

May 17, 2024

VIA FEDERAL EXPRESS

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

Dear Secretary Becerra,

On behalf of Informed Consent Action Network (“ICAN”), we write with increasing concern regarding your continued failure to establish a COVID-19 vaccine injury countermeasures table, despite the passage of more than three years since the government’s rollout of the COVID-19 vaccines.

The PREP Act states that “[t]he Secretary **shall** by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a [covered countermeasure](#) and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply.”¹

It is well established that COVID-19 vaccination causes certain adverse reactions in some recipients. In fact, your companion subagencies admitted this years ago. The Centers for Disease Control and Prevention (“CDC”) has publicly acknowledged various adverse events associated with the COVID-19 vaccine² and has published numerous safety studies regarding those adverse events.³ Furthermore, nearly three years have passed since the United States Food and Drug Administration (“FDA”) required that both Pfizer and Moderna include warnings associated with certain adverse events on their patient and provider fact sheets.⁴ Despite the availability of robust scientific research regarding adverse events following COVID-19 vaccination,⁵ you have failed to establish any table injuries for those injured.

¹ See 42 U.S.C. § 247d-6e(b)(5)(A) (emphasis added).

² See CDC Selected Adverse Events Reported After Covid-19 Vaccination, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>.

³ See CDC Covid-19 Vaccine Safety Articles and Studies by Topic, <https://www.cdc.gov/vaccinesafety/research/publications/index.html>.

⁴ Newberger, Emma. *FDA Adds Warning About Rare Heart Inflammation to Pfizer, Moderna Covid Vaccines*, <https://www.cnbc.com/2021/06/26/fda-adds-warning-of-rare-heart-inflammation-to-pfizer-moderna-vaccines.html>.

⁵ Harshini Yaamika et al., *Review of Adverse Events Associated with Covid-19 Vaccines, Highlighting their Frequencies and Reported Cases*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10507236/>.

The United States is one of the few developed countries that has not added COVID-19 vaccines into its main vaccine injury compensation schemes,⁶ and instead, the U.S. requires injured individuals to seek compensation through the Countermeasures Injury Compensation Program (“CICP,”) which operates as a black hole: there are no clear guidelines for establishing causality; the identities of individuals deciding claims are unknown (and therefore it is unclear if they are qualified to decide these claims and/or if they should be conflicted out from doing so); there is a strict and excessively short statute of limitations; there is no provision for attorneys’ fees, nor a route for judicial review, among numerous other flaws.⁷ This means that people who are inexperienced (and seriously injured) are forced to put together a demand package meeting ambiguous and complex requirements within an extremely short time frame.

The CICP data clearly reflect this hardship on the vaccine injured: compensation rates for CICP claims currently sit at an abysmal .02%.⁸ It is notable that various other countries have implemented far more relaxed criteria for establishing causality for COVID-19 vaccine-related injuries, and as a result, their compensation rates are exponentially higher than CICP’s rates.⁹

Given that more than three years have passed since the rollout of COVID-19 vaccines, an injury table is surely long overdue and any further delay is inexcusable. The United States is at the forefront of COVID-19 vaccine development, was among the first countries to offer COVID-19 vaccines, and was one of the first high-income countries to mandate them.¹⁰ However, CICP’s shortcomings under your leadership have caused us to shamefully fail in the duty of caring for those who have been seriously hurt by these products.

To be clear, the creation of an injury table will not cure the myriad defects with CICP nor does it make right the government’s decision to grant immunity to liability to manufacturers at the cost of every American’s right to bring civil claims against those who injure them, however, it is the least that you can do for those injured by these products even though it is a necessary but still insufficient step in remedying the issues with CICP.

Due to our great concern for those who were (and remain) injured or who suffered an untimely death on account of a COVID-19 vaccine, and the lack of clarity to date from you and the Health Resources and Services Administration (“**HRSA**”) regarding this serious issue, we are requesting the following information:

- Whether or not you plan to establish a vaccine injury table for COVID-19;

⁶ Kang, Cho Ryok, et al. *COVID-19 Vaccine Injury Compensation Program: Lessons Learned from a Review of 10 Implementing Countries*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11004775/>.

⁷ See Verified Complaint, *Smith v. United States*, No. 4:24-cv-00334 (N.D. Tex. Apr. 18, 2024). See also Third Amended Verified Complaint for Declaratory Relief, *Smith v. United States Health Resources & Services Administration*, No. 3:23-CV-01425 (W.D. La., Mar. 17, 2024).

⁸ Countermeasures Injury Compensation Data, available at <https://www.hrsa.gov/cicp/cicp-data>.

⁹ Cho Ryok Kang et al., *COVID-19 Vaccine Injury Compensation Program: Lessons Learned from a Review of 10 Implementing Countries*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11004775/>.

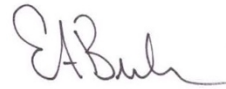
¹⁰ Emily Cameron-Blake et al., *A Panel Dataset of Covid-19 Vaccination Policies in 185 Countries*, <https://www.nature.com/articles/s41562-023-01615-8>.

- In the event you do plan to establish a vaccine injury table for COVID-19, the precise status of the table's development and when the table is expected to be released;
- The injuries that will appear on the table and how and by whom those are being selected for inclusion on the table; and
- In the event that HRSA has no immediate plans to establish a vaccine injury table for COVID-19, a justification as to why such a posture is deemed acceptable.

We also ask that you clarify the funding CICP will have available for compensating claims and whether you intend to bring the program into accord with the demands of due process.

Notably, this is a responsibility the government willingly took on in exchange for providing COVID-19 vaccine manufacturers with immunity to liability. We therefore look forward to your prompt response, as it has serious implications for the lives, health, and wellbeing of American citizens—Americans who “did the right thing,” relied on their government's assurances of effectiveness and safety, and got vaccinated—and for the reputation of our federal health authorities.

Very truly yours,



Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Dana Smith, Esq.

ebrehm@sirillp.com