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June 24, 2022

VIA EMAIL
Sen. Michael F. Bennet
C/o Chief of Staff
Amy Friedman
[redacted]

Re: Request for Immediate Action – Proposed Amendments to the National Childhood Vaccine Injury Act of 1986 and the Vaccine Injury Compensation Program

Dear Sen. Michael F. Bennet:

We write regarding the need for immediate reforms to the National Childhood Vaccine Injury Act of 1986 ("**NCVIA**") and the National Vaccine Injury Compensation Program ("**VICP**" or "**Program**").

The VICP, created by the NCVIA, is a compensation program wherein individuals who have been injured by certain vaccines, or a representative of a person who has died as a result of receiving certain vaccines, can submit a petition and request monetary compensation for the losses related to the injury. Having been enacted over 40 years ago, several of the statutory provisions are outdated and require immediate reform to allow this Program to function as it was intended. Reform would further help to reestablish public confidence in the federal vaccine program and the compensation program for those who are injured.

In the late 1980s, an increasing number of lawsuits were filed against vaccine manufacturers for causing catastrophic injuries to the children who received their products. [1] These lawsuits caused several vaccine manufacturers to pull out of the vaccine market, thereby destabilizing the vaccine market in the United States and causing vaccine shortages. [2] The mounting lawsuits against vaccine manufacturers were costly, difficult, and lasted for many years.[3] Families whose children suffered legitimate vaccine injuries waited years to receive compensation that they desperately needed in order to provide the medical care and support for their severely

[1] *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

[2] *Id.*

[3] *Id.*

injured children. For these reasons, public trust in the vaccine program declined and many parents began to decline vaccinations for their children.[4]

In response, Congress enacted the NCVIA which eliminated the vaccine manufacturers' financial liability for vaccine injuries and established the VICP as an alternative system to adjudicate claims for those injuries. Congress' intent in creating the VICP was to stabilize the vaccine market and to provide individuals a swift, flexible, and less adversarial alternative to costly and lengthy civil tort litigation.[5] This Program was designed so that individuals injured by a vaccine could file a petition for compensation in the U.S. Court of Federal Claims against the U.S. Secretary of Health and Human Services ("**HHS**"). After filing the petition and documentation including medical records and affidavits, a special master is to make an informal adjudication of the petition within two hundred and forty (240) days. While the intent of this Program was to swiftly and efficiently compensate those injured by vaccines in a less adversarial forum then traditional tort litigation, over the years, this intent has eroded, and the Program is currently not working as designed.

The Secretary of HHS is the Respondent in all vaccine injury cases and is represented by attorneys from the U.S. Department of Justice ("**DOJ**"). As Congressional reports have found, HHS and DOJ vigorously defend against vaccine injury claims, and employ a cadre of experts and specialists to defeat any claim that a vaccine caused an alleged injury.[6] This approach has left many children and adults who have suffered legitimate injuries following vaccination without compensation and has caused another decline in the public's opinion of the federal vaccine and compensation programs. Congress must act to reestablish the public's confidence in the vaccine and compensation programs.

Vaccines Routinely Recommended for Adults Should Be Added to the VICP

When the VICP was created in the late 1980s, there were only three (3) vaccines on the Center for Disease Control and Prevention's ("**CDC**") childhood vaccine schedule and there was

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[4] *Id.*

[5] *See* https://www.uscfc.uscourts.gov/vaccine-program-readmore.

[6] *See* https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf (Congressional report describing how the 1986 Act gave HHS the authority to set the rules for the Vaccine Injury Compensation Program (VICP) and that HHS used this authority to change the rules of the VICP in its favor so it can more readily defeat vaccine injury claims. Indeed, the 1986 Act created a Vaccine Injury Table (the 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 1986 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.").

no schedule of recommended vaccines for adults.[7] Currently, there are sixteen (16) vaccines on the CDC's childhood vaccine schedule with multiple doses of each vaccine recommended.[8] In addition, the CDC now recommends multiple doses of twelve (12) different vaccines for adults ages 19 and older.[9] Besides an exponential increase in the number of vaccines and the number of doses recommended, the total population in the United States has also significantly increased since the late 1980s leading to more vaccines being administered.

Amendments are Required to Increase the Number of Special Masters

As expected, with increased numbers of vaccines being administered, there are increasing numbers of vaccine injury claims being filed in VICP. In 1988, soon after the Program's inception, there were 24 vaccine injury cases filed in the VICP.[10] In 1990 and 1991, there were 1,492 and 2,718 cases filed, respectively, due to a lookback period that was added.[11] From 1992 until about 2001, once the lookback period ended, the number of claims ranged between 84 and 411 per year.[12] In 2002-2004, there was an increase in the number of cases filed.[13] Many of these cases claimed that childhood vaccines caused autism.[14] These cases were handled through the Omnibus Autism Proceedings and therefore, a majority of them were not handled individually by the Program.[15] From 2005-2015 the number of cases ranged from 325-803 per year, however since 2016, there have been approximately 1,000-1,200 cases filed in the VICP each year.[16] There are currently approximately 4,000 open cases in the program (and these do not include any claims for injuries following vaccination for COVID-19).

The vaccine injury claims brought in the Program are heard by special masters. The NCVIA provides that the office of special masters shall not consist of more than eight (8) special

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[7] 42 U.S.C. § 300aa-14.

[8] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html.

[9] https://www.cdc.gov/vaccines/schedules/hcp/imz/adult html.

[10] https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/vicp-stats-05-01-2022.pdf.

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] https://www.uscfc.uscourts.gov/autism-decisions-and-background-information.

[15] *Id.*

[16] https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/vicp-stats-05-01-2022.pdf. In 2021, the Program saw another spike in the number of cases filed likely due to the threat of the removal of certain injuries (SIRVA and syncope) from the vaccine injury table. https://www.federalregister.gov/documents/2020/07/20/2020-15673/national-vaccine-injury-compensation-program-revisions-to-the-vaccine-injury-table; https://www hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/vicp-stats-05-01-2022.pdf.

masters.[17] This number is no longer sufficient. Nonetheless, additional special masters cannot be added without an act of Congress amending this statutory cap. The limitation on the number of special masters in the VICP has gridlocked this Program and has created an unacceptable backlog of claims in the VICP resulting in vaccine injured individuals having to wait years for compensation for their serious vaccine injuries.[18] By way of example, cases that are ready to be set for entitlement hearings today are being scheduled towards the end of 2023 and into 2024. With post-hearing briefing and time required for the special masters to prepare the written decisions, the issuance of the decision is likely to be sometime in 2025. The NCVIA must be amended to provide for a minimum of eighteen (18) special masters and should allow the chief special master the power to appoint additional special masters should it be required in order for swift justice to be carried out for those who suffer from vaccine injuries.

There is a looming question about whether or not the COVID-19 vaccines will be added to the VICP. According to the Vaccine Adverse Events Reporting System ("**VAERS**") as of June 3, 2022, there have been over 42,300 reports of death, life-threatening adverse reactions, and adverse reactions claiming permanent disabilities following COVID-19 vaccines. If the COVID-19 vaccines are added to the VICP, the Program will need the ability to add additional special masters to handle the number of cases that are likely to be filed, along with the existing backlog.

The Statutory Cap on Pain and Suffering and the Death Benefit Amount Must Be Increased

Currently, there is a $250,000 statutory cap on damages that can be awarded for pain and suffering in a vaccine injury case and a $250,000 cap on the amount of compensation available in the case of a death.[19] These numbers have not increased since the inception of the Program in 1986. For there to be meaningful compensation to those injured by vaccines, the cap on both pain and suffering and on the death benefit should be increased to $850,000 and should continue to increase and adjust with inflation.

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[17] 42 U.S.C. § 300 aa-12

[18] *See*, e.g. https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2012vv0155-186-0 (a death case that took 10 years to be adjudicated) and https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2010vv0251-200-0 (another death case that took 7 years to fully adjudicated). *See also* https://news.bloomberglaw.com/product-liability-and-toxics-law/national-vaccine-injury-program-needs-modernizing ("While the Office of Special Masters has been operating valiantly under these circumstances, severe inefficiencies exist, which continue to delay adjudication and the speedy delivery of justice to injured petitioners. The two- to three-year waiting times for scheduling a hearing, resulting from the overwhelmed system, and the insufficient number of overworked special masters adjudicating the VICP claims, results in devastating difficulties to petitioners. When the long wait for decisions in a backlogged system deprives a child of potentially life-changing treatment, justice delayed is indeed justice denied. Even in cases where causation is presumed, the time necessary to conclude has dramatically increased as well.").

[19] *See* 42 U.S.C. § 300 aa-15.

Add Pre-Judgment Interest

We urge you to further amend the NCVIA to allow for pre-judgment interest on all awards and fees, thus disincentivizing HHS and DOJ from any unnecessary delay in adjudicating meritorious claims.

The Statute of Limitations in VICP Cases Must be Lengthened

The NCVIA only allows an individual thirty-six (36) months from the onset of symptoms after a vaccine injury and two (2) years after a death to file in the VICP.[20] Many individuals with vaccine injuries have complex medical histories and it is not always immediately apparent that their injuries were caused by a vaccine. Further, when it comes to children, the majority of vaccines are administered to children when they are infants or toddlers. Infants cannot express what they are feeling and, unfortunately, symptoms of vaccine injury in infants and children are ignored or misdiagnosed by treating physicians. These children can suffer for years before receiving proper diagnosis and/or treatment. It is often the case that by the time a parent realizes that their child's illness or injury could have been from a vaccine, the statute of limitations has passed leaving these families without any possibility of recovery in the VICP. Far too many parents have experienced this exact situation contributing to the public's declining trust in traditional medical providers and the vaccine program. The statute of limitations for a vaccine injury should be a minimum of five (5) years for adults and a tolling provision should be in place for minors allowing them to file a claim up to one year after they reach the age of eighteen (18).

Adding New Vaccines to the Vaccine Injury Table

The NCVIA provides that in order for a new vaccine to be added to the vaccine injury table, and therefore eligible for the VICP, the CDC must recommend the vaccine for routine administration in children and/or pregnant women.[21] Following this recommendation, HHS has up to two (2) years to add the vaccine to the vaccine injury table.[22] The addition of the vaccine to the vaccine injury table is what allows individuals to file a petition in the VICP for harms caused by that vaccine.[23] The allowance of up to two years for HHS to add such a vaccine to the vaccine injury table is too long. Considering how long it takes for the Program to process certain cases (due to the aforementioned, out-of-date statutory constraints), it could be seven years or more before a claimant is able to receive compensation for an injury from a vaccine that was recommended by the CDC. Congress should amend the NCVIA to allow HHS only up to six (6)

[20] *See* 42 U.S.C. § 300 aa-16.

[21] *See* 42 U.S.C. § 300 aa-14.

[22] *Id.*

[23] *See* 42 U.S.C. § 300 aa-11.

months to add a new vaccine to the vaccine injury table following the recommendation by the CDC for routine use of that vaccine for pregnant women or children.[24]

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In sum, we are requesting the following minimal actions:

- Amend the NCVIA to provide for a minimum of eighteen (18) special masters and allow the chief special master authority to appoint additional special masters should it be required for swift justice to be carried out for victims who suffer from vaccine injuries;
- Amend the NCVIA to increase the statutory cap on pain and suffering and for the death benefit in vaccine injury cases to $850,000 with continued increases to adjust with inflation;
- Amend the NCVIA to provide for pre-judgment interest on all awards and fees;
- Amend the NCVIA to increase the statute of limitations to five (5) years for adults and include a tolling provision for minors which would allow them to file up to one year after they reach the age of eighteen (18);
- Amend the NCVIA to allow HHS only up to six (6) months to add a new vaccine to the vaccine injury table following the recommendation by the CDC for routine use of that vaccine for pregnant women or children; and
- Amend the excise tax statute to allow any vaccine recommended for routine administration to children or pregnant women to be automatically subject to the excise tax and therefore eligible for the VICP.

We respectfully request your attention to the important concerns outlined above and hope you agree that addressing these concerns is in everyone's best interest. If you would like to meet and discuss the foregoing, we would welcome that opportunity and hope to work cooperatively to address these issues.

Sincerely,

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

[24] A new vaccine added to the table becomes effective when Congress adds an excise tax to that vaccine. Congress should also amend the excise tax statute to allow any vaccine recommended for routine administration to children or pregnant women to be automatically subject to the excise tax and therefore eligible for the VICP. *See* 26 U.S.C. § 4131-4132.