



---

GW Law Faculty Publications & Other Works

Faculty Scholarship

---

2020

## The Trump Administration's Flawed Decision on Coronavirus Vaccine Injury Compensation: Recommendations for Changes

Peter H. Meyers

*George Washington University Law School, [peter@law.gwu.edu](mailto:peter@law.gwu.edu)*

Follow this and additional works at: [https://scholarship.law.gwu.edu/faculty\\_publications](https://scholarship.law.gwu.edu/faculty_publications)



Part of the [Law Commons](#)

---

### Recommended Citation

Peter H. Meyers, "The Trump Administration's Flawed Decision on Coronavirus Vaccine Injury Compensation: Recommendations for Changes," *J. Law and the Biosciences*, Vol. 7, Issue 1, Isaa082 (Nov. 2020).

This Article is brought to you for free and open access by the Faculty Scholarship at Scholarly Commons. It has been accepted for inclusion in GW Law Faculty Publications & Other Works by an authorized administrator of Scholarly Commons. For more information, please contact [spagel@law.gwu.edu](mailto:spagel@law.gwu.edu).



# The Trump administration's flawed decision on coronavirus vaccine injury compensation: recommendations for changes

Peter H. Meyers\*

The George Washington University Law School, Washington, DC, USA  
Corresponding author. E-mail: Peter@law.gwu.edu

## I. INTRODUCTION

Individuals who suffer adverse reactions from the coronavirus vaccines now being developed must bring their claims for compensation in the Countermeasures Injury Compensation Program (CICP), according to a directive issued by Health and Human Services (HHS) Secretary Alex M. Azar II on March 17, 2020.<sup>1</sup> However, experience with the CICP since it was passed by Congress in 2005 as part of the Public Readiness and Emergency Preparedness Act (PREPA),<sup>2</sup> reflects significant process concerns. There is a lack of transparency and no meaningful opportunity for petitioners to participate in the administrative proceedings within the Department of Health and Human Services in which their claims for compensation are decided. In addition, only limited compensation is authorized by statute for those petitioners who successfully navigate the program.

Already there is concern that whereas many Americans will welcome a coronavirus vaccine, only 51 per cent of US adults will definitely or probably take the vaccine if it were available, according to a Pew Research Organization poll in September 2020,

---

\* Professor of Law Emeritus at The George Washington University Law School, where he directed the Vaccine Injury Litigation Clinic. He served as Chairman of the Advisory Commission on Childhood Vaccines Workgroup of the US Department of Health and Human Services, and as a Designated Reviewer of nine publications on vaccines issued by the National Academy of Sciences' Institute of Medicine. The author has no personal, financial, or academic bias or interest in the subject matter that might reasonably be expected to affect his research findings or the manuscript's content.

1 'Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,' 85 Fed. Reg. 15198 *et seq.* (March 17, 2020), amending 42 C.F.R. § 110.100.

2 Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified at 42 U.S.C. § 247d-6d).

down sharply from 72 per cent who said they would take the vaccine in May 2020.<sup>3</sup> Such a low level of vaccination would jeopardize the herd immunity necessary to protect Americans throughout the country.

The CICP is 'the perfect target for anti-vaccinationists and others who believe that unsafe pandemic vaccines [are being] foisted upon a vulnerable public.'<sup>4</sup> Congress needs to act to ensure that a better vaccine compensation program is in place that will provide confidence that when adverse reactions to the coronavirus vaccines occur—which one hopes will be very rare—that adequate compensation will be provided to the injured persons. It is important to have a safety net in place now for the tens of thousands of volunteers participating in vaccine trials and then when coronavirus vaccines become widely available, so that there is assurance that claims for vaccine injuries will be promptly paid for medical expenses, lost income, and pain and suffering.

Part II of this Article discusses the importance of preparing for the likelihood that COVID-19 vaccines will, like other vaccines, have adverse effects on some small percentage of the population. Part III describes the limitations and problems with the flawed Countermeasures Injury Compensation Program. Part IV describes the better but still problematic Vaccine Injury Compensation Program. Part V describes the highly successful September 11th Victim Compensation Fund. Part VI contains the proposed provisions for the new compensation fund that should be created to handle injury claims that may be filed in connection with the coronavirus vaccines currently being developed, based on the best features of the Vaccine Injury Compensation Program and the September 11th Victim Compensation Fund.

## II. RARE VACCINE INJURIES: AN INEVITABLE CONSEQUENCE

Vaccines are generally considered one of the greatest medical and public health accomplishments of the past 100 years.<sup>5</sup> Vaccines have eliminated smallpox and polio from the USA and have greatly reduced other diseases such as diphtheria and rubella.<sup>6</sup> Vaccines have been proven to be safe and effective for the great majority of persons who receive them.<sup>7</sup> Moreover, vaccines can be administered 'without exacting widespread social disruption', in contrast to quarantines and mandated business and school closings which impose 'enormous social costs'.<sup>8</sup>

---

3 Alec Tyson, *et al.*, 'U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine' Sept. 17, 2020, <https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/>.

4 Wendy E. Parmet, *Pandemics, Populism and the Role of Law in the H1N1 Vaccine Campaign*, 4 ST LOUIS U. J. HEALTH L. POL 113, 146 (2010) (hereafter 'Parmet').

5 Lainie Rutkow *et al.*, *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 PENN ST. L. REV. 681, 681 (2007) ('Vaccines are widely hailed as one of the greatest medical and public health accomplishments of the Twentieth Century.'). The Centers for Disease Control and Prevention (CDC) describes the decrease in infectious diseases due to the use of vaccines as 'one of the greatest success stories in public health.' [http://www.cdc.gov/vaccinesafety/vaccine\\_monitoring/history.html](http://www.cdc.gov/vaccinesafety/vaccine_monitoring/history.html) (last visited Oct. 21, 2020).

6 *Id.*

7 *Id.*

8 Wendy E. Parmet, *supra* note 4 at 124; Julia E. Aledort *et al.*, *Non-Pharmaceutical Public Health Interventions for Pandemic Influenza: An Evaluation of the Evidence Base*, 7 B.M.C. PUB. HEALTH 208, 213–14 (2007); Centers for Disease Control and Prevention, *Achievements in Public Health, 1900–1999: Impact of Vaccines Universally Recommended for Children*, 48 MORBIDITY AND MORTALITY WEEKLY REPORT 243, 247 (Apr. 2, 1999).

Vaccines have 'always been the subject of heated controversy' ever since Edward Jenner demonstrated the efficacy of the smallpox vaccine in 1798.<sup>9</sup> Unfortunately, in recent years there has been a substantial amount of misinformation about the effects and dangers of vaccines put forward by antivaccination groups.<sup>10</sup> There is also widespread distrust of the federal government and the large pharmaceutical companies by the American public.<sup>11</sup> And, as Justice Scalia wrote in his opinion for the Supreme Court in *Bruesewitz v. Wyeth LLC*, vaccines have become the 'victims of their own success':

They [have] been so effective in preventing infectious diseases that the public became much less alarmed at the threat of those diseases, and much more concerned with the risk of injury from the vaccines themselves.<sup>12</sup>

Although the great majority of people who receive vaccines gain immunity from serious illness without suffering any adverse consequences, a very small percentage of people who receive vaccines do suffer serious adverse reactions, for two reasons: First, no vaccine or any other substance introduced into the body will be totally harmless to all people. Some very small number can be expected to have serious adverse reactions.<sup>13</sup> For example, virtually everyone who received the polio vaccine benefitted enormously, but a handful of people developed a debilitating postpolio syndrome as a result of receiving the vaccine.<sup>14</sup>

It is impossible to tell what rare serious injuries a new coronavirus vaccine might cause until it is widely produced and used. Premarketing testing of even tens of thousands of people is unlikely to detect extremely rare injuries that may affect one out of every hundred thousand or million people.

Second, unexpected problems have arisen in the past when new vaccines were rushed onto the market. One example is the Cutter incident in 1955, when a tainted polio vaccine containing the live, infectious virus instead of the killed virus, paralyzed over 200 children, and resulted in the death of 10 children, before it was removed from the market.<sup>15</sup>

Another example is the swine flu vaccine disaster in 1976, when a new mysterious strain of swine flu turned up at Fort Dix in New Jersey, sickening several soldiers and killing one.<sup>16</sup> President Gerald Ford ordered a rushed program to come up with a vaccine to inoculate all Americans. After the vaccination program began, there were

---

9 *Id.* at 127.

10 Parmet, *supra* note 4 at 127.

11 *Id.*

12 562 U.S. 223, 226 (2011) (footnotes omitted).

13 Robert T. Chen, *Safety of Vaccines*, in VACCINES 1144, 1144 (Stanley A. Plotkin & Walter A. Orenstein eds., 3rd ed. 1999); Centers for Disease Control and Prevention (CDC), *Vaccine Information Statement on Diphtheria, Tetanus and Pertussis Vaccines* (current edition 4/1/2020), at <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html>, accessed Nov. 26, 2020 ('As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.').

14 See Peter Paradiso & Peter Wright, *Oral Poliovirus Vaccine Only*, in OPTIONS FOR POLIOMYELITIS VACCINATION IN THE UNITED STATES: WORKSHOP SUMMARY 14, 16 (Cynthia J. Howe & Richard B. Johnstone eds., 1996).

15 Paul A. Offit, M.D., *The Cutter Incident, 50 Years Later*, 352 NEW ENG. J. MED. 1411 (2005).

16 Parmet, *supra* note 4 at 116.

reports of sporadic deaths possibly connected to the vaccine and 94 cases of paralysis, and the dreaded swine flu pandemic failed to materialize.<sup>17</sup> By the end of 1976 the vaccination program was shut down, a total fiasco.<sup>18</sup>

### III. EXPERIENCE WITH THE COUNTERMEASURES INJURY COMPENSATION PROGRAM (CICP)

The CICP,<sup>19</sup> where the Trump Administration has decided that all coronavirus vaccine injury claims must be filed, was passed in 2005 at the direction of the George W. Bush Administration out of concern with a potential H1N1 avian flu pandemic as well as potential bioterrorism threats from anthrax and other toxins.<sup>20</sup> In order to encourage industry to participate in creating countermeasures to such threats, including developing new vaccines, the new law provided the industry with very sweeping liability protections. The CICP protects all manufactures, distributors, and dispensers of covered vaccines and other countermeasures from any liability for serious adverse consequences that result from the administration of the vaccines or other countermeasures, even when the company is guilty of gross negligence in producing its product or makes deceptive claims in marketing it.<sup>21</sup> The only exception is for 'willful misconduct' by the company.<sup>22</sup>

The CICP is an extremely restricted compensation scheme. All petitions for compensation are decided by HHS officials in secret, without the opportunity for petitioners to interact with the decision-makers.<sup>23</sup> There is no time limit for HHS to issue its decision, and no judicial review is allowed of adverse decisions.<sup>24</sup>

All decisions to grant or deny compensation are also kept secret and never published, so that the public never knows which adverse events HHS has found related to the vaccine and which were not.<sup>25</sup> Even for successful petitions, the compensation allowed is quite limited. Payments for medical expenses are allowed, but no compensation is allowed for pain and suffering, or for rehabilitation, special education or vocational therapies, and only partial, prorated compensation is allowed for lost income.<sup>26</sup> The program also has many other caps and exclusions for allowable compensation.<sup>27</sup>

17 *Id.* (citing J.S. Malik Peiris, Leo L.M. Poon & Yi Guan, *Emergence of a Novel Swine-Origin Influenza A Virus (S-OIV) H1N1 Virus in Humans*, 45 J. CLIN. VIROL. 169, 170 (2009)).

18 *Id.*

19 The CICP was attached to a 'must pass' military authorization bill without any Congressional debate or public scrutiny. Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J. L. PUB. POL. 537, 561 (2010) (hereafter "Apolinsky & Van Detta").

20 See Homeland Sec. Council, *National Strategy for Pandemic Influenza* (2005); Sarah A. Lister, *Pandemic Influenza: Domestic Preparedness Efforts*, RL 33145 CONG. RESEARCH SERV. 32 (2005).

21 42 U.S.C. §§ 247d-6d(a)(1), (b)(1).

22 *Id.* § 247d-6d(d)(1).

23 Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 835 (2011), and articles cited therein (hereafter 'Meyers').

24 42 U.S.C. §§ 247d-6e(b)(5)(C), -6e(b)(4).

25 Meyers, *supra* note 23 at 835. Individuals seeking compensation receive a letter notifying them that they have been awarded compensation or that their request has been disapproved, along with 'written notice of the basis for the disapproval,' 42 C.F.R. §§ 110.73-.74, but these letters are not publicly released.

26 42 U.S.C. § 247d-6e(b)(2).

27 *Id.*

The CICP does not authorize the program to pay for attorneys' fees and the fees of doctors who submit expert reports in support of the petition,<sup>28</sup> unlike the Vaccine Injury Compensation Program, that does authorize payment for these fees.<sup>29</sup> To deal with the complex medical and legal questions of whether the coronavirus vaccine caused the subsequent injury, or whether the injury merely occurred after the vaccination without being caused by it, will likely require the assistance of counsel and expert testimony in most cases. But the CICP, unlike the Vaccine Injury Compensation Program, will not pay for this necessary assistance.

Moreover, in response to a Freedom of Information Act<sup>30</sup> request filed by this Author, HHS revealed in June 2020 that it has rejected over 90% of the claims for compensation filed with the CICP for adverse reactions to other new vaccines:<sup>31</sup>

- 100% of petitions for compensation filed for injuries claimed to have resulted from a new anthrax vaccine were rejected (18 out of 18 petitions rejected).
- Over 90% of petitions for compensation filed for injuries claimed to have resulted from the 2009 H1N1 vaccine were rejected (372 petitions rejected out of 407 filed).
- 72% of petitions for compensation filed for injuries claimed to have resulted from a new smallpox vaccine were rejected (8 petitions rejected out of 11 filed).<sup>32</sup>

Although some commentators have argued that the broad liability protection in the CICP is desirable,<sup>33</sup> other commentators have criticized the CICP for the sweeping protection it affords the pharmaceutical industry and the limited compensation provisions it contains for the public.<sup>34</sup> In this Author's view, the CICP is a very inhospitable forum to bring claims for vaccine injuries as currently constituted and administered. As Professors Joanna B. Apolinsky and Jeffrey A. Van Detta have concluded, the CICP offers only a 'dim prospect of just compensation.'<sup>35</sup>

#### IV. THE VACCINE INJURY COMPENSATION PROGRAM

Instead of mandating that all coronavirus vaccine injury claims be filed in the CICP, it would be much better for the Administration or Congress to require these claims be filed in the significantly superior Vaccine Injury Compensation Program (VICP).<sup>36</sup>

---

28 42 U.S.C. § 247d-6e(b)(2); 42 C.F.R. § 110.44(d).

29 42 U.S.C. § 300aa-15(e).

30 5 U.S.C. § 552, as amended.

31 Attachment to letter from Anthony Clemons, Government Information Specialist, Dept. of Health & Human Servs. to Peter Meyers, Professor Emeritus, The George Washington University Law School, (Jun. 26, 2020) (on file with Author), at pg. 1.

32 *Id.*

33 See, e.g., Paul Taylor, *We're All in This Together: Extending Sovereign Immunity to Encourage Private Parties to Reduce Public Risk*, 75 U. CIN. L. REV. 1595, 1633-34, 1643-46 (2007).

34 See, e.g., Parmet, *supra* note 4 at 152 (CICP's provisions are 'far less protective of the public than is necessary or useful'); Mary S. Holland, *Liability For Vaccine Injury: The United States, the European Union, and the Developing World*, 67 EMORY L. J. 415, 450 (2018). Some adverse events that occur after the administration of the covered countermeasures have been designated Table Injuries which, if they occur within the specified time period, are presumed to be caused by the countermeasure, 42 C.F. R. § 110.100, but it is uncertain whether any individual who receives the Coronavirus vaccines being developed will suffer any of these designated Table Injuries.

35 Apolinsky & Van Detta, *supra* note 19 at 576.

The VICP, which began operation in 1988, covers injury and death claims resulting from the principal childhood vaccines, like the Diphtheria-Pertussis-Tetanus vaccination and the Measles-Mumps-Rubella vaccination; it also covers claims from the seasonal flu vaccines given to children and adults.<sup>37</sup>

The principal purpose behind passage of the VICP was to prevent vaccine manufacturers from leaving the US market over concerns about tort liability for the adverse effects of the vaccines; the VICP gave manufacturers protection from such liability, and thereby insured a continuing adequate supply of vaccines in the USA.<sup>38</sup> The VICP was also intended by Congress to compensate those individuals who were injured by the vaccines 'quickly, easily, and with certainty and generosity'.<sup>39</sup>

Proceedings in the VICP give petitioners a much more meaningful opportunity to participate than proceedings in the CACP. There are hearings before independent special masters, where petitioners are typically represented by attorneys, and have the assistance of expert witnesses, paid for by the program.<sup>40</sup>

At the conclusion of these proceedings, public decisions are issued by the special masters (with appropriate redactions to protect private medical information about the petitioners), so that the public will know which injuries have been found to be caused by the vaccinations and which not. There is also the availability of judicial review of adverse decisions in the US Court of Federal Claims, the US Court of Appeals for the Federal Circuit and the US Supreme Court.<sup>41</sup>

In stark contrast to the CACP, the VICP's special masters have compensated approximately 75% of the cases adjudicated in the past five years:<sup>42</sup>

- 79% of claims adjudicated in FY 2016 (698 claims compensated; 185 dismissed).
- 77% of claims adjudicated in FY 2017 (696 claims compensated; 202 dismissed).
- 73% of claims adjudicated in FY 2018 (544 claims compensated; 199 dismissed).
- 78% of claims adjudicated in FY 2019 (641 claims compensated; 181 dismissed).
- 78% of claims adjudicated as of Oct. 1, 2020 in FY 2020 (682 compensated; 191 dismissed).

Although the VICP is far better than the CACP, it has its problems. There is a large backlog of cases today, and years-long delays in scheduling hearings in many pending cases.<sup>43</sup> It now takes an average of five and one-half years to resolve cases in the VICP.<sup>44</sup> If coronavirus vaccines were added to the VICP it is essential that Congress also pass

36 National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34).

37 42 U.S.C. § 300aa-11(a)(1) to (4) (2006).

38 Meyers, *supra* note 23 at 841.

39 H.R. Rep. No. 99-908, pt. 1, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344.

40 Meyers, *supra* note 23 at 810-11.

41 42 U.S.C. § 300aa-12(e); Meyers, *supra* note 25, at 483.

42 <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf> (updated Oct. 1, 2020). Many of the compensated claims involved adverse reactions to the vaccines, and many involved shoulder trauma caused by flawed injection techniques.

43 The Act requires the special masters to issue final decisions within 240 days of the date that the petition for compensation is filed, 42 U.S.C. § 300aa-12(g), but this deadline is routinely waived.

44 Nora Freeman Engstrom, *A Dose of Reality for Specialized Courts: Lessons from the VICP*, 163 U. PA. L. REV. 1631, 1686 (2015).



legislation now pending before it to add additional special masters to adjudicate those claims.<sup>45</sup>

Proceedings in the VICP have been criticized for being much more adversarial than Congress intended.<sup>46</sup> The VICP has also been criticized for its low caps of only \$250,000 for death resulting from a vaccination and for pain and suffering resulting from vaccine injuries.<sup>47</sup> Even assuming those were appropriate caps in 1986 when the VICP statute was passed, those amounts would be over \$500,000 in 2020 dollars as a result of inflation, according to the US Department of Labor's Bureau of Labor Statistics.<sup>48</sup> Those caps should be raised substantially.<sup>49</sup>

## V. THE SEPTEMBER 11TH VICTIM COMPENSATION FUND

A good model to consider is the September 11th Victim Compensation Fund that Congress created in 2001 after the 9/11 attacks on the Twin Towers in New York City and the Pentagon outside of Washington, D.C.<sup>50</sup> The September 11th Victim Compensation Fund was established to help those who were injured or had a family member die as a result of the 9/11 attacks.<sup>51</sup> Congress also made clear, however, that the most important objective of the Act was 'to protect the airline industry, the World Trade Center's owners, and others from protracted, uncertain litigation.'<sup>52</sup>

The 9/11 compensation fund used informal procedures to adjudicate all injury and death claims filed in the program, with Kenneth Feinberg acting as Administrator.<sup>53</sup> Feinberg and his deputies gave all individuals who filed claims in the program an opportunity to meet in person and to advocate for what they believed were appropriate levels of compensation.<sup>54</sup> The September 11th Compensation Fund required final decisions to be issued within 120 days of the claims being filed, and this provision was largely followed.<sup>55</sup> The Fund even allowed advance benefits to be paid before final resolution of the claims to injured claimants and survivors who could show severe hardship. The Fund ultimately granted compensation for 75% of the claims filed (compensation awarded for 5560 claims out of 7403 filed).<sup>56</sup>

This author agrees with the many commentators who have concluded that the September 11th Fund largely succeeded in providing compensation that was gener-

---

45 National Vaccine Injury Compensation Program Improvement Act of 2019, introduced in the Senate and House on May 23, 2019, as S. 1638 and H.R. 3033, 116th Cong, 1st. Sess. (increasing from 8 to 16 the number of authorized special masters).

46 See H.R. Report No. 106-977 (2000), 'The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices' at 12.

47 42 U.S.C. § 300aa-15,

48 [HTTP://data.bls.gov/cgi-bin/gpicalc-pl](http://data.bls.gov/cgi-bin/gpicalc-pl) (last visited Oct. 20, 2020).

49 Apolinsky & Van Detta, *supra* note 19 at 580; Meyers, *supra* note 23 at 849-50.

50 September 11th Victim Compensation Fund of 2001, Pub. L. No. 107-42, 115 Stat. 237 (2001) (codified as amended at 49 U.S.C. §40101 note (2006) (Air Transportation Safety and System Stabilization)).

51 Robert M. Ackerman, *The September 11th Victim Compensation Fund: An Effective Administrative Response to National Tragedy*, 10 HARV. NEGOT. L. REV. 135, 159-60 (2005) (hereafter "Akerman").

52 Kenneth R. Feinberg, *9/11 Fund: Once was Enough*, WASH. POST, Sept. 11, 2008, at A17.

53 *Id.*; 49 U.S.C. § 40101 note (§404).

54 Kenneth R. Feinberg, *Final Report of the Special Master for the September 11th Victim Compensation Fund of 2001*, Vol. 1, at 8, 10 (2004).

55 Meyers, *supra* note 23 at 830.

56 Feinberg, *supra* note 54 at 98-99.



ous, prompt, and fair to the petitioners.<sup>57</sup> Other commentators have criticized the September 11th Fund for the enormous discretion given to the Administrator with little accountability or oversight,<sup>58</sup> but this Author believes that the broad discretion given to the Administrator, which was exercised with compassion and flexibility, was responsible for the success of the program.

The September 11th Compensation Fund was created in a different atmosphere than exists today, a time when Americans came together to respond to a national tragedy. The lawmakers who passed the September 11th Fund only 11 days after the attacks wanted to show the world that, in the face of such an unprecedented attack, the American people would rally around the victims. Like the Marshall Plan that rescued Europe after World War II, the 9/11 Fund was a demonstration of American resolve in the wake of tragedy. The Nation would stand as one.<sup>59</sup>

This spirit of national unity after the 9/11 attacks stands in sharp contrast to the deep divisions in American society today in addressing the COVID-19 crisis. Notwithstanding the different atmosphere, the provisions of the September 11th Compensation Fund offer a useful model for structuring a fair and just compensation program for coronavirus vaccine injuries.

## VI. RECOMMENDATIONS FOR ADJUDICATING CORONAVIRUS VACCINE INJURY COMPENSATION CLAIMS

Based on experience with prior compensation programs, the following recommendations are provided for the key provisions that should be part of the system for compensating claims for injuries caused by the new coronavirus vaccines currently being developed. These proposals are based on the best features of the September 11th Victims Compensation Fund, the National Vaccine Injury Compensation Program, and other recent compensation programs enacted by Congress. These provisions could be included in a new compensation program that the Administration or Congress adopts to cover coronavirus vaccine injuries, or they could be incorporated into the existing CICIP or VICP by legislative amendments to make those programs fairer in resolving coronavirus vaccine injury claims:

### VI.A. Adopt Open Decision-Making Procedures that Allow Meaningful Participation by Petitioners

Both the VICP and the September 11th Fund allow petitioners to actively participate in the proceedings that resolve their claims with the assistance of counsel and expert witnesses (if necessary). These same protections should be accorded to claimants filing petitions for coronavirus vaccine injury compensation.

---

57 See, e.g., James C. Harris, *Why the September 11th Victim Compensation Fund Proves the Case for a New Zealand-Style Comprehensive Social Insurance Plan in the United States*, 100 NW. U. L. REV. 1367, 1372 (2006); Robert L. Rabin, *September 11 Through the Prism of Victim Compensation*, 106 COLUM. L. REV. 464, 478 (2006) (reviewing KENNETH R. FEINBERG, *WHAT IS LIFE WORTH?: THE UNPRECEDENTED EFFORT TO COMPENSATE THE VICTIMS OF 9/11* (2005)) ('In fact, the resultant mix of presumptive scheduling tempered by personal empathy and pecuniary adjustments at the margin was the touchstone to the success of the program.')

58 See Matthew Diller, *Tort and Welfare Principles in the Victim Compensation Fund*, 53 DEPAUL L. REV. 719, 725–26, 753–60 (2003); Ackerman, *supra* note 51 at 138-39.

59 Feinberg, *supra* note 52 at A17.

### **VI.B. Authorize Independent Special Masters to Decide Claims for Compensation**

Both the VICP and the September 11th Fund use independent Special Masters to decide the claims for compensation, in contrast to internal HHS officials who decide on whether to compensate in the CICP. To insure more neutral, unbiased decision-making, independent Special Masters should rule on requests for coronavirus vaccine injury compensation. If an unexpectedly large number of claims are filed for compensation, the Chief Special Master should be authorized to add additional Special Masters as needed to adjudicate those claims.

### **VI.C. Impose Strict Time Limits for Final Decision-Making**

The September 11th Compensation Fund required that final decisions on claims be issued within 120 days of filing, and this requirement was largely followed.<sup>60</sup> The VICP requires that final decisions be issued within 240 days of filing the claim, but this time limit has been largely ignored.<sup>61</sup> Because vaccine injury claims are generally more complex than the claims filed in the 9/11 Fund, a 240-day limit for final decisions is appropriate, but it should be strictly enforced.

### **VI.D. Adopt a Legal Standard of Proof More Generous to Petitioners**

Several recent compensation laws have contained provisions that in close cases the petitioners should get the 'benefit of the doubt' and be awarded compensation.<sup>62</sup> Professors Joanna B. Apolinsky, Jeffrey A. Van Detta, and Efthimios Parasidis have also proposed that once the petitioner has presented credible evidence that the vaccine caused an injury, the burden of proof should shift to the government to demonstrate by a preponderance of the evidence that the vaccine did not cause the injury.<sup>63</sup> These generous standards should be adopted in resolving coronavirus vaccine injury claims.

### **VI.E. Adopt More Generous Limits on the Award of Compensation**

Compensation allowed in the CICP is quite limited. No payments are allowed for pain and suffering, and only partial, prorated compensation is allowed for lost income. These restrictions are unjustified. In the VICP and the September 11th Fund compensation is authorized for pain and suffering and lost income, as well as for medical expenses. Such compensation should also be provided for coronavirus vaccine injuries. The payment for death in the CICP is limited to the inappropriately small sum of \$250,000; in the September 11th Fund, the average award involving the death of a claimant was in excess

---

60 Meyers, *supra* note 23 at 830.

61 *Id.* at 789.

62 The Radiation Exposure Compensation Act provides that any 'reasonable doubt with regard to whether a claim meets the requirements of this Act shall be resolved in favor of the claimant'. 42 U.S.C. § 2210 note § 6(b)(1). The Japanese-American internment compensation law contained a 'benefit of the doubt' provision that mandated compensation if there was 'an approximate balance of positive and negative evidence' with respect to a claimant's eligibility. 50 U.S.C. § 1989b-4(a)(3) (2006). Similarly, the Department of Veterans Affairs statute provides that an injured veteran is entitled to the benefit of the doubt on whether the veteran is entitled to disability compensation in a close case. 42 U.S.C. § 300aa-13(a)(1).

63 Apolinsky & Van Detta, *supra* note 19 at 625; Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 BOST. U. L. REV. 2153, 2236 (2017).

of two million dollars.<sup>64</sup> Perhaps an appropriate compromise would authorize a benefit of up to one million dollars for death associated with a coronavirus vaccine and up to \$500,000 for pain and suffering.

#### **VI.F. Allow for Judicial Review of Final Agency Decisions**

Judicial review should be authorized in US District Court or the US Court of Federal Claims under the principles established in the Administrative Procedure Act that governs review of most administrative decisions.<sup>65</sup>

#### **VI.G. Insure Adequate Funding for the Compensation Program**

The VICP is funded by a 75-cent excise tax on every dose of the covered vaccines, which has resulted in a trust fund containing in excess of several billion dollars for the past decade.<sup>66</sup> This tax is paid by either a private citizen who is vaccinated or by the federal government when it buys vaccines for free distribution under one of the government's health and welfare programs. For the coronavirus vaccines, the federal government should provide free vaccinations to everyone as an inducement for all people to be vaccinated, and contribute a 75-cent excise tax per dose to pay for vaccine related injury and deaths. This is preferable to the present provision for funding the CACP through separate specific appropriation bills approved by the US Congress.<sup>67</sup>

#### **VI.H. Publish Final Decisions to Grant or Deny Compensation (With Appropriate Redactions)**

All decisions issued by special masters in the VICP are published so that other petitioners and the public will know which injuries have been found to be caused by the covered vaccines and which injuries were not found to be caused by the vaccines. Similarly, Administrator Feinberg published information about the decisions issued in the September 11th Compensation Fund so that petitioners and the public would know the number of petitions granted relief and the amounts of compensation awarded in injury and death cases. In sharp contrast, decisions in the CACP are never published, and it took a Freedom of Information Act request from this Author to make public even the number of claims that have been filed, accepted, and rejected in the CACP. In dealing with claims for injuries from the coronavirus vaccines, there should be a public record of what specific injuries have been found compensable and what injuries were found not compensable, and at least a brief description of the bases for these decisions. The names of the petitioners should be redacted at the request of petitioners to protect their privacy, as is done in the VICP.

---

64 Feinberg, *supra* note 54 at 110.

65 The judicial review provision of the APA, 5 U.S.C. § 706, provides: The reviewing court shall— (1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence....

66 <https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html> (last viewed Oct. 21, 2020); Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL L. 59, 62 (1999).

67 42 U.S.C. § 247d-6e(a).

## VII. CONCLUSION

Adequate vaccine injury compensation should be a bipartisan priority for the new Administration and Congress. Instead of the CICI, a new program should be designed based on the best features of the VICP and the September 11th Victim Compensation Fund. By providing more generous funding and elemental procedural safeguards, there will be fairer compensation for the rare serious injuries and an effective rebuttal to the antivaccination movement.