UNITED STATES DISTRICT COURT WESTERN DISTRICT OF LOUISIANA MONROE DIVISION

ALICIA SMITH, CAROLINA BOURQUE, EMMA BURKEY, CHRISTOPHER CODY FLINT, MICHELLE ZIMMERMAN, PhD, ERIN RHODES, JESSICA KROGMEIER, LORIN JEPPSEN, and REACT19, INC.,

Plaintiffs,

-VS.-

UNITED STATES HEALTH RESOURCES AND SERVICES ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and JOHN DOES 1-3,

Defendants.

Case No. 3:23-cv-01425

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

- 1. This case presents the heartbreaking plights of a cross-section of ordinary Americans who suffered and continue to suffer devastating and debilitating injuries which 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 with 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. Since her Pfizer shot, Alicia Smith suffers from a variety of vaccine injuries, including Bell's palsy, tremors, and tachycardia, that caused her to lose her job and clientele as a hairstylist in Louisiana. In Alicia's own words more than two years later:

I literally did out of sight out [o]f mind. I didn't look at anything about vaccines. I didn't look at injuries. I just worked my tail off in therapy, got back to work, and I have lived in the worst pain since the vaccine. My body has never hurt this bad and the damage it has caused ... I still hurt really bad.

3. Carolina Bourque used to travel extensively in her role with the Louisiana Department of Wildlife and Fisheries, but after receiving the Moderna vaccine, she cannot complete basic daily tasks, travel, or even drive. Carolina's husband has found that she is, quite literally, a different person today. Before the COVID-19 vaccine, Carolina "used to be very outgoing; loved to travel, hunt, and hike; was very alert and highly educated, patient, and calm... very laid back and ready for an adventure." Today, Carolina has:

no desire to hunt, hike, or make plans to go places. We can't do anything due to not knowing what the next day will bring. [Carolina now has] a short temper, cannot carry on a conversation as intelligently as before; her loss of memory now is unbelievable. Mood swings are not the person I knew before. Her sensitivity levels

to a light, sound, and smell are off the scale.... That is not to mention the lack of intimacy compared to before the injection.

4. Emma Burkey, a healthy Nevada high school student, suffered blood clots in her brain and seizures less than two weeks after receiving the Johnson & Johnson ("J&J") vaccine. She took the vaccine because she was told it would keep the children she cared for safe. Now, after three brain surgeries and thousands of hours of physical therapy, she struggles to walk, write, and care for herself. Her youth, as she knew it, is over. Instead of celebrating Emma's high school graduation, her parents work around the clock beneath mounting debt and with the somber reality that Emma could not possibly care for herself. Emma describes her experience below:

Most days I try to be happy and show my family, friends, and therapists that I appreciate their willingness to help me when I need it. I don't like to show people how much I struggle on days my best simply isn't good enough. I have never worked so hard in my life and it makes me feel awful that even after devoting over 2 years of my life to overcoming what they did to me I'm still nowhere near where I want to be. I know that most people see their jobs as chores but I never did. Before this, my favorite thing to do was babysit. Now I can barely care for myself let alone take care of a baby that would depend on me for everything. I think that's probably the hardest part for me. I've never really been so dedicated to something the way I am to helping kids. Now, because of what they did to me, I don't get to babysit or play with kids the way I used to. Instead of chasing children around the living room I'm relearning how to take steps, instead of working I'm taking 4-hour naps after therapy because I'm so exhausted and disappointed in myself the only thing I can do is cry. My whole life my parents have told me to just try my best and everything would work out. What am I supposed to do when my best is no longer good enough?

5. Cody Flint, a husband, father, and pilot from Mississippi with over 10,000 flight hours, suffered immediate adverse reactions to the Pfizer vaccine, culminating in vertigo and ruptured inner ears two days later which nearly resulted in a deadly plane crash. Cody will never

fly again because he cannot possibly afford all the treatment needed to repair his injuries. Cody describes the ordeal as follows:

When I took my first and only dose of the Pfizer Covid-19 vaccine in February 2021, I was a perfectly healthy 33-year-old dad and husband with a bright future, a young family, financial stability, and my dream job of 15 years. Within a few short hours of receiving that shot, my life and family's future was altered in ways we couldn't have imagined at the time. Now, my family is flat broke, swamped in debt, and has no real path forward.

6. Michelle Zimmerman, PhD, a highly educated K-12 worker in Washington, suffered severe adverse events after she received the J&J vaccine to comply with federal guidelines and to set a positive example for her students. She is now medically disabled, suffering from a severe brain injury, and unable to work, drive, or walk for more than a few minutes at a time. Michelle describes her experience this way:

I have been taken out of the career I loved as a frontline worker and found purpose in. I have lost public speaking engagements for having to turn them down... I went from a book author published in five languages and researcher to 2nd-grade reading level and 1st percentile in cognitive testing, needing speech therapy, vestibular therapy, and vision therapy for over two years and still a long way to go.

I have had everything that I love stripped from me.

7. Erin Rhodes spends most of her time constrained to her bed and wheelchair in Connecticut after receiving the Moderna vaccine. She has been forced to cash out her retirement accounts to pay for ongoing medical treatment and living expenses and care for her two children and she faces the prospect of losing her home. Erin states that, since receiving the vaccine,

I have unintentionally lost 50 pounds, use an electric wheelchair to avoid passing out or using up too much energy, need help with finances due to cognitive impairment, often forget what I'm saying mid-sentence and forget the question I was even asked. I am dependent on my family, have 2 very effective medications that cost

so much money that I can't afford them, and my savings, remortgage, and 401k are long gone. I'm burning through my dad's retirement.

- 8. Jessica Krogmeier, a mother, registered nurse, and respiratory therapist from Iowa, received the Pfizer vaccine to comply with requirements for her profession. She used to dream of furthering her education and advancing into nursing leadership. Now, she cannot work full time because of her ongoing symptoms. Jessica's life has dramatically changed: "I used to be hopeful about my future. Now I have no idea how it will feel day to day. I don't even think I will live to see my kid graduate."
- 9. Lorin Jeppsen, a husband and father of two children, ages 10 and 14, serves our country as a member of the Air National Guard and is a physical trainer in Utah who was forced to take the COVID-19 vaccine to avoid discharge from the military. He was in peak physical condition, but today he struggles to jog even a quarter mile. Beyond his physical injuries, Lorin reports: "The worst part of the entire process is not knowing if you are going to wake up in the morning, and the mental and emotional strain [the injuries] put on the entire family."
- 10. React19, Inc. is a Wisconsin non-profit organization composed of more than 36,000 Americans (and thousands more across the globe) who suffered severe adverse events from, or were injured by, COVID-19 vaccines. The organization includes individuals from all walks of life plagued by a variety of injuries following their vaccination. Its mission is to "bring healing to the moms, dads, friends, and loved ones who are facing or have faced life-altering side effects from their COVID-19 vaccine" by building bridges between patients and research institutions in order to develop a better understanding of vaccine complications. React19 programs include

¹ See https://react19.org/about.

funding; promoting and sharing relevant scientific research; bringing the right medical teams together with patients; educational outreach; and supporting communities where impacted people can begin to heal physically and emotionally. React19, Inc. stands for its current members and, tragically, a growing list of former members who have lost their lives to suicide when they could no longer manage the adverse effects of COVID-19 vaccines.

11. Despite their grievous injuries and the catastrophic effects on their lives, the only relief afforded to these Americans who "did the right thing" and got a COVID-19 vaccine is potential limited compensation under a federal program called the Countermeasures Injury Compensation Program ("CICP"). The federal law that created the CICP immunizes vaccine manufacturers from financial liability except for cases of "willful misconduct." In exchange, CICP is supposed to compensate those who are injured by "covered countermeasures" like the COVID-19 vaccine. The purported purpose of CICP is to "provid[e] timely, uniform, and adequate compensation to eligible individuals for covered injuries and severe adverse events directly caused by the administration or use of a covered countermeasure;" however, as detailed

² 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 U.S. 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. 42 U.S.C. §§ 247d-6d(c)(1)(A), (c)(3), (e)(1).

³ 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 the COVID-19 vaccines.

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

herein, CICP is akin to a Potemkin village; it is an elaborate façade designed to hide an undesirable reality. CICP is the epitome of a kangaroo court or a star chamber — a proceeding that ignores recognized standards of law and justice, is grossly unfair, and comes to a predetermined conclusion.

- 12. As a critical reminder: taxpayer funds were used to develop, test, purchase, distribute, and promote the vaccines. The federal government also mandated the vaccine through every avenue it legally could (and sometimes went beyond that until corrected by the judicial branch) or incentivized mandates by state and local governments or private employers and schools.
- 13. The government consistently tested limits in a stated effort to protect Americans from COVID-19. Indeed, according to Justice Gorsuch, during COVID-19, 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, shuttering businesses and schools, closing churches, surveilling 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 10 cases 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.
- 14. Now, on the heels of the COVID-19 pandemic, the government refuses to compensate those who heeded the call and suffered the most severe vaccine injuries and, in doing so, denies them even the most basic of due process measures. The CICP 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.

- 15. Congress could remedy the defects in CICP by amending the PREP Act so that it accomplishes the stated objective of providing timely, uniform, and adequate compensation to Plaintiffs and other individuals harmed by the COVID-19 vaccine. However, the legislation as currently drafted and implemented fails to provide the most basic protections required under the U.S. Constitution. The immunity to liability provisions 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. Accordingly, the PREP Act's immunity protections for vaccine manufacturers cannot stand as there is no constitutional alternative provided to vaccine injured citizens.
- 16. Plaintiffs are seriously injured. While they fight daily battles to survive physically, mentally, and emotionally, the demand of establishing a proof of causation has been additionally placed on their shoulders without support of experts, as no table of injuries has been created for the COVID-19 vaccine. Even while being wholly consumed by survival needs, they recognize the importance of the challenge they currently bring to this Court.
- 17. Plaintiffs respectfully request that the Court enter an order enjoining the federal government from enforcing those provisions of the PREP Act pertaining to CICP, including but not limited to 42 U.S.C. § 247d-6d. Plaintiffs are currently barred from litigating their claims in a court of law, and so consistent with the Fifth and Seventh Amendments to the U.S. Constitution, the federal government must provide a reasonable alternative remedy outside of court with the following basic legal and constitutional protections from CICP:

- A. provide an adequate statute of limitations that applies to all COVID-19 vaccine injury claims, but in any event is no less than three years from onset of symptoms;
- B. identify the name, title, and educational credentials of the individuals who are deciding COVID-19 vaccine injury claims;
- C. confirm that such decision-makers have no conflicts of interest and provide a process to challenge any particular decision-maker for conflicts of interest;
- D. provide claimants with a reasonable opportunity to question witnesses or review evidence used against claimants;
- E. provide claimants with a reasonable opportunity to obtain discovery, including discovery from companies that manufactured or distributed the COVID-19 vaccines that harmed them;
- F. produce copies of any records or documents used to decide COVID-19 vaccine injury claims;
- G. identify any expert witnesses or consultants used by the government in making determinations;
- H. provide claimants with a reasonable opportunity to question or obtain discovery from such experts, including producing copies of any expert reports;
- I. allow claimants the opportunity to present expert witnesses on their behalf;
- J. provide notice to claimants and a reasonable opportunity to be heard before any hearing;
- K. preserve the right of claimants to present claims for damages in court, before a civil jury, if a claimant elects to do so;
- L. provide an appeal/judicial review of a COVID-19 vaccine injury decision in a court of law; and/or
- M. maintain a written record of any hearings or proceedings for judicial review.
- 18. For the individual Plaintiffs; for the more than 36,000 members of the organizational Plaintiff, React19, Inc.; and for thousands more nationwide, this is their last hope.

JURISDICTION AND VENUE

- 19. 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.
- 20. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(e)(1)(C) because at least one Plaintiff resides in this district. Ms. Smith resides in Ruston, Louisiana, and Ms. Bourque resides in Youngsville, Louisiana. In addition, at least five of Plaintiff React19, Inc.'s members reside in this district.

PARTIES

A. Plaintiffs

- 21. Plaintiff Alicia Smith is and at all relevant times has been a citizen and domiciliary of the State of Louisiana, residing in Ruston, LA.
- 22. Plaintiff Carolina Bourque is and at all relevant times has been a citizen and domiciliary of the State of Louisiana, residing in Youngsville, LA.
- 23. Plaintiff Emma Burkey is and at all relevant times has been a citizen and domiciliary of the State of Nevada, residing in Henderson, NV.
- 24. Plaintiff Christopher Cody Flint is and at all relevant times has been a citizen and domiciliary of the State of Mississippi, residing in Cleveland, MS.
- 25. Plaintiff Michelle Zimmerman is and at all relevant times has been a citizen and domiciliary of the State of Washington, residing in Seattle, WA.
- 26. Plaintiff Erin Rhodes is and at all relevant times has been a citizen and domiciliary of the State of Connecticut, residing in Niantic, CT.
- 27. Plaintiff Jessica Krogmeier is and at all relevant times has been a citizen and domiciliary of the State of Iowa, residing in Donnellson, IA.
- 28. Plaintiff Lorin Jeppsen is and at all relevant times has been a citizen and domiciliary of the State of Utah, residing in Layton, UT.
- 29. Plaintiff React19, Inc. ("**React19**") is and at all relevant times has been a Wisconsin non-profit 501(c)(3) organization. Upon formation, React19 had its principal place of business located in Mequon, WI. In the summer of 2023, React19 moved its principal place of business to Oconomowoc, WI.

B. Defendants

- 30. Defendant United States Department of Health and Human Services ("HHS") is a cabinet-level executive branch department within the United States Federal Government.
- 31. Defendant United States Health Resources and Services Administration ("HRSA") is an Operating Division of HHS. HRSA administers the Countermeasures Injury Compensation Program ("CICP"), at issue in this suit.
- 32. 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. Alicia Smith

- 33. Alicia Smith is a married 36-year-old mom of two children, ages 11 and 13. From March 2007 through April 2021, Alicia was employed as a hairstylist. Her duties, as one could imagine, required prolonged standing, frequent bending, coordination, and fine motor control in her hands. For more than 14 years, Alicia went to work, often tired and sometimes a bit sore, but always with a smile and ready to tackle the job that she loved and come home to her husband and her two children.
- 34. Alicia received her first Pfizer COVID-19 vaccine on March 23, 2021, and her second on April 15, 2021. Before receiving the shots, Alicia was generally healthy despite medication-managed attention deficit disorder, anxiety, and depression.
- 35. Alicia did not experience anything very unexpected following her first vaccine and was relieved to have received it. She gladly dealt with the headache and vomiting, assuming this

was normal. Immediately after her second COVID-19 vaccine, however, Alicia developed severe swelling and redness at the injection site. On April 18, 2021, Alicia went to the emergency room at Northern Louisiana Medical Center, where she was diagnosed with Bell's palsy. Her symptoms progressed over the next three weeks to include left facial drooping, extremity weakness, paresthesias (abnormal sensation of the skin), gait disturbance with loss of ability to walk, speech and swallowing difficulties, visual disturbances, and extremity tremors.

- 36. Alicia has since been diagnosed with Bell's palsy, myoclonus (involuntary irregular twitching of a muscle or joint), thyroid dysfunction, lumbar spondylosis (degeneration of the spine), immunopathologic reaction to COVID-19 vaccination, and spasmodic dysphonia (a speech disorder in which the muscles in the larynx tighten or spasm when one tries to speak) for which she must receive routine Botox injections. She received eight days of inpatient occupational, physical, and speech therapy. She has also received countless hours of outpatient occupational, physical, and speech therapy.
- 37. Since receiving her second shot, Alicia has struggled to find suitable employment. Initially, she was forced to stop working as a hairstylist. After briefly working as a seasonal employee at United Parcel Service in late 2022, Alicia attempted to begin working as a hairstylist again in February 2023. She has slowly regained some clientele, but her physical limitations force her to work at a much slower pace now. In March 2023, Alicia obtained a position with the United States Postal Service; however, she struggled to perform basic work functions due to her vaccine injuries and limited ability to grasp objects with her right hand. Her doctor now tells her she cannot lift over 20 pounds due to issues with her spine.
- 38. More recently, beginning in February of 2023, Alicia began experiencing severe migraines for the first time since receiving the vaccine. The migraines were accompanied by

blurred vision. In August of 2023, Alicia visited the doctor because of her deteriorating medical condition, informing him of her severe migraines and accompanying side effects, which she had experienced for the first time. Alicia's treating physician was unable to diagnose her medical conditions with specificity, but did state there are definitive neurological problems that require further examination and diagnosis. Alicia's treating physician also expressed additional concern with possible spinal degeneration, a condition potentially linked to neurological issues. Alicia has incurred over \$25,000 in medical bills to date for treatment of injuries she suffered from Pfizer's COVID-19 vaccine. Despite her immense financial losses, Alicia did not file a CICP claim because she did not know of the program's existence until more than a year after her injury and so she was foreclosed from requesting benefits. Alicia has considered filing a claim, but, based on her research, she decided against it because of the applicable timelines and because she believes it would be futile to pursue relief under the CICP. If a procedure existed by which Alicia could seek redress for her injuries, including those that have arisen and/or been diagnosed later than one year after her date of vaccination, she would file a CICP claim.

B. Carolina Bourque

39. In 2021, Carolina had been working as a biologist at the Louisiana Department of Wildlife and Fisheries for 13 years. In her role as an oyster manager biologist, she traveled extensively, participated in conferences and meetings nationwide, and was charged with the responsibility of managing and protecting Louisiana's oyster natural resources, including management of approximately 1.7 million acres of public oyster areas. Louisiana has one of the largest oyster industries in the nation. Although Carolina managed seasonal allergies, she was otherwise in good overall health. She enjoyed a full and active life.

- 40. Everything changed on March 17, 2021, when Carolina received a Moderna COVID-19 vaccine. Carolina and her husband received the COVID-19 shot when it became available to caretakers because she did not want to expose her elderly in-laws, who have extensive health conditions and spend a lot of time in Carolina's home, to a potential infection.
- 41. After receiving the COVID-19 vaccine, Carolina immediately suffered an anaphylactic-type reaction, with a rash on her arm and torso, tachycardia, dizziness, shortness of breath, and intense gastrointestinal pains that would last for months. She lost her hearing and had veins that popped on the inside of her arm within two hours after receiving the vaccine. Carolina took Allegra, aspirin, and other medications to manage the symptoms at home that first day. She then suffered intense fatigue and was forced to sleep all afternoon.
- 42. On March 23, 2021, when her ongoing medical issues had not improved, Carolina visited her primary care physician. Her physician took blood work, completed an ultrasound of Carolina's abdominal area, and referred her to a gastroenterologist. Within a few weeks, she also visited an ear, nose, and throat ("ENT") specialist and a pain management doctor. Doctors performed an MRI and multiple other tests.
- 43. On June 17, 2021, at the recommendation of her physicians, Carolina proceeded with a second COVID-19 shot. She was immediately dizzy and stayed at the pharmacy for 30 minutes so she would not faint. By the second day, Carolina could not get out of bed. Her leg and arms were weak, and she developed facial paralysis/Bell's palsy and migraines. Carolina became dizzy and confused. She could barely perform work at her computer because her eyesight became blurry, preventing her from reading the words on the screen.
- 44. Carolina's primary care physician initially identified an adverse vaccine reaction to the COVID-19 vaccine, but he was unwilling to make a report to the Vaccine Adverse Event

Reporting System ("VAERS"). Carolina filed a VAERS report herself (ID #1502325) on July 26, 2021. She later filed an updated VAERS report (ID #1951207) on December 15, 2021. A true and accurate copy of the December 15, 2021 VAERS report is attached as **Exhibit 1**.

- 45. After multiple new doctor visits, including a neurologist, rheumatologist, and an ENT specialist, Carolina was ultimately diagnosed with dysautonomia/autonomic dysfunction, small fiber neuropathy, peripheral neuropathy, mast cell activation syndrome, hemiplegic migraines, vestibular migraines, and chronic fatigue syndrome, among other diagnoses. Even after 27 months, Carolina continues to receive new diagnoses. Although Carolina's primary care physician identified an adverse vaccine reaction at the outset, he refused to make a VAERS report. Her first post-vaccination diagnosis was finally recorded in her medical records by her primary care physician on September 7, 2021. By December 2021, doctors diagnosed Carolina with mast cell activation syndrome, small fiber neuropathy, and autonomic dysfunction. Doctors have been baffled by her vast array of symptoms. As of the date of this Complaint, Carolina continues to search for a knowledgeable neurologist who can develop a better treatment plan, and she continues to get referrals to other specialists to see who can help her.
- 46. Carolina is unable to complete basic tasks, including driving more than a 15-minute radius, talking in public, or attending any event with loud noises or lights. She suffers from brain fog, fatigue, and dizziness on a daily basis. Carolina also deals with inflammation and painful sensations that vary between shocking pains to tingling and numbness throughout her body.
- 47. Carolina's injuries forced her to leave her position as an oyster manager to become a low-level biologist, with lower pay, more basic daily tasks, and minimal public contact, phone calls, and travel. Carolina now works from home three days a week at a computer station, and once a week she rides to work with her husband because she cannot drive most of the time

without getting confused and dizzy. Carolina takes daily breaks and, most weeks, she cannot fulfill her basic 40-hour work schedule.

48. Since her injury, Carolina has spent over \$30,000 on medical expenses, including ongoing testing and treatment. Despite visits to numerous specialists, special diets, and supplements, Carolina has yet to find effective treatments to manage her vaccine injuries. She sees no pathway to improvement going forward.

49. In March 2022, she made a claim with the CICP before the expiration of her one-year deadline. Carolina directed her physicians to submit medical records, both in paper and online via the Injury Compensation electronic submission website, associating her new symptoms and diagnoses to a vaccine reaction. Almost a year later, CICP representatives continued to claim that they did not have any of her records. They could provide no guidance regarding the timeline for determining claims nor identify who would be reviewing and deciding claims. An excerpt of a transcribed conversation Carolina had with CICP on February 8, 2023, more than a year after submitting her request for benefits, follows:

0:03:33 Carolina Bourque

So you have received the medical records, correct?

<u>0:03:38 CICP Representative</u> (Juan)

No, they have not. They either have not or they have not updated.

0:03:42 Carolina Bourque

Because I know for sure two doctors have submitted the medical records. So who decides to upload, you know, the medical records or what's the timeline on that? It was submitted last year.

0:03:57 CICP Representative (Juan)

So unfortunately, **we don't really have a time frame**. But what I can do is I can get your information down, have the department take a look into it, give you a call back and confirm with you which documents were received or if they need any additional documentation.

0:04:13 Carolina Bourque

...[W]ho decides, you know, on the documentation, like, who do you guys have like, a panel to review the documentation or or how does it work?

0:04:26 CICP Representative (Juan)

The documentation is reviewed by medical staff team members. They, they go ahead and review those records and, and make that decision.

0:04:34 Carolina Bourque

OK. And this medical team like, where are they? You know, are they hired by you guys, specifically, contractors? Are they like consultants or something?

0:04:52 CICP Representative (Juan)

I'm, I'm not sure. I think the credentials are in the medical field, so they're, they're most likely doctors. From what I'm being told, that's, that's who essentially reviews those records. It's not someone who isn't qualified, and that's what I can assure you, as, as that they've informed us that they are accredited and they are knowledgeable in that field. So when they are reviewing the medical records you can rest assured it's someone that's qualified to review them.

0:05:25 Carolina Bourque

2023 is attached as **Exhibit 2**.

OK, now what happens if there's more than 240 days passed and there's no determination, especially for example, in my case, I submitted March of last year and it's close to 365 days. So what, what happens?

0:05:44 CICP Representative (Juan)

So it's, it's not uncommon that it's been this long. We've had individuals as well in your situation. What we do is we just escalate the matter and have the department contact you directly and kind of, like, reassure you that they, they still have your paperwork. In many cases ma'am, I'm going to be quite honest with you the medical records that I've sent, they are provided. It's just more so on the department to update that information, There, I believe there may be a big backlog and not giving any, any information in regards to that, but it's it's, it's better if we just have them contact you.

A true and accurate copy of a recording of Carolina's first telephone call to CICP on February 8,

50. Carolina called CICP a second time and spoke with a second CICP representative, who again could provide no timeframe for claim determination:

0:02:15 CICP Representative (Jennifer)

[CICP] does not give updates online. You receive letters throughout the process. It is a delayed process. So it does take time to receive letters from the CICP.

0:02:25 Carolina Bourque

So it takes time. Like how long? What's the usual time for revision for each application? I submitted mine last year.

0:02:35 CICP Representative (Jennifer)

There's no time frame, how long it can take.

0:02:38 Carolina Bourque

Oh, there's no time frame.

0:00:2:40 CICP Representative (Jennifer)

No ma'am.

A true and accurate copy of a recording of Carolina's second telephone call to CICP on February 8, 2023 is attached as **Exhibit 3**.

51. More than a year and a half after submitting her claim, Carolina has received no determination or updates from CICP.

C. Emma Burkey

- 52. Emma Burkey was a healthy 18-year-old senior attending high school in Nevada. She was full of energy and a consummate overachiever. By the spring of 2021, Emma had a 4.3 GPA, attended classes online, had a black belt in karate, and juggled multiple part-time jobs. She worked five days a week as a nanny for her church pastor, and she also worked with her mom as a job cost clerk at a local construction business. In the evenings, Emma often picked up babysitting jobs when she was not going to concerts or movies or enjoying meals with family and friends.
- 53. Emma planned to attend UNLV in the fall. Although she was undecided in her major, Emma always knew that her career path would involve children. Emma also loved going to the ocean. She looked forward to a mother-daughter trip to Hawaii after graduation where they planned to walk barefoot along the beach every morning.

- 54. On March 20, 2021, Emma received the J&J COVID-19 vaccine because she believed it would help keep the children around her safe. Emma trusted J&J because it is known as a "baby company."
- 55. For a week and a half following her vaccination, Emma experienced intermittent nausea, increased heart rate, and headaches. Emma was told to expect these side effects and so she was not immediately concerned.
- 56. On March 31, 2021, Emma returned to work with her mother. She left work early because of migraine headaches. On April 1, 2021, Emma went to work again. She experienced severe headaches, but she finished the day. Emma turned down a babysitting job and went to bed early that evening.
- 57. Emma woke early in the morning on April 2, vomited in bed, and had her first seizure, 11 days after her vaccination.
- 58. Emma was immediately transported by ambulance to the emergency room at Saint Rose Dominican Hospital in Las Vegas. She was diagnosed as a "Code White" because she was experiencing clear stroke-like symptoms. Scans revealed that Emma had a small brain bleed, which progressively worsened. Emma developed Cerebral Venous Sinus Thrombosis ("CVST") due to blood clotting in her brain. Her brain hemorrhaged and she began seizing constantly, with rapid temperature and heart rate increases. By the end of the day on April 2, 2021, Emma was no longer responsive.
- 59. Emma's infectious disease doctor, Dr. Brian Lipman, immediately suspected that Emma was suffering an adverse reaction to the J&J vaccine because Emma's symptoms mirrored

adverse events associated with the AstraZeneca vaccine in Europe.⁵ Doctors at Saint Rose began calling and emailing the CDC and J&J requesting guidance. They received no response from either the health agency or the pharmaceutical company over the weekend.

- 60. By the early hours of April 3, 2021, hospital staff struggled to control Emma's rising temperature and heart rate in the 180s. Emma's parents made the difficult decision to allow doctors to place Emma in a medically induced coma and intubate her.
- 61. The next day, April 4, doctors informed Emma's parents that their daughter would likely die if they did not perform brain surgery to open the clots in her brain. They proceeded with surgery. Unfortunately, a post-surgery MRI showed more clots filling inside Emma's brain. Doctors met with Emma's parents again and determined they needed to perform a second brain surgery. This more aggressive option presented additional risks, but they believed it was Emma's only chance at survival.
- 62. Emma endured a second brain surgery on April 5, 2021. She did not wake up. Brain scans showed no blood flow through the top of Emma's head after the surgery. The clots in Emma's brain had become so severe that physicians believed she would remain in a persistent vegetative state for the rest of her life. Her parents looked at their high school senior who only days earlier had her full life ahead of her and she was trapped in a coma, with little hope of recovery.
- 63. Doctors at Saint Rose had exhausted all options. They continued to request guidance from the federal government and J&J. Again, no response was provided. Without any guidance from the "experts" who had manufactured, marketed, promoted, and mandated the

⁵ <u>https://www.youtube.com/watch?v=iy9qBxGbGPw</u> at 1:25 (local news interview with Emma's doctor, Dr. Lipman, speaking about her case).

COVID-19 vaccines, hospital leaders leveled with Emma's parents: they needed to search nationwide for another hospital that could help.

- 64. On April 6, 2021, Emma was transferred to the Neurologic Intensive Care Unit at Loma Linda University Hospital in California. Two days later, physicians at Loma Linda performed a third brain surgery on Emma.
- 65. On April 9, 2021, Emma began to show signs that she was slowly regaining consciousness. When doctors pinched her arm, she furrowed her brow and cried. Her body was covered in bruises. Doctors told Emma's parents to prepare for months or even years on a ventilator.
- 66. Emma's story gained national attention in April 2021, when the FDA paused the rollout of the J&J vaccine because Emma and five other women between the ages of 18 and 48 suffered the same catastrophic reaction.⁶ As of January 2022, the CDC reported that eight people (six women, 2 men) had died from similar conditions shortly after receiving the J&J COVID-19 shot.⁷
- 67. In the days and weeks that followed, Emma began taking small steps that previewed the long journey ahead. On April 15, Emma's family first witnessed her wake from the coma when she stuck out her tongue to communicate with her mom.⁸ On April 17 and 18, she could mouth short sentences. And on April 21, she could slightly move her left arm.

⁶ FDA, *Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine* (Apr. 13, 2021), available at: https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine.

⁷ CDC, Use of the Jannsen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices (Jan. 21, 2022), available at: https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm.

⁸ See https://www.youtube.com/shorts/M2iiUxnEW3M.

- 68. As Emma gradually regained consciousness, she was left in a quadriplegic state and was constantly vomiting due to her inability to digest food. Emma eventually had her feeding tube removed on May 27, 2021. Days later, she cried with her parents as she had to watch her high school graduation from a hospital bed.
- 69. After hundreds of hours of therapy in the hospital, Emma was discharged in August 2021. Emma missed a large part of her senior year, prom, and her graduation. Instead of attending classes all day, Emma's life now consists of neurologic restorative therapy five days per week, from 9 am until 3 pm. Medical professionals work with Emma every day to re-map areas of her brain that have been damaged. Emma continues to fight to regain motor function, including the ability to walk, write, and care for her own personal hygiene.
- 70. Before receiving the vaccine, Emma was a healthy teenager. She laughed and enjoyed time with friends and family. She went to the beach. And she loved to hold babies.
- 71. Now, Emma struggles to walk with a cane and KAFO (knee/ankle/foot orthotic). This is needed because her left foot inverts and supinates, her left knee hyperextends, and she has increased tone and spasticity. Her mother still sleeps next to her most nights because she cannot pull the covers up and down when her body temperature fluctuates. Emma struggles to use the bathroom without assistance. Because of her limited motor function, Emma requires the use of voice recognition software to write or type.
- 72. Emma's dreams of working with children when she grows up have been shattered. Instead of holding babies and watching young children grow, develop, and learn to walk, Emma fights every day to regain her own basic motor functions and movements. She struggles to make new friends. Her old friends are long gone, off to college, and she never hears from them anymore.

Emma's boundless energy has been drained, and she returns from therapy each day to nap for hours.

- 73. In addition to the obvious trauma Emma's family has been through in watching their daughter suffer and wonder if she would live and, if so, with what quality of life, Emma's family has faced increased insurance premiums because of the ongoing medical expenses. The first bill they received was for \$650,000 and they have continued "to pour in since then." Emma's dad knows he and his wife will never retire. He asks, "How are we ever going to amass enough money to pay for Emma's health care for the rest of her life?"
- 74. Emma's family had to purchase a new home to accommodate her condition. They moved from the family home that was almost fully paid off and into a one-story home with an open floorplan that is easier for Emma to navigate. Emma's family now has a \$520,000 mortgage, having bought their home at the peak of the market, which they did not anticipate as they approached retirement age. Emma's family also purchased and repaired a wheelchair-accessible van, at an estimated cost of \$60,000. Because of the mounting repairs on the van, Emma's family purchased another used wheelchair van for over \$49,000. Emma's dad drives her to and from physical therapy, a 36-mile round trip, two times a day (72 miles per day), five days per week, spending hundreds of dollars on gas. They also rented a home while searching for a new home and spent thousands of dollars while at Loma Linda.
- 75. Emma submitted a claim to CICP in November 2021. In the most recent call, CICP representatives provided no timeline for deciding her claim, stating repeatedly and coldly that it would be a "hot minute" until any decision was made.

D. Cody Flint

- 76. Cody Flint is a husband, father of two boys, aged 5 and 10, and an experienced pilot from Mississippi with over 10,000 flight hours. For 15 years, he was employed as an agricultural crop-dusting pilot. As a requirement of his position, Cody was required by law to obtain annual Federal Aviation Administration ("FAA") physicals to keep his pilot license current. He has done so every year since he was 17 years old. Cody's annual physicals, including his last FAA flight physical in January 2021, showed he was in excellent health, with no pre-existing conditions.
- 77. On February 1, 2021, only twelve days after his most recent FAA flight physical, Cody received his first COVID-19 Pfizer vaccination due to extreme pressure to do so from his employer. Within 30 minutes, he developed a severe headache that started at the top of his head. Over the next few hours, the pain moved down the back of his neck and became a burning sensation at the base of his skull. Cody became dizzy, and his eyes could not focus properly.
- 78. On February 3, 2021, Cody resumed flying after observing the 48 hour no-fly rule required of pilots after COVID-19 vaccination. Immediately after takeoff on this crop-dusting flight (for which he was the only pilot and occupant of the plane), Cody experienced tunnel vision. Approximately one hour into the flight, his condition rapidly deteriorated with intensified headache, cold sweats, worsening dizziness, visual changes, disorientation, and uncontrollable shaking. Cody lost consciousness multiple times during the flight, but against extreme odds he was able to land safely before losing consciousness again and having to be pulled from the plane none of which he recalls. Cody was flying a non-pressurized plane at an altitude no higher than 200 feet.
- 79. Cody was diagnosed with vertigo and a subsequent MRI and CT scan of his brain revealed bilateral ethmoid, maxillary, sphenoid, and frontal sinus inflammatory changes, and

bilateral paranasal sinus inflammatory changes. Cody's symptoms progressed, and he was prescribed various medications for intracranial pressure and vertigo that prevented him from operating an aircraft. On February 12, 2021, Cody submitted a VAERS report documenting his injuries. A true and accurate copy of Cody's February 12, 2021 VAERS report is attached as **Exhibit 4**. Cody sought medical care from several physicians, one of whom stated, "I think that shot made you one sick son of a bitch," and each of whom noted his rapid onset of symptoms post-vaccination. In fact, Pfizer reached out to one of Cody's physicians regarding his VAERS Report.

- 80. After seeing numerous doctors and being seen by the Ear & Balance Center in Louisiana, Cody was ultimately diagnosed with left and right perilymphatic fistulas (a tear in the membranes that separate the air-filled middle and fluid-filled inner ear), elevated intracranial pressure, and bilateral eustachian tube dysfunction. Cody's simultaneous left and right perilymphatic fistulas, highly increased intracranial pressure, and rapid onset of a severe headache were all indicators of a vaccine injury.
- 81. On March 25 and June 3, 2021, Cody underwent surgery for left and right perilymphatic fistula repairs, bilateral ventilation tube placement, microdissection, and a lumbar puncture. He continues to suffer from ongoing symptoms and can no longer work as a pilot.
- 82. On April 25, 2021, Cody submitted his Request for Benefits form to CICP. Over a year later, after dozens of follow-ups by Cody, and after United States Senator Cindy Hyde-Smith contacted the CICP multiple times and even questioned the Secretary of HHS regarding Cody's case during a May 4, 2022 public hearing, Cody's request was denied on May 25, 2022. A true and accurate copy of the CICP's denial letter signed by George Grimes, M.D. is attached as **Exhibit 5**.

- 83. The denial letter absurdly stated that "barotrauma from flying is a known cause of perilymphatic fistulas, and the symptoms of the perilymphatic fistulas (severe vertigo) began while flying." This completely ignores that Cody was flying (as he did for 15 years) in an unpressurized plane at an altitude no greater than 200 feet, which would not induce barotrauma. In fact, barotrauma was the first condition ruled out by Cody's doctors because pilots do not suffer barotrauma by flying a few hundred feet above sea level in an unpressured cabin. By comparison, commercial airline pilots and passengers fly 8,000 feet above sea level (40 times higher) in a pressurized cabin and would face an exponentially greater risk of barotrauma.
- 84. On June 15, 2022, Cody requested reconsideration of the denial of benefits. CICP denied Cody's request for reconsideration on January 18, 2023 21 months after Cody submitted his original request.
- 85. Cody's salary is now reduced to 20% of what he had been making as a pilot. Flying is the only job he's had since he was 18 years old, and he does not have another career to fall back on. Compounding that ongoing loss, Cody did not have health insurance at the time of his vaccination and resulting injuries. He has already spent his family's entire savings, including his children's future college tuition, in an effort to get well enough to return to flying. That was a futile attempt that financially buried his family. His doctors tell him he needs significantly more treatment, but he cannot afford to get it.

86. In Cody's own words:

It was my understanding the federal government assumed responsibility for these vaccine injuries in return for the public's trust and willingness to take the vaccine. I kept up my end of the bargain. Sadly, the federal government did not. The federal government asked me to put an experimental drug into my body. That drug has taken everything from my family. In return, the federal government has protected the drug manufacturer and left me

no legal path forward. In my opinion, this is our country's 'Chernobyl.'

E. Michelle Zimmerman

- 87. Prior to her COVID-19 vaccination, Michelle Zimmerman was a book author, published in five languages, and a researcher commissioned by General Motors and International Society for Technology in Education on Artificial Intelligence in education. She had a meeting scheduled with the education advisor to Washington Governor Jay Inslee the week of her COVID-19 vaccination and was in the top running for the Global Teacher Prize.
- 88. Michelle was a full-time frontline worker in K-12 education in Renton, Washington, as a STEM educator. She was highly physically active, still teaching dance to students outdoors during social distancing up through her last day of teaching before vaccination, when HHS issued a directive to make available and administer vaccines to teachers, childcare workers, and staff. A true and accurate copy of the White House Press Release, dated March 7, 2021, concerning the prioritization of COVID vaccines for educators is attached as **Exhibit 6**. Consistent with these directives, Michelle's local public health officials confirmed she was required to obtain at least one dose of the COVID-19 vaccine by the end of March 2021.
- 89. On March 14, 2021, in an effort to remain in compliance with the President's authorization for frontline education workers in K-12 schools to obtain a first dose of the COVID-19 vaccine by the end of March 2021, to allow her to remain in a teaching position, and to set a good example for her students and those who were hesitant to get vaccinated with a new product, Michelle went with her parents to a mass vaccination site in King County, Washington. Michelle

⁹ See HHS, Secretarial Directive for Prioritization of COVID-19 Vaccines and Administration for Certain Educational and Child Care Workers, dated March 2, 2021, available at: https://www.hhs.gov/sites/default/files/secretarial-directive-prioritization-covid-19-vaccines.pdf.

informed the King County Public Health employees that she suffered a severe adverse reaction to the DTP vaccine as a child. When she asked about any known neurological risks for the J&J COVID-19 vaccine, the Public Health employees advised Michelle that there were no adverse reactions, not even anaphylaxis.

- 90. Michelle and her parents each received the J&J COVID-19 vaccine on March 14, 2021. Moments later, Michelle experienced shooting pain down her injection arm and wrist, and up to her left ear. Within 20 minutes of the injection, Michelle began experiencing tongue and throat swelling (anaphylaxis), which was recorded as an adverse event by healthcare officials at the mass vaccination site. Because those administering her vaccine failed to follow requirements for administering a vaccine under emergency use authorization ("EUA") and did not send her for medical observation or treatment, Michelle's medical condition worsened. Michelle has since experienced irreversible brain and vision damage. Michelle's parents both suffered serious adverse reactions following receipt of vaccines with the same vaccine lot number as Michelle.
- 91. Michelle and her parents each have medically verified records establishing vascular inflammation, amyloid fibrin microclots, and brain injury from the J&J vaccine, lots of which were later determined to have been contaminated with materials from the AstraZeneca vaccine's virus. Both the J&J and AstraZeneca COVID-19 vaccines were processed at the same facility. Michelle and her father also have documented vestibular and vision damage.
- 92. Michelle had no underlying medical conditions before receiving the COVID-19 vaccination. Since receiving the shot, Michelle has been medically disabled and not medically cleared to return to work, drive, or travel, or to engage in cardio exercise. When Michelle attempted to complete a six-minute walk test, doctors were forced to stop the test after four minutes because

it would be unsafe to continue. Michelle's doctors have not even cleared her to go to movie theatres or engage in any activity for over an hour at a time.

- 93. Michelle now lives with her parents because she is unable to live independently. She cannot even drive herself to medical appointments. She cannot make her own food, do her own laundry, or clean. Michelle cannot go grocery shopping on her own.
- 94. Michelle continues to suffer from a host of medical conditions, including brain damage, vision damage, vestibular damage, vascular damage, blood clotting, mitochondrial damage, damage to gut microbiome, skin and hair loss, and nerve damage. She has also experienced a substantial shift in body composition, including muscle waste and muscle coordination impairment (ataxia), not explained by dietary changes. In the over two years following her vaccine injury, extensive clinical and specialized medical testing have revealed no causes for her injuries other than the COVID-19 vaccine.
- 95. The frustration Michelle feels on a daily basis matches the devastation and severe physical pain of the physical symptoms. Michelle has lost her career, independence, and relationships. She had been saving all of her money to buy a house. Now, she could never hope to live independently and has instead burned away her savings on medical care.
- 96. Michelle learned through her own research that she could pursue a legal remedy through CICP. In September 2021, she contacted CICP to request a guide for the standard for proof of causation that would be required to ensure that she submitted all required information. CICP representatives advised Michelle that no standard or guideline existed, but that quantitative data and peer-reviewed, published scientific research would meet the standard for proof of causation.
- 97. On October 1, 2021, after spending weeks compiling it, Michelle submitted a Request for Benefits form to CICP through the electronic portal. Her claim package included 300

pages of her relevant medical records and proof of causation, meeting and exceeding all CICP requirements outlined in the Federal Register, which she had dutifully gathered, with assistance, over the previous month despite suffering debilitating symptoms. Michelle received online confirmation that her application and medical records were received in October 2021.

98. Michelle repeatedly requested updates from CICP officials and confirmation that her medical records had been received. Initially, she spoke with a CICP representative named David who could not confirm a timeframe for when her claim would be processed. On November 22, 2021, Michelle received a return call from a customer service representative who identified herself as Phyllis. A true and accurate copy of a recorded excerpt of Michelle's November 22, 2021 telephone conversation is attached as **Exhibit 7**. During the call, Michelle was informed that CICP had no record of her claim, that she must re-apply and wait 40 days to see if the claim was posted on the system, and then repeat the process of re-applying if CICP lost her claim again. When Michelle asked to speak with a supervisor or for a supervisor's contact information, Phyllis responded that she could not provide that information. *Id*.

99. Months later, after multiple communications, Michelle was connected with Captain Dale Mishler, Chief of Countermeasures and Review Panel Branch. During their April 24, 2022 telephone conversation, Captain Mishler assured Michelle that, contrary to prior statements by CICP representatives, CICP had received her medical records. Captain Mishler also confirmed that CICP provides no guideline to the public regarding the required standard of proof to be applied:

05:38 Michelle Zimmerman

So there's not actually a published document that's made public for people to access prior to submitting the claims.

<u>05:46 CICP Representative (Capt. Mishler)</u> Regarding?

05:48 Michelle Zimmerman

What you're using for the standard of proof, for example, what journals you're using, what medical research you're using, so that people have access to know what you are using to compare their submitted claims, and what your reviewers are using to determine if it meets those claims.

06:03 CICP Representative (Capt. Mishler)

Um, we're, we're using up to date, we're using, uh, PubMed, we're using the National Institutes of Health's, uh, medical library. Um, and all of those, all of the evidence has to be based in a peer reviewed published journal.

06:20 Michelle Zimmerman

And that makes sense, I under-, and I do understand that part. But what I'm saying is what guideline is available to the public — so before they submit their claim, they know what you're looking for, which journals you're using, which researchers you find acceptable or not — especially since...

06:35 CICP Representative (Capt. Mishler)

The [inaudible] guideline for that? No.

06:37 Michelle Zimmerman

Okay, so there is no guideline? Okay.

06:37 CICP Representative (Capt. Mishler)

No, no.

A true and accurate copy of a recorded excerpt of Michelle's April 24, 2022 telephone conversation is attached as **Exhibit 8**.

- 100. For nearly two years, CICP officials have delayed, providing contradictory answers without any indication that resolution of her claim is forthcoming. In March and April 2022, CICP told her that no case number had been assigned. But almost a year later, Michelle received an express mailer dated January 11, 2023, containing a letter backdated to January 1, 2022 (a federal holiday and weekend), with a case number, signed by Dr. George Grimes. A true and accurate copy of the letter and mailer are attached as **Exhibit 9**.
- 101. Michelle also received a letter in an extremely urgent mailer stating that CICP was missing medical records, even though she had been assured previously that her records were

received. Michelle submitted records both online through the CICP portal and via certified mail, but CICP repeatedly provided conflicting information.

102. Almost two years after submitting her claim, there is no indication when a determination will be made on Michelle's claim. Michelle still suffers daily with all of the above-described symptoms and her life has not returned anywhere close to her pre-vaccination "normal."

F. Erin Rhodes

- 103. From 2006 through January 5, 2021, Erin Rhodes was employed as a speech pathologist, treating disorders with swallowing, communication, cognition, and voice. Due to the high occupational risk of infectious exposure, Erin was offered the COVID-19 vaccine early in the vaccine rollout.
- 104. Before receiving her COVID-19 vaccine, Erin was seeing a physical therapist for a minor medical condition, but she was described by her primary care provider as "healthy." Erin was full of energy. On a typical day, she would return home and work out by running or weightlifting in her garage gym, and then make dinner for her husband and children (ages 12 and 15). She helped other moms in the neighborhood develop workout routines. On January 5, 2021, the day before she received the COVID-19 vaccine, Erin ran a few miles with friends.
- 105. Everything changed the next day. On January 6, 2021, Erin received her first dose of the Moderna COVID-19 vaccine. Within five minutes of the injection, Erin felt sick and she spent the following weeks in bed experiencing headaches, fatigue, and nausea.
- 106. On January 26, 2021, Erin presented to the Yale New Haven Emergency Department. She reported feeling weak and wobbly in her legs and her blood pressure was elevated to 150 systolic. Medical staff explained to Erin that she was merely experiencing a robust immune response and advised her to proceed with the second dose.

- 107. On February 8, 2021, Erin had a telemedicine visit with a Yale immunologist. She explained the ongoing side effects she experienced after receiving the COVID-19 vaccine. He advised Erin that she was experiencing a strong immune response and advised her to proceed with the second dose per CDC guidelines.
- 108. Relying on this medical advice, Erin received her second dose on February 12, 2021. She woke up the following day experiencing chills, headache, and flu-like symptoms. Afterward, Erin continued to experience waves of these symptoms which made work and household chores nearly impossible. Erin saw her primary care physician twice more, who ordered lab work.
- 109. On March 11, 2021, Erin filed a VAERS report (temporary ID #349875). A true and accurate copy of the March 11, 2021 VAERS report submission confirmation is attached as **Exhibit 10**.
- 110. Erin's symptoms persisted and subsequently expanded to include chest pain, racing heart rate, brain fog, shortness of breath, joint and body pains, stomach pain, diarrhea, itchiness, insomnia, runny nose, difficulty swallowing, scratchy throat, heat and cold intolerance, gluten insensitivity, pre-syncopal episodes with visual disturbance, electric shock feelings, and tingling in her hands and feet.
- 111. Erin continued to see specialists including cardiologists, chiropractors, neurologists, rheumatologists, naturopaths, geneticists, and allergists/immunologists and had countless tests, including blood work, chest x-rays, EKGs, MRIs, echocardiograms, oculomotor testing, and balance testing. Her diagnoses include, among others, an "adverse reaction to the COVID-19 vaccine," Postural Orthostatic Tachycardia Syndrome (POTS), chronic fatigue syndrome, hypermobile Ehlers Danlos syndrome, unspecified polyneuropathy, unspecified

dysphagia, disturbances of skin sensation, postnasal drip, dizziness, mood disorder, antibody deficiency, and craniocervical instability. To date, almost none of the numerous treatments, therapies, or prescriptions have alleviated Erin's symptoms. Although two medications have provided some relief for Erin's symptoms, she cannot afford them.

- 112. On June 16, 2021, Erin submitted a VAERS report directly to Moderna (Case #21-017951). A true and accurate copy of the June 16, 2021 VAERS report is attached as **Exhibit 11**.
- 113. Despite her symptoms, Erin attempted to return to work twice, from April 19-July 31, 2021, and August 23, 2021-January 5, 2022. During these time periods, Erin was frequently forced to call in sick due to her symptoms. Erin went on medical leave and short-term disability beginning on January 5, 2022, and was forced to resign from her position as a speech pathologist in March 2022 because she could not work any longer.
- 114. Erin has suffered tremendous financial harm as the result of her inability to work and medical bills she incurred from her COVID-19 vaccine injury. Erin estimates that her medical treatments alone have cost over \$20,000. As a result, she has had to remortgage her house and is fighting to get social security disability insurance.
- 115. Erin's injury has destroyed her marriage. Recently, Erin's husband filed for divorce because of her illness, leaving her unable to pay living expenses for herself and her two young children. Erin is mostly confined to her wheelchair and bed, fights persistent brain fog, and struggles to stay hydrated due to nausea, diarrhea, and vomiting. She cashed out retirement accounts to pay ongoing expenses but now faces the prospect of losing her home.
- 116. Erin is a shell of her prior self. She was once full of life and energy. Now she spends most of her waking hours in bed or her electric wheelchair. She hopes to squeeze a couple of good

hours out of each day. Erin cannot go to the pool, the beach, or the mall with her kids. She cannot run with friends or enjoy the active life she once knew.

117. Erin 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.

G. Jessica Krogmeier

- 118. From 2004 through 2020, Jessica Krogmeier had extensive experience in the healthcare industry. During that time period, she attended nursing school and was employed in various roles as a respiratory therapist and registered nurse. She was ambitious, goal-oriented, and had dreams of advancing her education and moving into a nursing leadership position.
- 119. Jessica resigned from her position in October 2020 to recover from a pregnancy loss. Fortunately, Jessica subsequently had a successful pregnancy and delivered her third child, a daughter, in May of 2021. In the following months, Jessica began making plans to return to work as a nurse.
- 120. While preparing to return to work in summer of 2021, Jessica understood that the COVID-19 vaccine would be required for any nursing position she would obtain. Thus, on September 3, 2021, Jessica received her first Pfizer COVID-19 vaccine.
- 121. Before receiving her shot at a pharmacy, Jessica spent time discussing potential side effects with the pharmacist. Jessica was concerned because her son was getting surgery the following week. The pharmacist counted the number of days (four) on his fingers and told Jessica, "You should be fine by then." Jessica also expressed concerns because she was breastfeeding at the time. The pharmacist said he had just read a study out of Israel and he was comfortable with Jessica taking the shot, and that she could continue feeding her daughter.

- 122. Jessica also believed that the vaccine was fully approved by the FDA. Jessica would not have taken the vaccine if she knew it was only approved through EUA.
- 123. Immediately after receiving her first COVID-19 vaccine, Jessica felt dizzy, numbness, tingling, exhaustion, severe arm pain, chest pain, and the inability to sweat. A VAERS report (ID #1678480-1) was submitted on September 7, 2021. A true and accurate copy of Jessica's September 7, 2021 VAERS Report is attached as **Exhibit 12**.
 - 124. Jessica was unable to stay with her infant daughter by herself for almost four weeks.
- 125. Eventually, Jessica's symptoms progressed to irregular and painful periods, numb arms at night, chest pain, dry eyes, lipomas in limbs, hives on the back of her knee and ankle, brain fog, joint pain, elevated heart rate, right foot pain, trigeminal nerve pain, teeth sensitivity, difficulty concentrating, and a burning skin sensation.
- 126. Before receiving the COVID-19 vaccine, Jessica rarely had to go to the doctor. Since receiving the shot, Jessica has been evaluated by many specialists including general neurology, neuromuscular neurology, neuro-immunology, autonomic neurology, allergy immunology, cardiology, otolaryngology, endocrinology, and dermatology. She has had multiple diagnostic tests including CT of her brain, MRI of her brain and cervical spine, EMG/NCS, stress echocardiogram, and skin biopsies, as well as countless laboratory tests. Jessica's providers consistently noted the rapid onset of symptoms after she received the COVID-19 vaccine.
- 127. Following her vaccine, Jessica has been diagnosed with small fiber neuropathy, pre-diabetes, and autonomic dysfunction. She continues to suffer from dizziness, extreme fatigue, internal tremors, tinnitus, painful periods, numbness and tingling in all the limbs, ear pain and fullness with changes in hearing, chest pain, elevated heart rate, trigeminal nerve pain, brain fog,

abdominal pain, diarrhea, lumps under the skin, night sweats, and orthostatic lightheadedness.

Jessica's symptoms have left her feeling completely exhausted.

- 128. Jessica's vaccine injuries have also significantly limited her employment prospects. She currently works on a reduced schedule as a cardiac and pulmonary rehab nurse. She educates patients on dietary changes, helps them make exercise routines, and monitors them while they use a treadmill. Although she performs her duties to the best of her ability, Jessica can barely work three days per week and could not consider a more rigorous nursing position. She no longer dreams of nursing leadership. Today, Jessica just hopes to feel well enough to get out of bed, to endure the dizziness, joint pains, and burning sensations, and to work part-time for as many years as she has left.
- 129. To date, Jessica has spent close to \$10,000 out of pocket to cover her ongoing medical treatments and out-of-state travel to see specialists, with this amount expected to increase. Because her vaccine injury has significantly limited her ability to manage a full-time workload, Jessica has also lost at least \$35,000 per year in earning potential. Jessica was also forced to withdraw \$10,000 from her 401(k) account to make ends meet.
- and despite her vaccine injury, she was told that she could continue to breastfeed. Jessica's daughter had been a healthy, growing baby for the first four months of her life. After Jessica received the COVID-19 vaccine and continued to breastfeed, her infant daughter suffered from rashes, diarrhea, and stopped gaining weight for six months. Jessica's daughter was hospitalized and received breathing treatments and was diagnosed with asthma. Her daughter received steroid treatments six times. Jessica submitted a CICP claim for her daughter but has received no response.

- 131. In September 2021, Jessica submitted an online request for benefits to CICP. Jessica also submitted a CICP claim with supporting documentation for her daughter before the one-year deadline in September 2022. To date, she has not received a response to either request.
- 132. On February 9, 2023, Jessica called CICP to confirm the status of her claim. Although Jessica's physicians had already submitted records, the CICP representative informed Jessica that no records had been provided and that CICP had no timeline for determining claims. The following is an excerpt from a transcript of that call:

0:07:47 Jessica Krogmeier

OK. Well, what is the timeline for deciding the request, then, once you get everything that you need?

0:07:54 CICP Representative (Phyllis)

There is no timeline.

0:07:56 Jessica Krogmeier

OK.

0:07:56 CICP Representative (Phyllis)

The only timeline on this is the one for opening a claim. You have one year to open the claim, but after that there's no timeline.

0:08:04 Jessica Krogmeier

So it could take several years to decide a claim.

0:08:08 CICP Representative (Phyllis)

It can. It can, but right now with yours, it's not going anywhere because we don't have medical records. So it's still just sitting in the beginning stage.

0:08:18 Jessica Krogmeier

And that's interesting because I sent them, so I'll have to check into that. But excuse me, what happens if more than 240 days passed? Then? Because I've seen some stuff about that and there hasn't been a determination what happens then?

0:08:33 CICP Representative (Phyllis)

You know they have however long they need to make a determination.

A true and accurate copy of Jessica's recorded telephone call to CICP on February 9, 2023 is attached as **Exhibit 13**.

Jessica's claim would be decided by an unidentified team of doctors, lawyers, or other individuals; (ii) appeals may or may not be determined by the same team or teams; and (iii) the representative did not know whether individuals deciding claims have conflicts of interest. A true and accurate copy of Jessica's second recorded telephone call to CICP on February 9, 2023 is attached as **Exhibit 14**.

H. Lorin Jeppsen

- 134. In 2021, Lorin Jeppsen was a member of the Air National Guard. Over his 15-year military career, Lorin spent seven years on active duty, from 2008-2015. He flew aircraft for several years and then transferred to an on-ground tactical unit providing support to air units.
- 135. Lorin actively trained with his unit, the 124 Air Support Operation Squadron ("Unit 124-ASOS"). Unit 124-ASOS is a tactical air control unit that supports special warfare operations in the Air Force. Unit 124-ASOS regularly engaged in rigorous training with the servicemembers they supported, including Army Rangers and Navy Seals. A typical workout included running a 7-minute mile to warm up, intense weightlifting, and distance swimming. Over the course of his career, Lorin's training would include long-distance runs carrying a 60-pound equipment pack.
- 136. Pursuant to the federal mandate, Lorin was required to obtain the COVID-19 vaccine as a member of the U.S. military. Lorin researched the COVID-19 vaccine to the best of his ability with the data available at the time and weighed his options. Initially, he had reservations about getting the shot, but he knew that he would not qualify for a medical exemption. And although he had a deep and firm conviction that the COVID-19 vaccine was not right for him,

Lorin was concerned about getting a religious waiver; his concern was later justified when the military sent blanket denial letters to most every servicemember who requested a religious exemption.

- 137. In late October 2021, after delaying for as long as he could, Lorin's commanding officer delivered an ultimatum: take the COVID-19 vaccine, submit a waiver, or face administrative paperwork leading to discharge. Believing any waiver attempts would be futile, Lorin complied and received his first Pfizer COVID-19 vaccine on October 29, 2021. In the following days, Lorin experienced neurological issues, dizziness, headaches, and tingling in his left arm.
- 138. On November 5, 2021, a week after receiving the vaccine, Lorin's wife, Mandy, urged him to go to the emergency room as his symptoms continued without relief and began to increase. Lorin presented with ongoing symptoms described above along with elevated blood pressure. The emergency room physician was unable to diagnose Lorin's condition. He was directed to see his primary care physician and a neurologist for further treatment and evaluation.
- 139. When Lorin went home, his symptoms worsened. He experienced brain fog, heart palpitations, headaches, dizziness, inflamed sinuses, and numbness and tingling throughout his body. At night, Lorin would sometimes wake with the sensation that someone was scratching his head or with shocking sensations in his throat along with various nerve pain throughout his body.
- 140. On November 9, 2021, Lorin was able to see his primary care physician, who acknowledged that Lorin was likely experiencing neurological inflammation due to the COVID-19 vaccine. Lorin obtained his first medical waiver from receiving the second dose of the Pfizer COVID-19 vaccine.

- 141. In late November 2021, a month after his vaccination, Lorin attempted to run a short distance at a comfortable, 10-minute mile pace. Within approximately a quarter mile, Lorin experienced sharp pain in the back of his head and almost blacked out. Lorin had to rest for an hour to be sure that he did not faint something that had never happened to him before in all of his years of running and physical exertion. Lorin saw a cardiologist for further evaluation, who conducted a range of tests, including an echocardiogram, stress test, and additional heart monitoring. The cardiologist was unable to determine the cause of Lorin's symptoms. However, he provided a medical waiver stating it is his medical opinion that Lorin should not receive additional COVID-19 vaccines.
- 142. In the months that followed, Lorin continued to experience ongoing symptoms, including continued chest palpitations and vertigo. Lorin saw a neurologist to address his ongoing symptoms. The neurologist acknowledged that Lorin's neurological inflammation was likely from the COVID-19 vaccine. Lorin received a third medical waiver from receiving additional COVID-19 shots.
- 143. Today, Lorin can no longer train with Unit 124-ASOS. During training, he is assigned to desk duty where he completes paperwork or works on a computer to complete administrative tasks. He is incapable and not medically cleared to engage in rigorous physical activity the very activities that used to define him. The only way for Lorin to avoid severe side effects is a detailed regimen that includes: (1) cold showers and plunges; (2) several supplements including turmeric, omega-3, vitamin B, and other supplements; (3) sleep therapy; (4) hyperbaric oxygen therapy; (5) fasting; and (6) an anti-inflammation diet. As a rough estimate, Lorin devotes approximately 25% of his time to managing this regimen to minimize symptoms. Without this regimen, and sometimes in spite of it, he experiences chest pain, heart palpitations, numbness,

joint pain, vertigo, dizziness, and fatigue. He used to engage in long distance and cardio training, including cycling. Today, he barely does any cardio workouts because they trigger severe side effects. The most he has run since taking the COVID-19 shot is about a half mile at a 10-minute pace, eventually slowing to an incline walk. When Lorin experiences severe side effects, he typically feels dizziness and heart palpitations, followed by numbness and tingling. If symptoms persist without relief, Lorin is required to sleep for almost the entire day to find relief.

- 144. Lorin estimates his total medical costs to date are between \$5,000 and \$10,000 and continuing to climb. Lorin cannot put a price on the rest of the losses he has suffered.
- 145. Lorin did not file a CICP claim within a year of his first shot because he was unaware that CICP existed.

I. React19, Inc.

146. React19 is a 501(c)(3) non-profit organization organized under the laws of Wisconsin. React19 was formed and exists solely to provide financial, physical, and emotional support to those suffering from long-term adverse events from COVID-19 vaccines. React19's mission is "to bring healing to the moms, dads, friends, and loved ones who are facing life-altering side effects from their Covid-19 vaccine." React19 was founded by vaccine-injured medical professionals and clinical trial participants and in two short years has grown to over 36,000 members in the United States (and thousands more internationally), all of whom have suffered adverse events following COVID-19 vaccination. React19 has also lost members to suicide — those who could no longer live with the adverse health conditions they endured following their COVID-19 vaccines. At least five of React19's members reside in the Western District of Louisiana, in Oak Ridge, Lafayette, Shreveport, and Youngsville, LA.

147. React19 conducted a survey of its members and found that only approximately 32% of its members filed a request for benefits in CICP, 27% were aware of the program but did not file, and 41% had never heard of the program and so did not file.

J. CICP Program

- 148. CICP was established under the Public Readiness and Emergency Preparedness Act of 2005 ("PREP Act")¹⁰ 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).
- 149. 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).
- 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).
- 151. 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, the injured person or the person's survivors must first file in CICP and, if denied or if they do not accept the offered compensation, 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). For most claims against manufacturers or distributors with respect to a covered

¹⁰ Public Readiness and Emergency Preparedness Act of 2005, Pub L. No. 109–148, 42 U.S.C. §§ 247d-6d, 247d-6e, (2005).

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). In all other cases, individuals injured by a covered countermeasure must also seek redress from the CICP without any option of filing suit in a federal court.

152. 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.

153. As of September 1, 2023, 12,110 CICP claims have been filed related to COVID-19 countermeasures. The statistics speak for themselves: to date, the Program has compensated only **four** of those claims, three for myocarditis and one for anaphylaxis. The average payout on COVID-19 claims to date is \$2,148.14. By comparison, CICP's average payout on injuries related to the H1N1 vaccine was \$198,450.12. Over 90% (10,949/12,110) of the COVID-19 countermeasure claims remain "pending review or in review." In rare instances where a decision has been reached, over 97% of those COVID-19 countermeasure claims have been denied (1,129/1,161). CICP has awarded compensation to a lamentable 0.033% of total COVID-19 claimants (4/12,110), and benefits determinations remain pending for 0.2% of total COVID-19 claimants (27/12,110). Over 13 claimants (27/12,110).

¹¹ HRSA, Countermeasure Injury Compensation Program (CICP) Data (Sep. 1, 2023), available at: https://www.hrsa.gov/cicp/cicp-data.

HRSA, *Table 4. CICP Claims Compensated (Fiscal Years 2010-2023)*, available at: https://www.hrsa.gov/cicp/cicp-data/table-4.

¹³ HRSA, Countermeasure Injury Compensation Program (CICP) Data (Sep. 1, 2023), available at: https://www.hrsa.gov/cicp/cicp-data.

- 154. CICP's claims submission and review process is shrouded in secrecy. Claims are submitted to unidentified CICP "representatives" for review, are reviewed according to undefined standards, and no clear process or timeline for the review is disclosed.
- 155. The government does not identify the name, title, or educational credentials of the individuals deciding CICP claims. There is no mechanism to interact with, much less question or challenge, those who are deciding Plaintiffs' requests. Nor is there any way to confirm whether such individuals ever reviewed, promoted, or mandated the COVID-19 vaccine or otherwise have any conflicts of interest.
- 156. The government provides no timeline for deciding requests. Plaintiffs have no way of tracking requests until they receive a case number, at some uncertain time in the future.
- 157. The government provides no opportunity for discovery or method to request or review documents relied upon to reach its determination.
- 158. The government provides no rubric, manual, or set of guidelines or standards that are used to decide requests. Instead, the government purports to make its determinations based on "compelling, reliable, valid, medical, and scientific evidence" determined by unidentified individuals, based on unidentified information and evidence.
- 159. 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. Plaintiffs cannot present their own expert witnesses. If the government does not rely upon experts, that presents other obvious concerns.

- 160. 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, 14 although hundreds of millions of doses of COVID-19 vaccines were administered.
- 161. CICP lacks cost-effectiveness efficiency, with 94% of its total costs spent on administration rather than compensation to Plaintiffs and others.
- 162. CICP appears unable to adequately compensate 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 which is 72.1 times its current balance.
- 163. Additionally, 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). 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").
- documented. *See* "The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices" (6th Rep. 2000), available at: https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf. Since Congress passed the Vaccine Act, HHS has used its authority to change the rules of the Vaccine Injury Compensation Program ("VICP") in its favor so it can more readily defeat vaccine injury claims. Initially, the Vaccine Act created a Vaccine Injury Table (the

¹⁴ HRSA, FY 2023 Operating Plan, available at: https://www.hrsa.gov/about/budget/operating-plan.

"Table") which quickly compensated certain common vaccine injuries. If the petitioner suffered a Table injury, the burden shifted to HHS to prove the vaccine did not cause the injury. After passage of the Vaccine Act, almost 90 percent of claims were Table claims and settled quickly. Soon after, in 1995 and 1997, HHS amended the Table such that 98% of new claims are off-Table. This change greatly increased the difficulty of obtaining compensation for vaccine injuries; and while HHS changed the VICP rules in its favor, "DOJ attorneys make full use of the apparently limitless resources available to them," "pursued aggressive defenses in compensation cases," "establish[ed] a cadre of attorneys specializing in vaccine injury" and "an expert witness program to challenge claims." *Id*.

- 165. The CICP invites even more egregious abuses by removing any legal or constitutional protections for claimants. As stated above, CICP provides no judicial oversight.
- 166. 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 and the submission of 12,110 CICP claims and 1,664,184 reports made to VAERS to date following any COVID-19 vaccine. CICP operates entirely off the record and tramples on Plaintiffs' constitutional rights.
- 167. The Court should strike down the PREP Act to the extent it fails to provide basic due process protections, transparency, and judicial oversight.

COUNT I

DECLARATORY JUDGMENT

- 168. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.
- 169. Plaintiffs are entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that the PREP Act provisions related to immunity to liability and CICP, found in 42 U.S.C. § 247d-6d, violate the Fifth and Seventh Amendments for deprivation of federal constitutional rights.
- 170. 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 related to immunity to liability and CICP, found in 42 U.S.C. § 247d-6d violate the United States Constitution.
- 171. The case is presently justiciable because the CICP constitutional deficiencies apply to Plaintiffs, who are currently harmed by the CICP.
 - 172. Declaratory relief is therefore appropriate to resolve this controversy.

COUNT II

FIFTH AMENDMENT – PROCEDURAL DUE PROCESS VIOLATION

- 173. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.
- 174. The Fifth Amendment provides that no person shall "be deprived of life, liberty, or property, without due process of law."
- 175. The United States Supreme Court has considered three factors to determine whether government action satisfies 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)).

176. 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. v. Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 88 (1978) (stating that the Price-Anderson Act provided a "reasonably just substitute" for common-law or state law remedies for injuries related to nuclear accidents).

177. However, legislative bodies do not possess limitless power to abrogate commonlaw 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, 894-895 (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.").

- 178. By prohibiting judicial relief except in certain extremely limited circumstances, CICP has extinguished Plaintiffs' tort causes of action under state law and has instead implemented a convoluted, underfunded, not transparent, and opaque process that is wholly inadequate for Plaintiffs to seek 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.
- 179. Each of the three *Mathews v. Eldridge* factors considered by the Supreme Court favors striking down the PREP Act to the extent it violates fundamental due process protections.
- 180. <u>First</u>, Plaintiffs' private interests in this case are substantial. Plaintiffs' sole remedy for their injuries is through CICP.
- 181. <u>Second</u>, CICP provides a clear risk of erroneous deprivation by operating as a modern-day "star chamber" in which unidentified individuals review claims, under the alleged review of an unidentified panel. *See, e.g., Schultz v. Medina Valley Indep. Sch. Dist.*, 2011 U.S. Distr. 140330, 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)).
- 182. Thus, CICP fails to provide notice and an opportunity to be heard at a meaningful time and in a meaningful manner. It lacks any basic due process protections: it holds no hearings, provides no meaningful opportunity to be heard, and operates entirely off the record. The government refuses to identify who makes decisions, the standards upon which decisions are made, the materials relied upon, or any experts or consultants involved in their decisions.

- 183. Plaintiffs request that the Court impose basic due process protections to address the defects in CICP listed above. *See Mathews v. Eldridge*, 424 U.S. 319, 335 (1976) (considering "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").
- 184. Third, the protections requested by Plaintiffs do not impose greater fiscal and administrative burdens on the government than already exist under the Vaccine Act. *See Mathews v. Eldridge*, 424 U.S. 319, 335 (1976) (considering "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail"). The Vaccine Act is already subject to judicial review and affords claimants minimal due process protections. *See, e.g., Richardson v. Sec'y of HHS*, 89 Fed. Cl. 657 (2009) (determining that a special master's procedures failed to satisfy fundamental due process requirements).
- 185. CICP, established by the PREP Act, violates Plaintiffs' rights under the Fifth Amendment by eliminating rights that otherwise exist under state law and instead direct Plaintiffs' claims through CICP, which fails to provide essential due process protections.
- 186. Accordingly, CICP directly and proximately deprives Plaintiffs of their procedural due process rights. The Program is unconstitutional on its face and as applied to Plaintiffs, and Plaintiffs are entitled to a declaratory judgment and the issuance of an injunction.

COUNT III

FIFTH AMENDMENT – SUBSTANTIVE DUE PROCESS VIOLATION

- 187. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.
- 188. The Due Process Clause guarantees more than fair process; it also includes a substantive component that "provides heightened protection against government interference with

certain fundamental rights and liberty interests." *Troxel v. Granville*, 530 U.S. 57, 65 (2000) (quotation marks omitted).

- 189. Each Plaintiff suffered severe and significant injuries believed to be caused by one or more doses of the COVID-19 vaccine.
- 190. Unlike the Vaccine Act's judicial review process, CICP operates off the record, without meaningful notice to claimants and opportunity to be heard. Plaintiffs cannot review the government's evidence, confront or question the government's experts or witnesses, or present their case in court or any formal hearing.
- 191. CICP's 97% denial rate and *de minimis* compensation show that, in effect, CICP extinguishes Plaintiffs' legal claims for their injuries in exchange for no compensation.
- 192. Thus, CICP falls woefully short of the PREP Act's stated objective of providing "timely, uniform, and adequate compensation" to individuals injured by covered countermeasures.
 45 U.S.C. § 247d-6e(a).
- 193. CICP fails to provide a "reasonably just substitute" or "reasonable alternative remedy" for taking Plaintiffs' state or common-law rights to recover damages for their injuries.
- 194. Simply, CICP offers no quid pro quo to Plaintiffs or any others subject to its limitations. CICP strips Plaintiffs of their fundamental right to pursue relief for injuries in state or federal court and, specifically, the right to have their claims for damages heard by a jury of their peers.
- 195. CICP is unconstitutional on its face and as applied to Plaintiffs, and Plaintiffs are entitled to a declaratory judgment and the issuance of an injunction.

COUNT IV

SEVENTH AMENDMENT - VIOLATION OF RIGHT TO A JURY TRIAL

- 196. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.
- 197. 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."
- 198. The Seventh Amendment applies "to actions enforcing statutory rights, and requires a jury trial upon demand, if the statute creates legal rights and remedies, enforceable in an action for damages in the ordinary courts of law." *Curtis v. Loether*, 415 U.S. 189, 194 (1974). "In a just sense, the [Seventh] amendment then may well be construed to embrace 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).
- 199. The Supreme Court has deemed government benefits and entitlements to be core private rights in certain circumstances. *See, e.g., Axon Enter. V. FTC*, 143 S.Ct. 890, 909 n.5 (2023) (Thomas, J., concurring) (stating that the Supreme Court previously equated "mere Government benefits and entitlements with core private rights" in *Goldberg v. Kelly*, 397 U.S. 254, 261-263 (1970)).
- 200. CICP displaces Plaintiffs' legal rights to litigate core private rights for negligence and claims for other injuries rights that should be heard by a jury under the Seventh Amendment. Thus, the government is not merely conferring a benefit; the government is replacing a legal right for monetary damages with a purported benefit under CICP.

- 201. Negligence was a legal claim at common law that existed when the Seventh Amendment was adopted. 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, *Symposium, 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).
- 202. Plaintiffs allege that they have suffered significant injuries from COVID-19 vaccines. But for CICP established under the PREP Act, each Plaintiff could seek recovery of monetary damages for, among other things, physical injuries and loss of income or earning potential.
- 203. CICP violates Plaintiffs' Seventh Amendment rights because it denies their right to a trial by jury.
- 204. Accordingly, CICP directly and proximately deprives Plaintiffs of their federally protected Seventh Amendment right to a trial by jury as stated above.
- 205. CICP is unconstitutional on its face and as applied to Plaintiffs; therefore, Plaintiffs are entitled to a declaratory judgment and the issuance of an injunction.

PRAYER FOR RELIEF

- 206. **DECLARE** that the provisions of the PREP Act which provide immunity to liability and pertain to CICP, including but not limited to 42 U.S.C. § 247d-6d, are unconstitutional under the Fifth Amendment both on their face and as applied to Plaintiffs;
- 207. **DECLARE** that those provisions of the PREP Act which provide immunity to liability and pertain to CICP, including but not limited to 42 U.S.C. § 247d-6d, are unconstitutional under the Fifth Amendment both on their face and as applied to Plaintiffs to the extent they fail to provide minimum procedural due process safeguards;
- 208. **DECLARE** that those provisions of the PREP Act which provide immunity to liability and pertain to CICP, including but not limited to 42 U.S.C. § 247d-6d, are unconstitutional under the Seventh Amendment both on their face and as applied to Plaintiffs to the extent they fail to preserve the right of Plaintiffs and other individuals injured by a COVID-19 vaccine from litigating their claims for damages before a civil jury;
- 209. **ENJOIN,** preliminarily and permanently, Defendants, their agents, servants, employees, and any other persons acting on their behalf, from enforcing those provisions of the PREP Act which provide immunity to liability and pertain to CICP, including but not limited to 42 U.S.C. § 247d-6d, until the federal government provides the following constitutional protections for individuals seeking compensation for COVID-19 vaccine injuries:
 - a. provide an adequate statute of limitations that applies to all COVID-19 vaccine injury claims, but in any event is no less than three years from onset of symptoms;
 - identify the name, title, and educational credentials of the individuals deciding
 COVID-19 vaccine injury claims;

- c. confirm that such decision-makers have no conflicts of interest and provide a process to challenge any particular decision-maker for a conflict of interest;
- d. provide claimants with a reasonable opportunity to question witnesses or review evidence used against a claimant;
- e. provide claimants with a reasonable opportunity to obtain discovery, including discovery from companies that manufactured or distributed the COVID-19 vaccines that harmed them;
- f. produce copies of any records used to decide a claimant's COVID-19 vaccine injury claims;
- g. identify any expert witnesses or consultants used by the government in making determinations;
- h. provide claimants with a reasonable opportunity to question or obtain discovery from such experts, including copies of any expert reports;
- i. allow claimants the opportunity to present expert witnesses on their behalf;
- j. provide notice to claimants and a reasonable opportunity to be heard before any hearing and to conduct a hearing where factual issues are present;
- k. preserve the right of claimants to present claims for damages in court, before a civil jury, if a claimant elects to do so;
- provide an appeal/judicial review of any COVID-19 vaccine injury claim decision in a court of law; and/or
- m. maintain a written record of any hearings or proceedings for judicial review; and
- 210. **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: October 10, 2023

Respectfully submitted,

/s/ Charlotte Y. Bergeron

Charlotte Y. Bergeron, Esq. Louisiana Bar Number: 24293 1040 Audubon Street Lake Charles, LA 70605 Tel: (225) 229-7135

cbergeronlaw@gmail.com

/s/ Aaron Siri

Aaron Siri, Esq.* [Trial Attorney] New York Bar Number: 4321790

Elizabeth A. Brehm, Esq.*

New York Bar Number: 4660353

Kevin Mitchell, Esq.*

Michigan Bar Number: P84639

Catherine Cline, Esq.*

Florida Bar Number: 125955
SIRI & GLIMSTAD LLP
745 Fifth Ave, Suite 500
New York, NY 10151
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com
ebrehm@sirillp.com
kmitchell@sirillp.com
ccline@sirillp.com

/s/ Walker D. Moller

Walker D. Moller, Esq.* Texas Bar Number: 24092851 SIRI & GLIMSTAD LLP 1005 Congress Avenue Suite 925-C36 Austin, TX 78701

Tel: (512) 265-5622 Fax: (646) 417-5967 wmoller@sirillp.com

Attorneys for Plaintiffs

^{*}Pro vac vice application to be submitted.

I, Alicia Smith, a citizen of the United States and of Louisiana, have read the foregoing Verified Complaint and know the contents thereof as to myself in paragraphs 2, 21, 33-38, that the same is 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 t	hat the foregoing is true and correct.
Executed on .	10 / 04 / 2023	in Ruston, Louisiana.
		Alicia Smith

I, Carolina Bourque, a citizen of the United States and of Louisiana, have read the foregoing Verified Complaint and know the contents thereof as to myself in paragraphs 3, 22, 39-51, that the same is true to my knowledge and as to all other matters on information and belief and I believe them to be true.

Executed on _	10 / 04 / 2023	in Youngsville, Louisiana.	
		Carolina Bourgue	

I, Emma Burkey, a citizen of the United States and of Nevada, have read the foregoing Verified Complaint and know the contents thereof as to myself in paragraphs 4, 23, 52-75, that the same is true to my knowledge and as to all other matters on information and belief and I believe them to be true.

Executed on _	10 / 04 / 2023	in Henderson, Nevada.	
		Emma Pensey	
		Emma Burkey	

I, Christopher Cody Flint, a citizen of the United States and of Mississippi, have read the foregoing Verified Complaint and know the contents thereof as to myself in paragraphs 5, 24, 76-86, that the same is true to my knowledge and as to all other matters on information and belief and I believe them to be true.

Executed on _	10 / 05 / 2023	in Boyle, Mississippi.	
		Cody-Flint	
		Christopher Cody Flint	

I, Michelle Zimmerman, a citizen of the United States and of Washington, have read the foregoing Verified Complaint and know the contents thereof as to myself in paragraphs 6, 25, 87-102, that the same is true to my knowledge and as to all other matters on information and belief and I believe them to be true.

Executed on _	10 / 04 / 2023	in Seattle, Washington.	
		Michelle Firmwon-	
		Michelle Zimmerman	

I, Erin Rhodes, a citizen of the United States and of Connecticut, have read the foregoing Verified Complaint and know the contents thereof as to myself in paragraphs 7, 26, 103-117, that the same is true to my knowledge and as to all other matters on information and belief and I believe them to be true.

Executed on _	10 / 05 / 2023	in Niantic, Connecticut.	
		Erin Rhodes	

I, Jessica Krogmeier, a citizen of the United States and of Iowa, have read the foregoing Verified Complaint and know the contents thereof as to myself in paragraphs 8, 27, 118-133, that the same is true to my knowledge and as to all other matters on information and belief and I believe them to be true.

Executed on .	10 / 04 / 2023	_ in Donnellson, Iowa.
		Jessica Kroomeier

I, Lorin Jeppsen, a citizen of the United States and of Utah, have read the foregoing Verified Complaint and know the contents thereof as to myself in paragraphs 9, 28, 134-145, that the same is true to my knowledge and as to all other matters on information and belief and I believe them to be true.

Executed on _	10 / 05 / 2023	in Layton, Utah.	
		4	
		Lorin Jeppsen	

I, Brianne Dressen, co-chairman of React19, Inc., a non-profit organization in the United States and Wisconsin, have read the foregoing Verified Complaint and know the contents thereof as to React19, Inc. in paragraphs 10, 29, 146-147, that the same is true to my knowledge and as to all other matters on information and belief and I believe them to be true.

Executed on _	10 / 04 / 2023	in Oconomowoc, Wisconsin.
		Brianne Dressen
		React19, Inc. By:
		Its: Co-Chair