting Form directly to Moderna. A true and accurate copy of Dr. Wallskog's Moderna form dated February 5, 2021 is attached as **Exhibit 4**.

57. Dr. Wallskog felt completely abandoned by the medical community and public health authorities on which he relied throughout his entire career.

58. Since receiving the Moderna COVID-19 vaccine, Dr. Wallskog's life has changed dramatically. His career as an orthopedic surgeon is over. He still suffers from numbness, weakness, and lacks the balance necessary to perform surgeries. Dr. Wallskog also suffers from disabling symptoms of dysautonomia which include, but are not limited to, labile heart rate and blood pressure, syncopal and near-syncopal events, chronic nausea, and insomnia.

59. Dr. Wallskog has been determined by the Social Security Administration to be permanently disabled from any and all occupations as of February 24, 2021. Although Dr. Wallskog is fortunate to receive some compensation for his financial loss through social security disability insurance and private insurance, losing his medical career has been devastating.

60. On or around May 2021, Dr. Wallskog filed an electronic Request for Benefits with CICP. During the CICP process, Dr. Wallskog had no opportunity to challenge or even learn the identities of the individuals making decisions related to his claim; review the documentation relied upon by government officials in deciding his claim; confirm whether those deciding his claim possessed conflicts of interest; or present expert witnesses in support of his claim. He had no opportunity to attend a hearing, present witnesses, or question any experts used by CICP.

61. On November 29, 2022, Dr. Wallskog's CICP claim was denied. A true and accurate copy of CICP's denial letter is attached as **Exhibit 5**. CICP stated, among other things, as follows:

> The current medical and scientific evidence does not show a causal link between the Moderna COVID-19 vaccine and transverse myelitis, other neuro-inflammatory disorders, myelopathy, or thrombotic disorders, including spinal cord infarction. Furthermore, there is no evidence that your symptoms of lower extremity numbness and tingling with neck flexion, and chronic thoracic pain with weakness and numbness in your legs, is caused by the Moderna COVID-19 vaccine.

Id., p. 2.

62. On December 19, 2022, Dr. Wallskog provided a timely written request for reconsideration within the 60-day deadline. A true and accurate copy of Dr. Wallskog's written request for reconsideration is attached as **Exhibit 6**. In it, Dr. Wallskog explained several bases for reconsideration and noted that CICP took nineteen months to consider his original claim:

> First, the denial letter makes no reference to my medical notes from Pierre Kory, MD. Dr. Kory documented the causal relationship between my one Moderna shot I received on 12/30/20 and my symptoms. These medical notes were provided to you previously. The denial letter also fails to recognize the autoantibodies in my work up. No mention is made of my headaches, nausea, hypertension, and other symptoms which have been attributed to dysautonomia from my Moderna shot. My hypertension is well documented in my medical notes to start in January of 2021. My spinal cord symptoms started approximately 8 days after my shot. An exhaustive work-up revealed no other cause of my symptoms besides my Moderna shot. Dr. Nath from the NIH was an author of an article entitled, "COVID-19 and Vaccination in the Setting of Neurologic Disease" published in Neurology in 2021. In this article on page 723, the authors write, "a number of neurologic complications of these vaccines are now being reported in the most comprehensive registry, the Vaccine Adverse Events Reporting Systems (VAERS) database. These include strokes, cranial neuropathies including Bell palsy, tinnitus and trigeminal neuralgia, peripheral neuropathies, dysautonomia, acute disseminated encephalomyelitis, transverse myelitis and AIDP."

Id.

63. In October 2023, Dr. Wallskog relocated to Texas. He continues to await a decision regarding his request for reconsideration. Dr. Wallskog has not received any information concerning who is reviewing his claim or whether that person/persons has any conflicts of interest, nor has CICP provided any avenue to obtain such information.

C. T.C.

64. Ted Cabaniss watched President Biden on CNN when he announced that the vaccine was "safe and effective." He trusted the government and medical community. Therefore, Ted's son, T.C., received the first Pfizer vaccine on June 7, 2021.

65. Eleven days after receiving the vaccine, T.C. was rushed to the emergency room with red spots all over his body from burst blood vessels. The doctors initially believed he had leukemia and transferred him immediately to Rady Children's Hospital. Physicians at Rady determined that T.C. suffered from Immune Thrombocytopenic Purpura ("**ITP**").

66. ITP causes a decrease in platelet count and presents serious risks of internal bleeding because of clotting issues. For several months, his platelet levels were low and doctors used steroids to increase those levels. After almost a year of treatment, doctors told Ted that the ITP was chronic and would be with T.C. the rest of his life.

67. On April 13, 2022, a Request for Benefits form was submitted on T.C.'s behalf through CICP's website.

68. No response or acknowledgment from the government has been received to date.

69. Before receiving the shot, T.C. excelled in school. He was a straight-A student in the seventh grade. T.C. was perfectly healthy and physically active. He was the youngest boy in his area to receive a black belt in Tae Kwon Do.

70. Since his ITP diagnosis, T.C. has been told he cannot play any sports with physical contact. He is no longer involved in Tae Kwon Do and could not try out for football. T.C.'s life has been adversely changed forever.

71. As part of his treatment, T.C. was prescribed prednisone along with a very expensive drug, Promacta, which costs approximately $14,000/month without insurance. These medications led to migraines, diarrhea, and other side effects.

72. Most recently, T.C. received a series of Rituximab infusions. These infusions, which are typically used in the treatment of leukemia, require one day a week of eight-hour treatment, for four consecutive weeks. It remains unclear whether T.C. will require further Rituximab treatments going forward. T.C. has additionally received three IVIG treatments.

73. T.C. is currently insured through his mother's insurance, but Ted has long-term concerns about what happens if T.C.'s mother loses her insurance or if T.C. will be able to get coverage when he is older as there is no cure for his ITP.

74. Because of his illness, T.C. has missed numerous days of school while battling side effects of various medications and infusions. Last year, Ted had to request accommodations and a 504 plan—an academic program for students with disabilities—for T.C. Ted is concerned that T.C. will fall further and further behind in school.

75. In June 2022, Ted filed a pro se lawsuit against Pfizer on T.C.'s behalf in the United States District Court for the Southern District of California. The District Court ultimately dismissed Ted's claim for lack of subject matter jurisdiction, holding that the PREP Act immunized Pfizer from the claims asserted in the complaint. *T.C. v. Pfizer, Inc.*, No. 22-cv-01242-WQH-AHG, 2022 WL 17578871, at *1–2 (S.D. Cal. Nov. 9, 2022). The decision was recently affirmed by the Ninth Circuit Court of Appeals. *Cabaniss v. Pfizer, Inc.*, No. 23-55297, 2024 WL

511872 (9th Cir. Feb. 9, 2024).

76. Thus, T.C.'s recovery for his vaccine injuries, if any, is currently limited to any recovery he may receive from his request for benefits in the CICP program.

D. Elizabeth Thiele, M.D., Ph.D.

77. Dr. Thiele is a 63-year-old Professor of Neurology at Harvard Medical School and is a full-time pediatric neurologist and Director of the Pediatric Epilepsy Program, the Carol and James Herscot Center for Tuberous Sclerosis Complex, and the Dravet Syndrome Comprehensive Clinical Program at the Massachusetts General Hospital ("**MGH**"), the largest teaching hospital of Harvard Medical School. MGH is the third-oldest general hospital in the United States with a patient capacity of approximately 1,000 beds. At the time of her injury, Dr. Thiele had a thriving clinical practice, a comprehensive educational program for training future pediatric neurologists, and a vibrant clinical practice. Her patients come to her from all over the world as Dr. Thiele is one of very few pediatric neurologists who treats tuberous sclerosis complex as well as seizures recalcitrant to traditional anti-seizure medications. Dr. Thiele additionally serves as the principal investigator on several studies evaluating new anti-seizure medications. Given her expertise, Dr. Thiele travels frequently to present at various national and international scientific conferences.

78. On August 29, 2021, Dr. Thiele received a COVID-19 booster immunization at her neighborhood CVS pharmacy. She immediately experienced extreme pain, unlike the minimal discomfort she experienced after multiple previous COVID-19 vaccine injections. The intensity of the pain increased rapidly during the entire fifteen-minute post-injection waiting period.

79. Soon thereafter, Dr. Thiele developed limited range of motion in her right shoulder and, to a lesser extent, further down her right arm.

80. Thereafter, because of the pain and very limited range of motion, activities of daily

living, such as cooking, dressing, washing her hair, etc. became difficult or impossible for her to perform.

81. Dr. Thiele struggled to use a computer keyboard, as maintaining her right arm in a position to use a computer keyboard was difficult and required frequent breaks. Dr. Thiele found driving to be extremely difficult, as she could only shift her car into drive or reverse by reaching over and utilizing her left hand and she sometimes needed help buckling her seat belt. Dr. Thiele had great difficulty sleeping because it was hard for her to find a comfortable position, and she would frequently wake up if she moved her right arm in her sleep.

82. Because of Dr. Thiele's routine clinical responsibilities and the excessive demands the COVID-19 pandemic placed on all healthcare providers at the Massachusetts General Hospital, taking time off from work or strong opioid pain medications were not options.

83. However, at her clinic, Dr. Thiele could not perform complete neurologic examinations on her patients or pick up her infant and toddler patients. The limitations imposed by the pain, as well as the decreased range of motion, significantly impacted her clinical practice and significantly impaired her work ability as a pediatric neurologist. Dr. Thiele's clinical days consequently became longer because it took her additional time to examine her patients and use a computer to document their care.

84. Dr. Thiele's serious pain persisted for three weeks, after which it seemed to improve slightly. However, in mid-November 2021, Dr. Thiele's shoulder pain significantly worsened, again radiating down her right arm. Once again, the pain caused a significantly reduced range of motion and difficulty performing activities as detailed above. Dr. Thiele began to experience benign paroxysmal positional vertigo (periods of intense dizziness).

85. On December 16, 2021, Dr. Thiele was seen by a Massachusetts General Hospital

primary care physician, who ordered conventional radiological examinations of the right shoulder and humerus which failed to reveal a fracture or dislocation or any explanation for Dr. Thiele's symptoms. However, a follow-up MRI on January 27, 2022, showed thickening of the right shoulder anterior capsule, consistent with capsulitis (joint capsule inflammation), as well as other findings consistent with shoulder injury related to vaccine administration ("**SIRVA**").

86. SIRVA is an exceedingly common vaccine injury. According to HRSA, which administers the National Vaccine Injury Compensation Program (the venue through which vaccine injury victims can seek compensation for most non-emergency-use-authorized vaccines): "Over 63% of petitions filed in the last 2 [fiscal years of 2022 and 2023] allege shoulder injury related to vaccine administration (SIRVA)." Health Resources & Services Administration (HRSA) presentation, *National Vaccine Injury Compensation Program (VICP) Update – Advisory Commission on Childhood Vaccines (ACCV)*, September 7, 2023, p. 11. https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/dicp-update-090723.pdf.

87. On February 1, 2022, following the MRI, Dr. Thiele was seen by an MGH orthopedic surgeon, Director of Emergency Sports Medicine and Head Team Physician at Northeastern University, as well as a Team Physician for the New England Patriots and Assistant Professor of Orthopedic Surgery, Harvard Medical School.

88. Dr. Thiele was referred to another MGH orthopedic surgeon specializing in Sports Medicine and shoulder injuries and an Assistant Team Physician for the New England Patriots and Harvard College, as well as an Instructor in Orthopedic Surgery at Harvard Medical School.

89. On February 2, 2022, Dr. Thiele was seen by the second orthopedic surgeon, who thought that the MRI scan also showed a partial-thickness tear of the rotator cuff which is another manifestation of SIRVA. According to the orthopedic surgeon, "her symptoms are largely from

the adhesive capsulitis." The doctor diagnosed Dr. Thiele with "SIRVA, secondary adhesive capsulitis" and performed a subacromial steroid injection.

90. The doctor also referred Dr. Thiele to an MGH sports medicine physiatrist, a Sports Medicine Physiatrist and Team Physician for the Boston Red Sox, and Instructor of Physical Medicine & Rehabilitation at Harvard Medical School.

91. On February 9, 2022, after carefully documenting Dr. Thiele's history of the incident since August 2021, its overall impact, and the treatment course, the sports medicine physiatrist diagnosed Dr. Thiele with "[r]ight shoulder pain and restricted ROM, chronic with progression -- consistent with SIRVA (shoulder injury related to vaccine administration) with secondary adhesive capsulitis in the setting of likely preexisting rotator cuff tendinopathy with high-grade partial-thickness supraspinatus tearing."

92. The sports medicine physiatrist then performed an ultrasound-guided glenohumeral joint injection on February 9, 2022. While the glenohumeral joint injection improved Dr. Thiele's symptoms, she continued to have substantial difficulty with dressing and overhead motions, lifting and carrying, and sleeping.

93. On March 2, 2022, Dr. Thiele was seen by a physical therapist and, with exercises as recommended by the physical therapist, Dr. Thiele's symptoms largely (though not completely) resolved by mid-2022.

94. Dr. Thiele would like to return to activities of daily living without pain or limitation, but she continues to have discomfort in her right shoulder with occasional exacerbations. Dr. Thiele is currently being treated for psoriasis with arthropathy and there is concern that the inflammation caused by the COVID-19 vaccine will always be a catalyst for the development of arthritis as she ages.

95. Because Dr. Thiele's injuries were caused by a negligent misplaced injection and/or by negligent training of an unknown pharmacist in the administration of upper extremity injections, Dr. Thiele made a demand to CVS, which self-insures its pharmacists.

96. In its response, CVS's position was that CICP preempts ***any*** state law claims of negligence related to the administration of COVID-19 pharmaceuticals no matter what caused the claims. The conclusion is that no matter what the injury—e.g., infection, SIRVA, etc.—and no matter what the cause—e.g., a dirty needle, injecting COVID-19 biologicals in the wrong place, poorly trained vaccine administrator, etc.—the patient has no recourse except through the CICP program.

97. However, when Dr. Thiele presented to the CVS pharmacy, she was not informed that Defendants had limited her constitutionally protected rights to recourse for injuries that might result from injection of the various COVID-19 pharmaceuticals.

98. Having missed the right to seek compensation from CICP as more than a year has passed since the date of her injection, Dr. Thiele is left with only her continuing injury and the negative ramifications of that injury on her personal and professional life. She has no other option for being made whole even while her SIRVA limits her ability to perform major daily life activities.

E. The PREP Act and CICP

99. The PREP Act authorizes the HHS Secretary to issue a declaration that "a disease or other health condition or other threat to health constitutes a public health emergency." 42 U.S.C. § 247d-6d(b). The HHS Secretary has issued numerous declarations pursuant to 42 U.S.C. § 247d-6d(b) related to COVID-19 (hereinafter "declarations").

100. The PREP Act provides immunity to "covered persons" from liability under federal

and state law for "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 if a declaration under subsection (b) has been issued with respect to such countermeasure." 42 U.S.C. § 247d-6d(a)(1).

101. CICP was established under the PREP Act 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).

102. The PREP Act carves out a narrow exception to immunity for cases of serious injury or death caused through "willful misconduct." In cases of willful misconduct, however, the injured person (or the person's survivors) must first file in CICP. If denied or if they do not accept the offered compensation, the plaintiff(s) must then file suit in the United States District Court for the District of Columbia and prove the injuries by clear and convincing evidence. 42 U.S.C. § 247d-6d(c)(3), (e)(1).[9] In all cases aside from willful misconduct claims, individuals injured by a covered countermeasure must seek redress from CICP without any option of filing suit in court.

103. In order to seek redress from CICP, however, individuals must abide by the PREP Act's strict one-year statute of limitations. 42 U.S.C. § 239a(d) ("The Secretary shall not consider any request for a benefit … unless … the individual files with the Secretary an initial request for benefits or compensation … not later than one year after the date of administration of the vaccine."); 42 C.F.R. § 110.42(a).

[9] For most claims against manufacturers or distributors with respect to a covered countermeasure, either the Secretary of HHS or the Attorney General must first initiate an enforcement action as a condition of suit. *See* 42 U.S.C. § 247d-6d(c)(5)(A).

F. Claims for COVID-19 Vaccines Injuries Under CICP

104. On January 31, 2020, the former HHS Secretary, Alex M. Azar II, declared a public health emergency for the entire United States in response to the COVID-19 outbreak. The January 2020 declaration and thirteen subsequent renewals provided protections to, among others, manufacturers and distributors of COVID-19 vaccines (countermeasures).

105. As of March 5, 2024, 13,031 CICP claims have been filed related to COVID-19 countermeasures. The statistics speak for themselves: to date, CICP has compensated only **eleven** of those claims, ten for myocarditis/myopericarditis and one for anaphylaxis.[10] The average payout on COVID-19 vaccine injury claims to date is $3,535.73. By comparison, CICP's average payout on injuries related to the H1N1 vaccine was $198,447.45.[11] Nearly 81.3% (10,588/13,031) of the COVID-19 countermeasure claims remain "pending review or in review." According to Commander George Reed Grimes, who oversees program management of CICP, CICP resolved an average of 90 claims per month in 2023.[12] At that rate, it will take approximately 10 years to adjudicate the currently pending requests for benefits assuming no further requests are submitted. In rare instances where a decision has been reached, over 98% of those COVID-19 countermeasure claims have been denied (2,400/2,443). CICP has thus awarded compensation to a lamentable

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[10] *Countermeasure Injury Compensation Program (CICP) Data*, HRSA, (March 5, 2024), https://www.hrsa.gov/cicp/cicp-data.

[11] *Table 4. CICP Claims Compensated (Fiscal Years 2010-2023)*, HRSA, (March 5, 2024), https://www.hrsa.gov/cicp/cicp-data/table-4.

[12] *See* Transcript of *House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic Holds Hearing on Assessing Vaccine Safety Systems*, February 15, 2024, attached as **Exhibit 7.**

0.08% of total COVID-19 claimants (11/13,031), and benefits determinations remain pending for 0.24% of total COVID-19 claimants (31/13,031).[13]

106. The federal government appears to be determined that COVID-19 vaccine injuries will not be compensated. The staff at CICP, which account for over 94% of the budget with their salaries and administrative costs,[14] spend their days looking for every possible technicality to throw out otherwise legitimate claims. Of the 2,990 claims for which CICP has issued a decision, it has denied 2,907. Of those denied, 1,556 were denied because these seriously injured Americans did not file within one year of receiving the vaccine,[15] a time period set by the PREP Act. *See* 42 U.S.C. § 239a(d). Another 477 were denied because medical records were not submitted.[16] And 360 were denied because the product was not specified or was not covered by the CICP.[17] Only 514 have been dismissed for not meeting the standard of proof and/or a covered injury was not sustained—these are the only substantive decisions to date.[18]

107. The rate at which CICP has been deciding claims since 2023 is around 90 claims per month[19] but that will, as it runs out of technical reasons, likely slow down greatly as CICP will need to find other reasons to continue denying claims or giving near-nothing compensation. This

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[13] *Countermeasure Injury Compensation Program (CICP) Data*, HRSA, (March 5, 2024), https://www.hrsa.gov/cicp/cicp-data.

[14] *See infra* ¶¶ 121-22.

[15] *See* https://www.hrsa.gov/cicp/cicp-data.

[16] *Id.*

[17] *Id.*

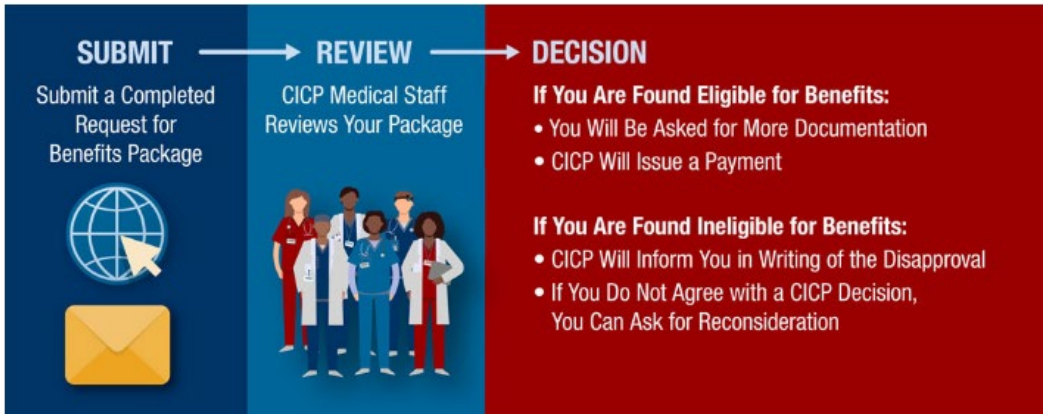
[18] *Id.*

[19] *See* Transcript of *House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic Holds Hearing on Assessing Vaccine Safety Systems*, February 15, 2024, at **Exhibit 7**. Even at this rate, it will take approximately 10 years to adjudicate the current requests for benefits submitted to the program assuming no further requests are submitted.

is because—as explained further below—CICP has almost no money to pay for compensable injuries even if it were not a star chamber. The added insult of having to wait years, possibly a decade or far more for others, for many who are seriously injured, goes beyond a deprivation—it is the precise form of governmental tyranny the founders stood against.

108. CICP's process is shrouded in secrecy. Although only Defendants have full access to their internal policies and procedures for deciding and rejecting requests for compensation, Plaintiffs identify herein all of the facts presently known below about the claims submission and review process.

109. HRSA's website[20] describes the process as follows:



110. Thus, publicly available information suggests that the process for submitting a COVID-19 vaccine injury claim, or a "Request for Benefits" to CICP has four steps:

- First, a claimant submits a Request for Benefits Package to CICP, via mail or the electronic portal available on the CICP website. The Request for Benefits Package is comprised of (i) a completed CICP Request for Benefits Form;[21] (ii) a completed Authorization for Use or Disclosure of Health Information Form for each health care provider that treated the claimant;[22] (iii) proof of administration or use of a COVID-19 vaccine; and (iv) medical records and hospital records on or after the date of

[20] *See* https://www.hrsa.gov/cicp.

[21] *See* https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-request-form.pdf.

[22] *See* https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-authorization-form.pdf.

administration of the COVID-19 vaccine, and medical records for one year prior to use or administration of the COVID-19 vaccine, as necessary, to show pre-existing medical history.

- Second, after submitting the Request for Benefits Package, the claimant's case is placed in the CICP queue for review by unidentified "CICP medical staff."[23] CICP's website states that "the time it takes for the CICP to process a Request for Benefits depends partly on the complexity of [the] case."[24]

- Third, CICP makes an eligibility determination. If eligible, CICP may request additional documentation to determine how much compensation should be provided. If not approved, CICP will provide written notice that the claim has been denied.

- Fourth, when CICP issues a denial, the claimant may request reconsideration from HHS within 60 days by mail (to the same address to which the original Request for Benefits was submitted).[25]

111. Beyond this high-level information provided online by the government, there are very few details concerning the CICP process available to the public.

G. Lack of Transparency and Safeguards in CICP Process

112. Initially, CICP claims are submitted (by electronic portal or by hard copy via mail) to unidentified representatives for review.[26] The government refuses to identify the name, title, or educational credentials of the individuals deciding CICP claims. Defendants provide no

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[23] https://www.hrsa.gov/cicp (*see* question "What Is the CICP Claims Process?").

[24] https://www.hrsa.gov/cicp/faq (*see* question "How much time does it take to process my Request for Benefits?").

[25] https://www.hrsa.gov/cicp/faq (*see* question "What if the CICP determines that I am not eligible for benefits?").

[26] *See* https://www.hrsa.gov/cicp/filing-process ("Submission Instructions" state: Send your request for benefits by U.S. Postal Service mail or private courier service (e.g., FedEx or UPS) to the address below:

U.S. Department of Health and Human Services
Health Resources and Services Administration
Countermeasures Injury Compensation Program
5600 Fishers Lane, Room 8W-25A
Rockville, MD 20857.

opportunity to interact with, much less question or challenge, those who are deciding Plaintiffs' requests. In fact, in response to a FOIA request submitted to HRSA by undersigned counsel seeking "[a]ll records sufficient to identify all agency personnel involved with [CICP]," HRSA's response redacted all but two names of CICP personnel, stating: "Due to credible threats and harassment against the DICP [Division of Injury Compensation Programs] staff and to protect the safety and wellbeing of the DICP staff, we withheld the identities and contact information of DICP staff members below the Deputy Director-level." (**Exhibit 8**)

113. Plaintiffs have no way to confirm whether any individuals deciding claims have any conflicts of interests, including whether any of them have ever reviewed, promoted, profited from, or mandated the COVID-19 vaccine.

114. The government provides no timeline for deciding requests. Indeed, Plaintiffs do not even have a way of tracking requests until they receive a case number at some uncertain time in the future.

115. The government provides no opportunity for discovery nor any method to request or review documents relied upon to reach its determination.

116. Defendants review claims according to unknown, undefined standards. The government provides no rubric, manual, or set of guidelines or standards that are used to decide requests. Instead, the government states that: "To establish a covered injury, the CICP must determine that the injury sustained was the direct result of the administration or use of a covered countermeasure. Under the Public Readiness and Emergency Preparedness Act (PREP Act), the CICP may only make such determinations based on compelling, reliable, valid, medical, and

scientific evidence."[27] This standard appears to be determined by unidentified individuals, based on unidentified information and evidence.

117. The government does not identify any expert witnesses or consultants used in making determinations. If the government relies on such experts or consultants, the government does not produce their written reports or materials or allow Plaintiffs the opportunity to question or cross-examine the experts. If the government does not rely upon experts, that presents other obvious concerns regarding the CICP process.

118. Plaintiffs cannot present their own expert or fact witnesses.

119. If denied benefits, Plaintiffs may request reconsideration from HHS within 60 days by mail (to the same address to which the original Request for Benefits was submitted).[28] The same issues detailed above pertain to this "appeals" process and the same questions remain unanswered: Who is deciding the request for reconsideration?; What is the timeline?; What is the standard of review?

120. Almost nothing else is disclosed about the inner workings of CICP.

H. Lack of CICP Funding

121. In addition to the complete lack of transparency about the program, CICP is also grossly underfunded. According to HRSA's operating plan, HRSA budgeted $5 million and $7 million for "administration" of CICP in 2022 and 2023, respectively,[29] although hundreds of millions of doses of COVID-19 vaccines were administered.

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[27] https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred.

[28] https://www.hrsa.gov/cicp/faq (*see* question "What if the CICP determines that I am not eligible for benefits?").

[29] *FY 2023 Operating Plan*, HRSA, https://www.hrsa.gov/about/budget/operating-plan.

122. Moreover, CICP is unreasonably inefficient, with 94% of its total costs spent on administration rather than compensation to Plaintiffs and others. *See* J. Zhao, et al, *Reforming the Countermeasures Injury Compensation Program for COVID-19 and Beyond: An Economic Perspective*, DUKE J. OF LAW & THE BIOSCIENCES, p. 2 (2022), https://academic.oup.com/jlb/article/9/1/lsac008/6555422.

123. CICP's self-evident inability to compensate victims adequately is further evidence that the program is simply theatre. If COVID-19 claims were compensated at CICP's historical rate, CICP would face around $21.16 million in compensation outlays and $317.94 million in total outlays—72.1 times its current balance. *Id.* Its dramatic underfunding demonstrates that it was not meant to serve as a legitimate tool for rerouting claims granted immunity by the federal government.

I. Lack of Judicial Review

124. As noted, individuals harmed by a covered countermeasure like the COVID-19 vaccine cannot obtain judicial review of CICP determinations. *See* 42 U.S.C. § 247d-6e(d) (discussing exhaustion requirement and limited appeal rights).

125. Thus, CICP fundamentally differs from other compensation schemes such as the National Childhood Vaccine Injury Act of 1986 ("**Vaccine Act**"), which is subject to judicial oversight pursuant to specialized rules before the United States Court of Federal Claims ("**Vaccine Court**").[30]

[30] Even the Vaccine Act's (which does permit judicial review) flaws have been well documented. *See* "The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices" (6th Rep. 2000), https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf.

J. Lack of COVID-19 Vaccine Injury Table

126. Although the HHS Secretary is authorized to create a CICP COVID-19 injury table, he has not done so despite the passage of nearly three years after the widespread administration of the COVID-19 vaccine, the submission of 12,700 CICP claims, and 1,683,039 reports made to VAERS (to date) following any COVID-19 vaccine.

127. According to the government: "An injury meeting the requirements of a covered countermeasures injury table [] is **presumed** to be the direct result of the administration or use of a covered countermeasure unless the Secretary determines there is another more likely cause."[31] Therefore, satisfying the necessary element of proving one has a covered injury is a lower standard for table injuries.

128. But unlike other vaccine-induced injury scenarios, the Secretary has failed to create a COVID-19 vaccine injury table. Therefore, Plaintiffs and all those requesting benefits from CICP must meet the higher burden of proving the injury is a direct result of the administration of a COVID-19 vaccine.

K. Plaintiffs' Experiences with CICP

129. On or around May 2021, Dr. Wallskog submitted a request for benefits to CICP, along with supporting documentation. On November 29, 2022, his request for benefits was denied. On December 19, 2022, Dr. Wallskog requested reconsideration of the denial and he continues to await a decision.

130. On or around November 2021, Jessica submitted a request for benefits to CICP, along with supporting documentation. She has not received any communication from CICP since

[31] https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred (emphasis added).

filing and she continues to await a decision.

131. On or around April 2022, T.C.'s family submitted a request for benefits to CICP on his behalf. No response or acknowledgment has been received from the government to date.

132. Dr. Thiele did not file a CICP claim because she was unaware of the program and was instead focused on meeting with specialists and seeking treatments when the one-year deadline had passed.

133. CICP operates entirely off the record and tramples Plaintiffs' constitutional rights. The Court should strike down the PREP Act to the extent it fails to provide basic due process protections, transparency, and judicial oversight.

134. In sum, the PREP Act extinguishes an individual's state and common law claims against "covered persons," and instead thrusts them into CICP, a program that offends the most basic safeguards of due process. This is because **CICP does not and will not provide claimants**:

A. the name, title, and educational credentials of the individual(s) deciding claims;
B. confirmation that the individual(s) deciding claims have no conflicts of interest *or* provide a process to challenge potential conflicts of interest;
C. the identity of the government's expert witnesses or consultants;
D. an opportunity to obtain discovery;
E. an opportunity to review and challenge evidence used against them;
F. an opportunity to question and challenge witnesses relied upon to deny claims;
G. an opportunity to obtain copies of any expert reports;
H. an opportunity to obtain discovery from experts relied upon to deny claims;
I. an opportunity to question and challenge experts relied upon to deny claims;
J. an opportunity to present expert witnesses on their behalf;
K. an opportunity to challenge the government's arguments and positions;
L. notice and an opportunity to be heard orally before any decision;
M. the ability to obtain just compensation for their damages (because (i) an individual must suffer a "serious injury," and even then, can only recover annual lost wages of up to $50,000 and payor-of-last-resort-medical-expenses; and (ii) CICP cannot even pay these patently insufficient damages to even a tiny fraction of claimants due to underfunding);
N. the ability to obtain attorney representation in most instances because, given the above, most attorneys will not handle these claims on contingency and it is not economical to pay an hourly rate for representation;
O. a written record of any hearings or proceedings;

P. a date by which a claim will be decided or any alternative for obtaining compensation irrespective of the duration CICP takes to decide a claim;
Q. the ability to seek any judicial review of any decision in a court of law;
R. the right to present claims for damages in court; or
S. the right to present claims before a civil jury.

135. These deficiencies are hereinafter referred to as "**CICP Deprivations**."

COUNT I

DECLARATORY JUDGMENT

136. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.

137. Plaintiffs are entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that the PREP Act provisions providing liability protection and a compensation process for COVID-19 vaccines, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, violate the Fifth and Seventh Amendments for deprivation of federal constitutional rights.

138. An actual and substantial controversy exists between Plaintiffs and Defendants as to their legal rights and duties with respect to whether the PREP Act provisions which create the scheme providing liability protection and a compensation process for COVID-19 vaccines, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, violate the United States Constitution.

139. The case is presently justiciable because the CICP constitutional deficiencies apply to Plaintiffs, who are currently harmed by the CICP.

140. Absent the PREP Act, Plaintiffs could bring tort claims against vaccine manufacturers, distributors, administrators, and others who may be liable for their injuries under state law. However, Plaintiffs are foreclosed from bringing such claims because the PREP Act, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, provides liability protection and purports to establish a separate compensation process for COVID-19 vaccines. The PREP Act

scheme is thus unconstitutional as carried out through CICP. Plaintiffs are injured by this unconstitutional statute because they are barred from bringing claims that would otherwise exist under state law and no adequate remedy has been offered in the alternative.

141. Declaratory relief is therefore appropriate to resolve this controversy.

COUNT II

FIFTH AMENDMENT –DUE PROCESS CLAUSE VIOLATIONS

142. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.

143. The Fifth Amendment provides that no person shall "be deprived of life, liberty, or property, without due process of law." U.S. CONST. amend V. Plaintiffs bring a claim under the Due Process Clause of the Fifth Amendment.

A. Plaintiffs' Liberty or Property Interests at Stake

144. CICP implicates recognized liberty and property interests. The government extinguished Plaintiffs' common law and state tort law claims and replaced them with a federalized claim requiring proof of causation—a claim that has no discernable value.

145. First, the Supreme Court has long recognized that a cause of action is a species of property protected by the Due Process Clause. *See Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982); *see also Tulsa Prof'l Collection Servs., Inc. v. Pope,* 485 U.S. 478, 485 (1988) (holding that "little doubt remains" that a cause of action is a Constitutionally protected property interest); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 656 (S.D. Tex. 2004) (recognizing that a claim brought under the Vaccine Act "is a property interest protected by the Due Process Clause" (citing *Mullane v. Central Hanover Bank & Trust*, 339 U.S. 306 (1950))); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 807 (1985); *Duke Power Co. v. Carolina Envtl. Study Grp.*, 438 U.S. 59, 94 (1978) (stating that the Price-Anderson Act's elimination of common law-based tort claims was

a recognized property right and that the "Act impinges on that right by limiting recovery in major accidents" (Stewart, J., concurring)).

146. Second, to the extent the PREP Act provides a right to relief for Plaintiffs and others injured by COVID-19 vaccines, Plaintiffs have a liberty or property interest in seeking proper relief for their injuries. *See, e.g.*, *Axon Enter. v. FTC*, 598 U.S. 175, 201 n.5 (2023) (Thomas, J., concurring) (discussing Supreme Court precedent equating government entitlements with core private rights); *see also Arthritis & Osteoporosis Clinic of E. Tex., P.A. v. Azar*, 450 F. Supp. 3d 740, 747 (E.D. Tex. 2020) (granting preliminary injunction on plaintiff's due process claim where government failed to provide timely review of alleged overpayment of Medicare payments).

B. The Supreme Court's Procedural Due Process Test

147. The United States Supreme Court has considered three factors to determine whether government action satisfies procedural due process requirements:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Gibson v. Tex. Dep't of Ins., 700 F.3d 227, 239 (5th Cir. 2012) (quoting *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976)).

148. Each of the three *Mathews v. Eldridge* factors favors striking down the PREP Act to the extent it violates fundamental procedural due process protections:

1. Plaintiffs' Private Interests

149. First, Plaintiffs' private interests in this case are beyond substantial. Each Plaintiff suffered, and continues to suffer, injuries that substantially impact his or her body and, in turn,

substantially impact his or her daily life, with typically devastating consequences. They have incurred, and continue to incur, substantial medical bills and other expenses with no end in sight. Multiple Plaintiffs have had their careers destroyed and all of them have had their futures altered. Plaintiffs require intensive medical care to get their health back to a point where they can work or pursue education again, if ever. Plaintiffs' and/or their families' livelihoods have been and will continue to be severely impacted.

150. Plaintiffs' private interests at issue extend even beyond their interest in their bodies and in their futures; their private interests also include having access to an appropriate process for obtaining compensation for the injuries they have suffered due to products developed, funded, authorized, licensed, promoted, and mandated by the government. Absent the PREP Act, Plaintiffs would be able to bring a private right of action against the manufacturers of the products that harmed them—a right that predates our nation: the right to obtain relief for personal, physical, and emotional harms against tortfeasors. Specifically, Plaintiffs desire to prosecute claims such as negligence, IIED, and product liability against the pharmaceutical companies that designed and produced the products that injured them before a civil jury. However, Plaintiffs are foreclosed by the PREP Act from bringing such claims. The PREP Act extinguishes that right. At the same time, the government repeatedly assured every American (including Plaintiffs) that the product they were injecting was safe. Plaintiffs relied upon these government assurances when they decided to inject a product into their bodies. They were then severely harmed and CICP affords them no actual relief or remedy as detailed.

151. If, on the other hand, Plaintiffs had not been deprived of their claims, they could assert them in court; have a known trier of fact; confront the evidence, witnesses, and experts used to defend against their claim; address any arguments opposing their claim; have a hearing

regarding their claim; seek the full measure of their damages; and have a jury of their peers. If they did not prevail, they would have access to a record of the hearing and proceedings and could appeal that determination. These traditional due process rights and protections eliminated by the PREP Act have been extinguished by the government, indefinitely, and Plaintiffs are left with an inability to bring traditional tort claims and the illusory hope of desperately needed compensation through an administrative channel.[32] One would be hard-pressed to find a private right that was more adversely affected by government action.

2. *CICP's Established Record of Erroneous Deprivation and the Value Additional Safeguards Would Provide*

152. Second, the CICP Deprivations provide a clear risk of erroneous deprivation because they allow CICP to operate as a modern-day "star chamber" in which unidentified individuals review claims, under the alleged supervision of an unidentified panel. *See, e.g.*, *Schultz v. Medina Valley Indep. Sch. Dist.*, Civ. SA-11-CA-422-FB, 2011 WL 13234886, *2 (W.D. Tex. Dec. 6, 2011) (noting that early Americans came to the United States to escape England's "star chamber of secret trials") (citing JOHN SOUTHERDEN BURN, THE STAR CHAMBER (2008)).

153. The PREP Act's non-existent procedural safeguards, including the CICP Deprivations, will always generate "erroneous deprivations" of recognized property interests. *See Mathews*, 424 U.S. at 335. While suffering from life-altering injuries, the PREP Act extinguished all of Plaintiffs' state and common law claims and left them with the sole remedy of filing a claim

[32] In addition, the deprivation suffered by Plaintiffs is permanent. The PREP Act does not allow, at any time, civil causes of action to move forward against manufacturers or other covered persons. This factor also makes plain that Plaintiffs' private interests have been severely and permanently adversely impacted by the government. *See Mathews*, 424 U.S. at 341 (holding that the "possible length of wrongful deprivation . . . is an important factor in assessing the impact of official action on the private interests.").

in the CICP where Plaintiffs' requests for information about, and from, CICP and their attempts to receive compensation have been consistently ignored, delayed, or denied, without any meaningful opportunity to be heard or to challenge those making decisions on their claims.

154. The "erroneous deprivations" of rights is baked into the fabric of the PREP Act's sole remedy it left Plaintiffs with—CICP—both on its face and through its implementation by the Executive Branch. Plaintiffs incorporate herein the detailed allegations which explain how the PREP Act has extinguished an individual's right to bring state and common law claims for their COVID-19 vaccine injuries and, in exchange, created the CICP process which erroneously deprives claimants of virtually every due process right imaginable, including all of the CICP Deprivations detailed *supra* ¶¶ 134-35. These CICP Deprivations deprive Plaintiffs of: the right to know the identity/credentials of the individuals actually deciding their claims; the identity of any of the government's expert witnesses relied upon to challenge their claims; any opportunity to obtain any discovery; any opportunity to challenge evidence used against them; any opportunity to challenge witnesses relied upon by the government to deny their claims; any opportunity to obtain copies of any expert reports relied upon by the government; any opportunity to challenge experts relied upon to deny their claims; any opportunity to present expert witnesses; any opportunity to challenge the government's arguments; notice and any opportunity to have a hearing; the ability to obtain reasonable compensation for their damages (because an individual must suffer a "serious injury," and even then, can only recover annual lost wages of up to $50,000 and payor-of-last-resort-medical-expenses, and CICP cannot even pay these patently insufficient damages to even a tiny fraction of claimants due to intentional underfunding); the ability to obtain legal representation in most instances due to the unconscionable cap on damages; a written record of any proceedings; a date by which a claim will be decided or any alternative for obtaining

compensation irrespective of the duration CICP takes to decide a claim; the ability to seek any judicial review in a court of law; and the right to present claims before a civil jury.

155. Of note, unlike other due process cases, there was an existing system of due process in place that was eliminated here, and there were substantive rights—state and common law claims—that were extinguished. Both deprivations happened at the same time upon the person suffering an injury. In contrast, in almost all other due process claims either there was no right to begin with—and only a government benefit conferred upon people—or there was never previously a constitutionally sufficient process with regard to adjudicating an existing right. The fact that the state and common law rights to bring a claim already had an adequate due process system that was extinguished makes this situation unlike almost all other due process cases and heightens the need for due process protections.

156. When analyzing what procedures are needed to avoid erroneously depriving Plaintiffs, the starting point is the already-existing due process procedures that existed prior to the government action and which were carefully honed over hundreds of years precisely to avoid erroneous deprivation. The more of these due process protections that are eliminated, the more likely there is to be an erroneous deprivation in the present case. And here, the analysis is simple because the PREP Act did not just remove some of these due process protections or even most of them—it removed all of them. And then the PREP Act replaced those protections with their antithesis—a program that offers none of the due process protections Plaintiffs otherwise would have had. Instead, a system was established that assures Plaintiffs they will be erroneously deprived of compensation.

157. In sum, Plaintiffs have identified myriad flaws which, taken together, demonstrate the government's disregard of basic due process protections and which do more than create a mere

risk of erroneous deprivation; instead, they assure, by design, an unconstitutional outcome.

3. *Governmental Interest*

158. Third, striking down the PREP Act leans in the government's favor. In considering this factor, courts examine "the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." *Mathews*, 424 U.S. at 335.

159. Here, striking down the PREP Act to restore pre-existing procedural safeguards will impose no additional financial burden on the federal government. In fact, it will have the opposite effect because the government will no longer need to administer CICP or pay out any benefits to claimants therein. Claimants could instead seek compensation under appropriate due process safeguards, as they could for centuries prior, in court against the private parties that earned billions of dollars (mostly taxpayer money) selling the products (developed with billions of dollars of taxpayer money) which caused their harm.

160. If this Court declares the PREP Act unconstitutional, this would eliminate CICP claims and decrease the administrative burden on Defendants. Claimants could presumably pursue relief, in a court of competent jurisdiction, from those who manufactured, distributed, and/or administered the COVID-19 vaccines.

C. Supreme Court Precedent Regarding Compensation Programs

161. The Supreme Court has upheld legislative programs that modify common law rights and provide alternative compensation schemes. *See, e.g.*, *New York Central Railroad Co. v. White*, 243 U.S. 188, 202 (1917) (stating that the no-fault worker's compensation system was a "just settlement" of the problem the legislature sought to address); *Duke Power Co.*, 438 U.S. at 88 (stating that the Price-Anderson Act provided a "reasonably just substitute" for common-law or state law remedies for injuries related to nuclear accidents).

162. However, legislative bodies do not possess limitless power to abrogate common-law rights:

> I do not understand the Court to suggest that rights of property are to be defined solely by state law, or that there is no federal constitutional barrier to the abrogation of common-law rights by Congress or a state government. The constitutional terms "life, liberty, and property" do not derive their meaning solely from the provisions of positive law. They have a normative dimension as well, establishing a sphere of private autonomy which government is bound to respect. Quite serious constitutional questions might be raised if a legislature attempted to abolish certain categories of common-law rights in some general way. Indeed, our cases demonstrate that there are limits on governmental authority to abolish "core" common-law rights, including rights against trespass, at least without a compelling showing of necessity or a provision for a reasonable alternative remedy.

Pruneyard Shopping Ctr. v. Robins, 447 U.S. 74, 93 (1980) (Marshall, J., concurring); *see also Fein v. Permanente Medical Group*, 474 U.S. 892, 894–95 (1985) (White, J., dissenting) ("Whether due process requires a legislatively enacted compensation scheme to be a quid pro quo for the common-law or state-law remedy it replaces, and if so, how adequate it must be, thus appears to be an issue unresolved by this Court, and one which is dividing the appellate and highest courts of several States.").

D. The Federal Government Failed to Provide a Reasonably Just Substitute

163. By prohibiting judicial relief except in certain extremely limited circumstances (none of which are available to Plaintiffs), the PREP Act has extinguished Plaintiffs' tort causes of action under state law and has instead implemented a convoluted, underfunded, and opaque process that is wholly inadequate for Plaintiffs to seek just compensation for their injuries. Thus, the government has failed to provide a "reasonably just substitute" or "reasonable alternative remedy" for taking Plaintiffs' state or common-law rights to recover damages for their injuries.

164. CICP, established by the PREP Act, violates Plaintiffs' rights under the Fifth

Amendment by eliminating rights that otherwise exist under state law and instead directs Plaintiffs' claims through CICP, which fails to provide essential due process protections.

165. The right to pursue redress for injuries or wrongs is a bedrock principle of America's legal system. *Zinermon v. Burch*, 494 U.S. 113, 125 (1990) ("[T]he Due Process Clause contains a substantive component that bars certain arbitrary, wrongful government actions regardless of the fairness of the procedures used to implement them." (internal quotation marks omitted)). Legislation that modifies or abrogates a common law right to a tort claim will be upheld provided that the extinguished right is replaced with a just and reasonable substitute. *See, e.g.*, *Duke Power*, 438 U.S. at 88 (noting that the Price-Anderson Act's nuclear energy liability limitation did not violate due process because it provided a "reasonably just substitute" for common-law or state law remedies for injuries related to nuclear accidents—that is, assurance of a $560 million fund for recovery); *White*, 243 U.S. at 202 (holding that New York's no-fault worker's compensation system, which permitted judicial review of questions of law, was a "just settlement" for the common law tort claim the system modified).

166. Here, the fundamental rights and liberty interests involved are Plaintiffs' right to redress their grievances by bringing common law claims against the manufacturers of the products that grievously harmed them. In place of that right, the government has created CICP, which is constitutionally insufficient. While other replacement schemes have been held to pass as constitutional, this was because they were: (i) adequately funded; and (ii) incentivized responsible behavior. *See Duke Power*, 438 U.S. at 66; *White*, 243 U.S. at 194.

167. The opposite is true of CICP. CICP is a severely underfunded program and rife with perverse incentives. It is no accident that CICP denies 98% of claims. In point of fact, the average payout for COVID-19 CICP claims is $3,535.73 (a fraction of what other vaccine programs pay

out), and less than 1% of CICP claimants filing claims related to COVID-19 countermeasures have received compensation. This result is unsurprising given HRSA's paltry 2023 budget of $7 million dollars. CICP was intentionally underfunded and now must somehow make up for that shortfall. Because of the number of claims filed, there is simply no way those harmed by a COVID-19 vaccine could ever receive fair redress for the harms caused. If the current total of 13,031 claimants were all paid from the $7 million budget, each would be able to receive a maximum of $537.18 for their life-altering injuries. And what little funds are allocated to CICP are extracted from the public, providing no deterrent for risky and socially destructive behaviors by the actors who caused the harms.

168. In short, CICP violates due process because its compensation scheme is not a "just and reasonable substitute" for the state tort claims that it extinguished. Because of severe underfunding and due to its shockingly low damage caps, amongst other CICP Deprivations, it is guaranteed that catastrophically injured citizens are prohibited from receiving just compensation for the injuries the federal government's policies caused.[33]

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[33] CICP also extinguishes state constitutional rights to a just alternative remedy. Where state legislatures interfere with a common law right, even *modifications* to common law causes of action are regularly struck down in state courts where a fair alternative is not supplied. *See, e.g.*, *Mello v. Big Y Foods, Inc.*, 826 A.2d 1117, 1124–25 (Conn. 2003) ("It is settled law that [the Connecticut Constitution] restricts the power of the legislature to abolish a legal right existing at common law prior to 1818 without also establishing a 'reasonable alternative to the enforcement of that right.'"); *Tillman v. Goodpasture*, 485 P.3d 656, 667 (Kan. 2021) (observing that, while the legislature can modify the common law right, it must provide "an adequate substitute remedy for the right infringed or abolished"); *Virlar v. Puente*, 664 S.W.3d 53 (Tex. 2023), *reh'g denied* (holding that legislation withdrawing common-law remedies is valid under the Texas Constitution only if "it is reasonable in substituting other remedies" or "it is a reasonable exercise of the police power in the interest of the general welfare"); *Busch v. McInnis Waste Sys.*, 468 P.3d 419 (Or. 2020) (holding statutory damages cap unconstitutional under Oregon Constitution and, therefore, void); *Waite v. Utah Labor Comm'n*, 416 P.3d 635, 642 (Utah 2017) (holding Utah's Constitution requires "an effective and reasonable alternative remedy" where a common law right is abrogated); *see also Fein v. Permanente Med. Group*, 474 U.S. 892, 893–95 (1985) (White, J., dissenting from dismissal of appeal) (observing the open question whether due process forbids states from enacting

169. In sum, the provisions of the PREP Act pertaining to CICP, including but not limited to 42 U.S.C. § 247d-6d, extinguished Plaintiffs' tort causes of action under state law. CICP's provisions are arbitrary and capricious because, both facially and as applied to Plaintiffs, the program fails to provide a "reasonably just substitute" or "reasonable alternative remedy" for eliminating Plaintiffs' fundamental right to recover damages for their injuries. As delineated above, CICP decides claims off the record, without meaningful notice to claimants and opportunity to be heard or appeal errant bureaucratic decisions. Plaintiffs cannot review the government's evidence, confront or question the government's experts or witnesses, or present their cases in court or in any formal hearing. These and the other CICP Deprivations, along with CICP's 98% denial rate and *de minimis* compensation show that, in effect, CICP extinguishes Plaintiffs' legal claims for their injuries in exchange for no compensation.

170. Consequently, because the PREP Act interferes with Plaintiffs' fundamental rights and liberty interests—insofar as it substitutes their right to redress their grievances before a jury with an egregiously insufficient, secretive, administrative process replete with arbitrary rules—the PREP Act is violative of Plaintiffs' due process rights.

171. CICP is unconstitutional on its face and as applied to Plaintiffs, and Plaintiffs are entitled to a declaratory judgment.

COUNT III

FIFTH AMENDMENT - TAKINGS CLAUSE VIOLATION

172. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.

173. The Fifth Amendment limits the government's power to take private property without just compensation: "nor shall private property be taken for public use without just

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damage caps without providing a *quid pro quo* to persons whose claims are capped).

compensation."

174. A Court analyzing whether there is a taking must address four inquiries: (i) whether there is a taking; (ii) whether it is property being taken; (iii) whether the taking is for public use; and (iv) whether just compensation is paid.

175. With CICP, the federal government has taken away the right of any person vaccinated with, and injured by, a COVID-19 vaccine to bring tort claims against the manufacturer or other covered persons. These common law claims would, absent the PREP Act, be available to Plaintiffs.

A. PREP Act Is a Regulatory Taking

176. A regulatory taking occurs when a government regulation or action goes too far and renders property valueless. In considering whether an action amounts to a regulatory taking, the court should consider: "(1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with investment-backed expectations; and (3) the character of the governmental action." *Connelly v. Pension Benefit Guar. Corp.*, 475 U.S. 211, 225 (1996) (internal quotation marks omitted).

177. First, the economic impact of the PREP Act is financially devastating on Plaintiffs. They have each already suffered financially and will continue to suffer indefinitely. Dr. Wallskog has been outright denied by CICP and will very likely receive not a penny. Jessica and T.C.'s requests for benefits have effectively been ignored, and so they must continue to fund their ongoing medical care.

178. Second, instead of being able to retain counsel and determine the value of any claims they may have had against manufacturers or other covered persons, Plaintiffs are stuck with the mirage of a compensation program—a kabuki dance that denies all but 2% of claims and is not

even funded adequately enough to compensate those injured if it wanted to. *See Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1015 (1992) (holding that a governmental taking occurs "where regulation denies all economically beneficial or productive use" of the property). Plaintiffs' extinguished tort claims have no economic benefit due to the PREP Act. Dr. Wallskog has lost everything he had invested in himself and in his career. Jessica had to leave her job and struggles to now work only part-time. T.C. is a minor who now has a lifelong blood disorder that he must contend with both physically and financially.

179. Plaintiffs' takings claim is not foreclosed by the fact that the PREP Act was enacted prior to Plaintiffs' injuries. *Palazzolo v Rhode Island*, 533 U.S. 606, 630 (2001) (holding that one can bring a takings claim even where a challenged regulation was in place at the time the plaintiff's property was acquired).

180. Third, the governmental action here is broad and egregious. Plaintiffs have no recourse for the taking and no way to opt out. The same government that took away Plaintiffs' claims in order to protect the manufacturers subsequently encouraged (if not coerced) Plaintiffs to take the vaccine, while reassuring them that it was "safe and effective." During this time, the government knew that CICP had only four employees, an extremely limited budget, and a near impossible burden of proof on those who would inevitably be injured. While there is no strict formula to determine when it is "too much" regulation, if the complete stripping of common law and state claims in exchange for nothing is not "too much," it is unclear what ever would be.

B. Plaintiffs' State Law Claims Are Property That the Government Has Taken

181. The Supreme Court has taken a broad view of what constitutes property as it relates to a regulatory taking:

> It is conceivable that the [word "property"] first was used in its vulgar and untechnical sense of the physical thing with respect to

> which the citizen exercises rights recognized by law. On the other hand, it may have been employed in a more accurate sense to denote the group of rights inhering in the citizen's relation to the [] thing, as the right to possess, use and dispose of it. In point of fact, the construction given the phrase has been the latter… In other words, it deals with what lawyers term the individual's "interest" in the thing in question. … The constitutional provision is addressed to every sort of interest the citizen may possess.

United States v. General Motors Corp., 323 U.S. 373, 377-78 (1945).

182. Legal claims are interests that each citizen possesses and, as described above in the due process analysis, common law and state claims are indisputably property.

C. The Government's Taking Is for Public Use

183. Presumably, the federal government—in drafting and enacting the PREP Act—made the judgment call that taking every citizen's otherwise-existing right to bring state and common law claims for vaccine injury was rationally related to a conceivable public purpose. "Public use" has been broadly defined by the Supreme Court in assessing takings claims and the Court has deferred to the legislature in deciding whether a taking is for public use. *See Berman v. Parker*, 348 U.S. 26 (1954). But of course, if the taking is not for public use, then the property must be returned.

D. Plaintiffs Have Not Been Paid Just Compensation

184. When the Constitution allows the government to deprive people of property for public use, it requires that the government justly compensate people for their loss. This compensation should be measured in what the property holder has lost and not what the taker has gained. *See Boston Chamber of Commerce v. Boston*, 217 U.S, 189, 195 (1910); *see also Brown v. Legal Foundation of Washington*, 538 U.S. 216 (2003).

185. Here, each Plaintiff has lost the value of any tort claim he or she otherwise could have brought absent the PREP Act. Those claims can be measured and valued; if that value is

anything other than zero dollars, not one Plaintiff has been justly compensated by the government. The government benefited by being able to provide manufacturers and covered persons immunity to liability, which resulted in fast-tracked vaccines that could be pushed out to the American public. The manufacturers and covered persons benefited by receiving, aside from billions of dollars, immunity to liability. Plaintiffs' trade off, on the other hand, was nothing. They had their existing property right to bring common law and statutory claims stripped from them and, in return, they were given the façade of a compensation program that has an unmeetable standard: prove the precise mechanism by which this novel vaccine caused your injury with "compelling, reliable, valid, medical, and scientific evidence" that, according to CICP's denial rate, does not and cannot yet exist.

186. Once again bringing to life that this standard is impossible to meet is Dr. Wallskog's denial and the extremely high denial rate of CICP as a whole with regard to COVID-19 vaccine requests for benefits. While the government and manufacturers have only gained vis-à-vis the PREP Act, it is clear that Plaintiffs have suffered loss all around: they lost their health, their livelihoods, their finances, and compounding that, they lost their property rights to obtain any just compensation for their injuries.

187. In sum, the PREP Act was a complete regulatory taking of Plaintiffs' common law and statutory claims without just compensation and, therefore, the Court should declare the PREP Act unconstitutional pursuant to the Fifth Amendment.

COUNT IV

SEVENTH AMENDMENT – VIOLATION OF RIGHT TO A JURY TRIAL

188. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.

189. The Seventh Amendment guarantees that: "In Suits at common law, where the

value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law." U.S. CONST. amend. VII. It "remains one of our most vital barriers to governmental arbitrariness." *Reid v. Covert*, 354 U.S. 1, 10 (1957).

190. The Seventh Amendment applies to "all suits which are not of equity and admiralty jurisdiction, whatever may be the peculiar form which they may assume to settle legal rights." *Parsons v. Bedford*, 28 U.S. 433, 447 (1830). While suits at common law are clearly legal in nature and protected by the Seventh Amendment, the issue arises where an individual's claim is statutory and/or seeks relief that is both legal and equitable in nature. *Granfinanciera v. Nordberg*, 492 U.S. 33, 41 (1989).

191. To determine whether a statutory cause of action involves legal rights (and is therefore subject to the Seventh Amendment), the court employs a two-step test: (1) the court "compare[s] the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity," *Chauffeurs, Teamsters & Helpers, Local No. 391 v. Terry*, 494 U.S. 558, 565 (1990) (internal citations and quotation marks omitted); and (2) the court "examine[s] the remedy sought and determine[s] whether it is legal or equitable in nature. The second inquiry is the more important in [this] analysis." *Id.* With respect to the "more important" second prong, an action for money damages is traditionally "legal" relief.

192. Plaintiffs desire to bring claims for negligence, IIED, and products liability. All of these claims existed at common law and therefore are protected by the Seventh Amendment.

193. The PREP Act/CICP scheme directly and proximately violates Plaintiffs' Seventh Amendment rights because it denies their right to have these claims heard before a jury. It is therefore unconstitutional on its face and as applied to Plaintiffs.

A. Negligence

194. Negligence was a legal claim at common law that existed when the Seventh Amendment was adopted and, therefore, Plaintiffs are entitled to a jury trial on their negligence claims. *Wooddell v. Int'l Bhd. of Elec. Workers, Local 71*, 502 U.S. 93, 98 (1991) ("A personal injury action is of course a prototypical example of an action at law, to which the Seventh Amendment applies."). The "origin of negligence cases dates back as early as the fifteenth century." Peter A. Arhangelsky, *Nullifying the Constitution: Federal Asbestos Tort Reform and the Abrogation of Seventh Amendment Rights*, 40 Suff. U.L. Rev. 95, 114 (2006). "When the Seventh Amendment was enacted in 1791, personal injury cases sounding in negligence were ubiquitous in the English court system." *Id.* Juries decided these early negligence cases. *See* Patrick J. Kelley, *Restating Duty Breach, and Proximate Cause in Negligence Law: Descriptive Theory and the Rule of Law*, 54 Vand. L. Rev. 1039, 1057 (2001) (arguing that the early preference for jury trials was instrumental in shaping modern tort law). *See also Rogers v. Loether*, 467 F.2d 1110, 1116 n.21 (7th Cir. 1972) (noting the tort law of negligence is "prescribed by the common law").

195. The PREP Act is unconstitutional insofar as it circumscribes Plaintiffs from trying their negligence claims before a jury.

B. Intentional Infliction of Emotional Distress

196. IIED is a tort recognized at common law. The Supreme Court has indicated that the Seventh Amendment right to a jury trial extends to an action for IIED since the damages sought in these actions, including actual and punitive damages, are legal as opposed to equitable remedies. *See Curtis v. Loether*, 415 U.S. 189, 195–96 n.10 (1974) (likening the plaintiffs' civil rights action for racial discrimination in housing to an action for IIED and holding that the Seventh Amendment

applied, in part, because the plaintiff sought actual and punitive damages—"the traditional form of relief offered in the courts of law"); *Rogers*, 467 F.2d at 1116–17 (noting "the developing common law of torts recognizes a cause of action for the intentional infliction of emotional harm" and that the remedies sought, including actual and punitive damages, were "the relief most typical of an action at law"); *Wooddell*, 502 U.S. at 98 ("A personal injury action is of course a prototypical example of an action at law, to which the Seventh Amendment applies.").

197. The PREP Act is unconstitutional insofar as it circumscribes Plaintiffs from trying their IIED claims before a jury.

C. Products Liability

198. The Seventh Amendment extends to causes of action seeking liability for dangerous or defective products since tort law. Products liability-type causes of action were recognized at common law. *See Cimino v. Raymark Indus., Inc.*, 151 F.3d 297 (5th Cir. 1998) (holding that a modified trial plan in an asbestos (products liability) personal injury and wrongful death class action was invalid where it failed to provide for the Seventh Amendment right to a jury trial for an individualized determination of causation and damages under state law); *Pickle v. Char Lee Seafood, Inc.*, 174 F.3d 444, 450 (4th Cir. 1999) ("We have previously noted that when general maritime claims for negligence and products liability are alleged in a single complaint together with common law claims for negligence and products liability, all of which arise out of the same incident, the entire case is tried to the jury."); *Robert L. Dawson Farms, LLC v. Meherrin Agric. & Chem. Co.*, No. 4:20-CV-29-FL, 2020 WL 1485673, at *3 (E.D.N.C. Mar. 23, 2020) ("The products liability claims[—claims regarding negligence, negligent misrepresentation, unfair and deceptive trade practices, and fraud regarding tobacco crop—]standing alone, are legal claims.").

199. The PREP Act is unconstitutional insofar as it circumscribes Plaintiffs from trying

their products liability claims before a jury.

PRAYER FOR RELIEF

200. **DECLARE** that 42 U.S.C. §§ 247d-6d and 247d-6e, and their implementing declarations and regulations, are facially unconstitutional under the Fifth and Seventh Amendments;

201. **DECLARE** that 42 U.S.C. §§ 247d-6d and 247d-6e, and their implementing declarations and regulations, are unconstitutional under the Fifth and Seventh Amendments as applied to COVID-19 vaccines; and

202. **AWARD** Plaintiffs their costs and attorneys' fees under 28 U.S.C. § 2412 and any other applicable authority, and any other such relief this Court deems just and proper.

Dated: April 18, 2024

Respectfully submitted,

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VERIFICATION

I, Jessica Smith, a citizen of the United States and of Texas, have read the foregoing Complaint and know the contents thereof as to myself in paragraphs 4, 19, 20, 27-42, 130, 177-178 that the same are true to my knowledge and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on 04 / 15 / 2024 in Haslet, Texas.

Jessica Smith

Jessica Smith

VERIFICATION

I, Joel Wallskog, a citizen of the United States and of Texas, have read the foregoing Complaint and know the contents thereof as to myself in paragraphs 5, 19, 21, 43-63, 129, 177-178, 186 that the same are true to my knowledge and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on 04 / 16 / 2024 in Lakeside, Texas.

Joel Wallskog, MD

Joel Wallskog

VERIFICATION

I, Theodore Cabaniss, a citizen of the United States and of California, have read the foregoing Complaint and know the contents thereof as to myself and my minor son, T.C., in paragraphs 6, 22, 64-76, 131, 177-178 that the same are true to my knowledge and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on 04 / 15 / 2024 in Vista, California.

Theodore Cabaniss

Theodore Cabaniss

VERIFICATION

I, Elizabeth Thiele, M.D., Ph.D., a citizen of the United States and of Massachusetts, have read the foregoing Complaint and know the contents thereof as to myself in paragraphs 7, 23, 77-98, 132 that the same are true to my knowledge and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on 4/16/2024 in Newton, Massachusetts.

/s/ Elizabeth Thiele
Elizabeth Thiele, M.D., Ph.D.