

December 30, 2024

The Honorable Xavier Becerra Secretary Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Carole Johnson Administrator Health Resources & Services Administration 5600 Fishers Lane Rockville, MD 20857

Re: COVID-19 Vaccine Injury Compensation Program

Dear Secretary Becerra and Administrator Johnson:

We, the Attorneys General of Utah, Kansas, Arkansas, Idaho, Indiana, Louisiana, Mississippi, Montana, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota, and Texas, write to express our serious concerns with how individuals harmed by COVID-19 vaccines are being treated by the federal government. We seek answers to questions about the administration of the Countermeasures Injury Compensation Program (CICP).

During the height of the pandemic, many Americans wanted "to do their part" by participating in vaccine trials or getting vaccinated. The federal government gave COVID-19 vaccine manufacturers more than \$30 billion in taxpayer funds to develop and sell COVID-19 vaccines,¹ and spent billions more promoting these products to

¹ Hussain S Lalani, et al., US public investment in development of mRNA covid-19 vaccines: retrospective cohort study, BMJ (Clinical research ed. Mar. 1, 2023), https://pubmed.ncbi.nlm.nih.gov/36858453/.

the public.² The federal government both encouraged,³ and in many cases, mandated vaccination.⁴

But when some of these individuals were injured by the COVID-19 vaccine, they found that the federal government favored manufacturers over their health. In addition to providing manufacturers like Pfizer and Moderna billions of dollars,⁵ the federal government also gave these companies effective blanket immunity for harms caused by their products.⁶

The injured individuals, on the other hand, each experienced some form of health complications that were diagnosed by credible physicians as resulting from a Covid vaccination. Some of those injured were even seen by federal government employed physicians and the harm from a vaccination was validated and acknowledged by the federal government. The people for whom we advocate and for whom we are concerned are not opportunists looking for deep pockets for phantom injuries. These are honest people with verified injuries. They are our constituents of all backgrounds and political affiliations. This is not just a bi-partisan issue, it is nonpartisan in nature. Yet, in spite of credible diagnoses and real harm, these individuals injured by COVID-19 vaccines have only a single form of recourse: to file a claim with the CICP.

As attorneys general, we are seriously concerned about the lack of transparency and due process afforded by the CICP, as well as the substantial roadblocks claimants face in obtaining relief.

² U.S. Department of Health and Human Services, *Biden-Harris Administration secures 105 million doses of Pfizer's latest COVID-19 vaccine for fall vaccination campaign*, Press Release (June 29, 2022), https://www.hhs.gov/about/news/2022/06/29/biden-harris-administration-secures-105-million-doses-of-pfizers-latest-covid-19-vaccine-for-fall-vaccination-campaign.html.

³ U.S. Department of Health and Human Services, *Vaccines National Strategic Plan 2021-2025*, https://www.hhs.gov/sites/default/files/HHS-Vaccines-Report.pdf.

⁴ Exec. Order 14,043 86 FR 50989 (Sept. 14, 2021).

⁵ U.S. Government Accountability Office: Report to Congressional Addressees, *COVID-19: Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations*, GAO-21-207 (Nov. 2020), https://www.gao.gov/products/gao-21-207.

⁶ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (March 17, 2020).

To start, an individual who is injured by a COVID-19 vaccine has only one year from the date of injury to file a claim with the CICP.⁷ If this short timeframe lapses, the individual is ineligible for benefits.

Second, injured individuals are frequently left to navigate the program by themselves with no professional guidance. And the showing a claimant must make is substantial. The claimant "must demonstrate that the injury sustained was the direct result of the administration or use of a" COVID-19 vaccine "based on compelling, reliable, valid, medical, and scientific evidence."⁸ And the "temporal association" between receiving a vaccine and "onset of the injury . . . is not sufficient, by itself, to prove that an injury is the direct result" of a vaccine.⁹

Third, the CICP provides little or no transparency or due process. An individual filing a claim has no knowledge—or ability to find out—*who* will make a determination about his or her claim, *when* it will be decided, or *how* it will be decided. There is also no right to confront or question the government officials who denied a claim, no way to access or respond to any evidence the government may have relied on in denying a claim, no way to confront or question any experts who may have consulted in denying the claim, and no way for a claimant to introduce evidence from his or her own expert.

Fourth, even in those rare instances when the CICP approves a claim, the injured claimant is entitled to, at most, up to \$50,000 in lost wages per year and unreimbursed medical expenses. If the injured person is deceased, his or her estate may receive a limited death benefit.¹⁰

The data so far shows that the CICP fails to address the very real harms that have been suffered by individuals injured by COVID-19 vaccines. Of the over 10,473 COVID-19 vaccine—related claims that the CICP has received, most remain unadjudicated.¹¹ And of those claims that have been decided, only 65 were found

⁷ U.S. Health Resources & Services Administration, *Countermeasures Injury Compensation Program* (*CICP*) *Data* [hereinafter *CICP Data*], Table 8, https://www.hrsa.gov/cicp/cicp-data/table-8 (last updated Dec. 2024).

⁸ U.S. Health Resources & Services Administration, *Countermeasures Injury Compensation Program* (*CICP*): Criteria to Demonstrate that a Covered Injury Occurred, https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred (last updated September 2023),.

⁹ See CICP Data, supra n.7.

¹⁰ See CICP Data, Who Can File for Benefits?, https://www.hrsa.gov/cicp/who-can-file-benefits (last updated Sept. 2023).

¹¹ See CICP Data, supra n.7.

eligible for compensation, and only 20 of those have actually received any compensation.¹² And but for one extreme outlier (a \$370,376 award–likely a myocarditis fatality), the average COVID-19 vaccine-related award comes in well below \$5,000.¹³ It is unsurprising that so little in compensation has been paid out, given the insufficient resources allocated to the CICP for compensation.¹⁴ The program obviously cannot process claims in a timely manner, let alone pay claims, without adequate funding.

We have heard from numerous constituents who suffered serious injuries following administration of a COVID-19 vaccine. Indeed, among the approximately 10 million Americans who signed up for the Center for Disease Control's (CDC's) Vsafe program,¹⁵ which was designed to assess the safety of COVID-19 vaccines, more than 70 percent of individuals who reported needing post-vaccination medical care went to urgent care, the emergency room, or were hospitalized.¹⁶

The below stories provide just a few examples of individuals who were seriously injured by a COVID-19 vaccine and who have been unable to obtain appropriate compensation from the CICP or other sources for their injuries:

• Cathleen Roy-Dewely from **New Hampshire** was at the height of her career designing business systems for top Fortune 50 companies. She "had a wonderful, balanced life." April 2021 changed her life forever when she suffered a severe reaction after her second dose of the Pfizer vaccine. She was

¹³ *Id.*, Table 4.

 $^{^{12}}$ Id.

¹⁴ See Zhao, Junying, et al., *Reforming the countermeasures injury compensation program for COVID-19 and beyond: An economic perspective*, J. of Law and the Biosciences (Apr. 4, 2022), https://pubmed.ncbi.nlm.nih.gov/35382431/ (questioning CICP's ability to compensate claimants because "[a]ssuming current COVID-19 claims were to be compensated at the historical rate, without accounting for future claims after Aug. 2, 2021, the program would face about \$21.16 million in compensation outlays, 4.8 times its current balance of \$4.41 million, and face about \$317.94 million in total outlays, 72.1 times its current balance," if the program's historic rate of administrative costs were included).

¹⁵ Vaccine Safety Systems, https://www.cdc.gov/vaccine-safety-systems/v-safe/?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/v-safe/index.html (last visited Dec. 26, 2024).

¹⁶ Informed Consent Action Network (ICAN), *V-safe Dashboard – Medical Care Type*, https://icandecide.org/v-safe-data/ (last visited Dec. 26, 2024).

admitted to the stroke unit of the local hospital. She remains disabled, with mounting medical bills, struggling to find even a single doctor who will recognize her injury that leaves her plagued with body-wide inflammation.

- Olivia Teseniar, a young single mother in **South Carolina** participated in Moderna's clinical trial. She suffered an immediate reaction that resulted in multiple shoulder surgeries and lymph nodes being so severely disfigured that they had to be surgically removed. The underlying mechanisms for her post-vaccine lymphadenopathy were never addressed, and she is now diagnosed with T-Cell lymphoma. Moderna provided no medical or financial help. Now, permanently disabled, she struggles daily to care for not only herself but her young son.
- Nikki Holland, a physical therapist in **Tennessee**, was a busy mom of three active kids, leading a vibrant family life. Once a healthy 35-year-old, she endured repeated hospitalizations, intubations, and life flights due to multisystem complications. While her tracheostomy and feeding tube were recently removed after three grueling years, she remains disabled, relying on a wheelchair and crutch for mobility and battling daily to manage her medical conditions. Despite small improvements, the road ahead offers no cure, only efforts to slow the decline. The loss of her independence, career, and ability to fully engage in her children's lives is devastating.
- Ernest Ramirez, Jr., a 16-year-old boy from **Texas**, played on a baseball team his dad proudly coached. Five days after a single Pfizer dose, he collapsed in front of his best friend while running across a parking lot to play basketball. He passed away from sudden heart failure. His autopsy reported high levels of inflammation in his heart, liver, and other organs. His father, who had sole custody of his son, now lives entirely alone, struggling daily to find answers for how this could have happened to his pride and joy.
- Everest Romney, a healthy high school basketball star from **Utah**, had a promising college basketball career ahead of him. His vaccine injury escalated from swollen lymph nodes, neck pain and migraine headaches to life threatening blood clots in his brain that cut off oxygen causing a traumatic brain injury. He continues to throw clots despite being on anticoagulants. The repeated clots and subsequent brain damage has ended not only his basketball career but his aspirations to live a healthy and independent life. Now

permanently disabled, this 20-year-old lives at home, a dramatic change to his own quality of life and the lives of his supportive family.

- Mike Anthony, a healthy bank executive from **North Carolina**, had his whole life ahead of him. After receiving a COVID-19 vaccine, he was diagnosed with POTS/Dysautonomia, Stiff Person Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), and full body small fiber neuropathy (SFN). He was in chronic pain and become housebound, with no source of income. After receiving no help from government officials, Michael felt he had no choice other than to end his own suffering. He flew to Switzerland, accompanied by a pastor, and ended his life.
- Cody Flint, a young agricultural pilot from **Mississippi**, was the epitome of a hard-working family man who was living the American dream. He relished the time he was able to spend with his wife and two preschool-aged boys. His cropdusting business was flourishing. After receiving a COVID-19 vaccine, he suffered a severe neurological reaction that almost cost him his life when he collapsed in the cockpit of his plane as he was landing. Cody has lost his pilot's license permanently and his business, leaving his family in considerable debt. He filed a claim with the CICP, but his claim was denied.

With these and myriad other heartbreaking stories in mind,¹⁷ we write to you with the following questions:

Treatment and Study

- 1) What can be done to educate doctors about treatments for COVID-19 vaccinerelated injuries and possible diagnoses? In particular, when will the National Institutes of Health (NIH) be providing medical guidance on the protocols they have been using to diagnose and treat individuals who have suffered complications from a COVID-19 vaccine?
- 2) We have been told by constituents that NIH is privately helping patients across the country with COVID-19 vaccine-related injuries and is even bringing patients to NIH for study and treatment. Is that correct? Why have these

¹⁷ See, e.g, Apoorva Mandavilli, *Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?* New York Times (May 3, 2024), https://www.nytimes.com/2024/05/03/health/covid-vaccines-side-effects.html.

activities not been better publicized? What sorts of studies of these patients is NIH currently conducting? What treatments is NIH administering?

Diagnosis Codes

- 3) Individuals who have been injured by a COVID-19 vaccine often struggle to obtain insurance benefits or coverage for their injuries because insurance companies lack a diagnosis or medical code for COVID-19 vaccine adverse reactions. What can be done to encourage insurance companies to create such codes so that patients are able to obtain insurance coverage for their injuries?
- 4) When will the Centers for Medicare & Medicaid Services (CMS) begin implementing COVID-19 vaccine adverse reaction codes, as other countries are already doing?

CICP

- 5) What accounts for the extraordinarily low CICP approval rate for claims for COVID-19 vaccine injuries? It blinks reality to say that only 0.5 percent of claimants had valid, compensable injuries.
- 6) How does the CICP determine how much to award for valid, compensable claims? That the average amount awarded so far for COVID-19 vaccine-related claims is *less than \$4,000* suggests that the metrics being used are vastly underinclusive. What sorts of medical expenses are compensable? How does the CICP determine what medical expenses are or are not covered? What happens if a medical claimant has additional medical expenses after the claimant submits his or her claim? Has any of the compensation paid out so far to individuals injured by COVID-19 vaccines been for lost wages? What must a claimant prove to obtain compensation for lost wages?
- 7) Why is the period for filing a claim only one year from the date of injury? What happens if an injured individual doesn't obtain a diagnosis or other confirmation that his or her injuries are attributable to a COVID-19 vaccine until more than a year has passed since administration of the vaccine? Is the filing period for all vaccines one year from the date of injury, or just for the COVID-19 vaccine? If there are different filing periods for different vaccines, why is that the case and who decides what the filing period is?

- 8) What can be done to improve transparency and due process for individuals navigating the CICP labyrinth? Why is no hearing, appeal, or other adversary-type process provided at any stage of the proceedings?
- 9) What can be done to expedite the CICP adjudication process for COVID-19 vaccine-related claims? Why is the adjudication rate so slow? How does the adjudication rate for COVID-19 vaccine claims compare to claims for other vaccines?
- 10)How many employees does the CICP have? How many claims does each CICP worker on average adjudicate per year? How are claims processed? Who is involved in the claims process? What sort of oversight is there?
- 11)How do the claim success rates and payout amounts for COVID-19 vaccinerelated claims compare to the success rates and payout amounts for claims related to other vaccines?
- 12)Who funds the CICP? Why has only \$6 million been allocated to claimants for compensation? Is that \$6 million for COVID-19-vaccine claims only, or for all claims? What is the CICP's annual budget?

Just as Secretary Becerra was when he served as our colleague and Attorney General of California, we are committed as chief legal officers of our states to ensuring that our citizens receive transparency and due process. We thank you in advance for working with us to protect and educate our citizens in these difficult circumstances.

Sincerely,

Sean D. Reyes Utah Attorney General

Kis W.

Kris W. Kobach Kansas Attorney General

m

Tim Griffin Arkansas Attorney General

Liz Murrill Louisiana Attorney General

hike Hil

Mike Hilgers Nebraska Attorney General

alan Wilson Ma

Alan Wilson South Carolina Attorney General

Rail R. Jabradon (John

Raúl Labrador Idaho Attorney General

lC

Lynn Fitch Mississippi Attorney General

Drew Wrigley North Dakota Attorney General

Todd Rokita Indiana Attorney General

Austin Knudsen Montana Attorney General

Gentner Drummond Oklahoma Attorney General

Ken Paxton Texas Attorney General

Marty J. Jackley South Dakota Attorney General

cc: Robert F. Kennedy, Jr. Nominee, Secretary of the Department of Health and Human Services