

VIEWPOINT

A Viral Pandemic, Vaccine Safety, and Compensation for Adverse Events

H. Cody Meissner, MD
Tufts Children's Hospital, Tufts University School of Medicine, Boston, Massachusetts.



Related article

Great expectations have been placed on the ability of vaccines to bring an end to the current severe acute respiratory syndrome coronavirus 2 pandemic. Non-pharmacologic interventions have resulted in social disruption and disastrous financial consequences for many people.¹ Widespread immunity acquired from a vaccine is anticipated to enable return to a more normal lifestyle. The extraordinary progress in vaccine development and evaluation achieved under Operation Warp Speed, followed by rapid Food and Drug Administration (FDA) authorization, is one of the greatest achievements in vaccinology since development of polio vaccines.

No medical intervention, including vaccines, is devoid of adverse reactions for all people. In recognition of this fact, Congress passed the National Childhood Vaccine Injury Act of 1986 that created the national Vaccine Injury Compensation Program (VICP).² This federal program is a no-fault alternative to the traditional tort system for resolving and compensating vaccine injuries thought to be caused by childhood and adult vaccines. The VICP has contributed to historically high rates of vaccine acceptance and historically low rates of many vaccine-preventable diseases in the US.

People should understand that the benefit for individuals and for society far exceeds the risk of harm from a vaccine

Under most circumstances, biologics such as vaccines may be introduced into interstate commerce only if they have been licensed by the FDA. Under certain circumstances the FDA may permit a medical product such as a vaccine to be used outside the standard regulatory framework. The Public Readiness and Emergency Preparedness Act (PREP Act) was enacted in December 2005 to identify a public health emergency and to facilitate a coordinated national response. The PREP Act is designed to encourage timely development of potentially lifesaving medical countermeasures in the event of an emergency related to a terrorist attack or to a naturally occurring emerging infectious disease threat. Medical countermeasures include vaccines or antibody preparations, medications such as an antiviral drug, devices such as a diagnostic test, personal protective equipment or ventilator, or other items that are used to mitigate, prevent, diagnose, treat, or cure a public health emergency or a security threat.^{3,4} Covered infectious disease threats in the PREP Act include pandemic influenza, tularemia,

plague, glanders (*Burkholderia mallei*), melioidosis (*B pseudomallei*), typhus, multidrug-resistant anthrax, smallpox, the viral hemorrhagic fevers Marburg and Ebola, and the pandemic coronavirus (severe acute respiratory syndrome coronavirus 2).

A PREP Act declaration generally provides immunity from legal liability for manufacturers, distributors, program planners, licensed health professionals, and others authorized to administer a vaccine, except in the instance of "willful misconduct." The PREP Act authorizes creation of a US Treasury fund, a Countermeasures Injury Compensation Program (CICP) to compensate eligible individuals for serious physical injuries or death caused by administration of a coronavirus disease 2019 (COVID-19) vaccine. In contrast, the traditional VICP is funded by an excise tax on each vaccine. The VICP and CICP are different plans authorized by 2 distinct federal statutes with different requirements.

When first tested, a vaccine is considered experimental and may be referred to as an authorized vaccine after an Emergency Use Authorization (EUA) is issued. Once an authorized vaccine is licensed by the FDA, included in the Centers for Disease Control and Prevention vaccine schedule, and authorized by the secretary of Health and Human Services, and Congress has placed an excise tax on it, it is covered under the VICP. This distinction between a licensed vaccine and an authorized vaccine is intended to ensure an expedited review process and the availability of vaccines more rapidly than occurs through the traditional biologics license application process, which generally requires several years. An EUA enables rapid deployment of nonlicensed COVID-19 vaccines to provide individual and community protection as quickly as possible. In return for rapid deployment of a nonlicensed vaccine, such as during the present pandemic, in which nearly 450 000 individuals in the US have died, certain differences exist for compensation for alleged vaccine injuries compared with those from vaccines covered by VICP. For example, the VICP process for resolving a claim consists of the judicial process, whereas petitions covered by the CICP are resolved by an administrative process.^{4,5}

On January 31, 2020, the secretary of Health and Human Services declared a public health emergency in response to the current coronavirus pandemic. Subsequent amendments and declarations by the secretary invoked the PREP Act and resulted in liability protections for experimental vaccines authorized under an EUA as provided in the Coronavirus Aid, Relief, and Economic Security (CARES) Act.³ An

Corresponding Author: H. Cody Meissner, MD, Tufts Children's Hospital, Tufts University School of Medicine, 800 Washington St, Boston, MA 02111 (cmeissner@tuftsmedicalcenter.org).

individual who sustains a covered injury as the direct result of administration of a covered COVID-19 countermeasure (including a vaccine) may apply for compensation through the VICP. Serious physical injury is defined as an injury that is life-threatening, results in permanent impairment of a bodily function or permanent damage to a bodily structure, or necessitates medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a bodily structure. Available benefits include unreimbursed medical costs for serious physical injuries, lost employment income because of the injury, and survivor death benefits.

A request for benefits for an alleged injury must be submitted to CICIP within 1 year from the date of the event. Benefits awarded through VICP have different intervals for submission that are noted in Table 5 of the vaccine injury compensation section. The CICIP is the payer of last resort and may pay for medical services that are not covered by other third-party payers, such as worker's compensation, Medicaid, or veterans' benefits. The program is not authorized to provide reimbursement for attorney fees and expenses, and the standard of proof to demonstrate vaccine-related injury is higher than in the VICP.⁵

Since 2010, the CICIP has provided compensation for serious injuries that occurred as a result of the use of countermeasures, such as during the 2009 influenza A/H1N1 epidemic. Through November 1, 2020, the program received 494 claims from individuals alleging injury by a covered countermeasure. After review, 450 claims were deemed ineligible for compensation and 5 cases remain under evaluation. Compensation has been provided for 29 claims totaling more than \$6 million since the program began. The program determined 39 claims were eligible for compensation; however, 10 claims did not have any compensable expenses or losses.⁶

Addition of COVID-19 vaccine injuries to the vaccine injury compensation table will require well-established data regarding adverse reactions that may occur as a result of administration of a protective vaccine. The initial basis for assessment of whether an

event that occurs after administration of a novel vaccine is causal or simply a random event temporally associated with vaccine administration will rest on the results of blinded, randomized, placebo-controlled clinical trials. In time, a greater understanding will emerge regarding reactions and differentiation will be possible between adverse reactions related to the vaccine and events that are unrelated.

The goal of a clinical trial with an unlicensed vaccine is to generate sufficient data to fulfill FDA requirements for a biologics license application as rapidly as possible. Soon after a biologics license application is approved by the FDA, the licensed vaccine likely will be included in the VICP. It is anticipated that a biologics license application for the 2 authorized messenger RNA COVID-19 vaccines (as well as other vaccines presently in late-phase development) will be submitted by the companies for consideration of licensure by the FDA before the summer of 2021.

Several aspects regarding a severe acute respiratory syndrome coronavirus 2 vaccine are unique. A license has never been issued previously for any coronavirus vaccine. In 2005 the FDA issued an EUA for the unapproved use of a previously licensed vaccine (anthrax vaccine). However, for a previously unlicensed vaccine there has never been availability under an EUA instead of the standard biologics license application process. Even with an extraordinarily safe vaccine, a serious adverse event may not become apparent until millions of vaccine doses have been administered. The VICP provided compensation for injuries from licensed vaccines at a rate of 1.3 people per million doses of vaccine distributed during the 12-year period between 2006 and 2018.⁷ While an EUA remains in effect, a fact sheet is distributed to each vaccinee rather than a vaccine information sheet. The fact sheet provides information regarding how to submit a claim for alleged vaccine injuries to the CICIP.⁸

Ultimately, control of this devastating pandemic will require widespread acceptance of one of several vaccines. To date, the authorized vaccines appear to be extraordinarily safe. People should understand that the benefit for individuals and for society far exceeds the risk of harm from a vaccine.

ARTICLE INFORMATION

Published Online: February 5, 2021.
doi:10.1001/jama.2020.26792

Conflict of Interest Disclosures: Dr Meissner is a member of the National Vaccine and Advisory Committee for the US Department of Health and Human Services and a member of the Vaccines and Related Biological Products Advisory Committee for the Food and Drug Administration.

REFERENCES

- Honein MA, Christie A, Rose DA, et al; CDC COVID-19 Response Team. Summary of guidance for public health strategies to address high levels of community transmission of SARS-CoV-2 and related deaths, December 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(49):1860-1867. doi:10.15585/mmwr.mm6949e2
- Meissner HC, Nair N, Plotkin SA. The National Vaccine Injury Compensation Program: striking a balance between individual rights and community benefit. *JAMA.* 2019;321(4):343-344. doi:10.1001/jama.2018.20421
- Health and Human Services Department. Fourth amendment to the declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and republication of the declaration. *Federal Register.* December 9, 2020. Accessed December 18, 2020. <https://www.federalregister.gov/documents/2020/12/09/2020-26977/fourth-amendment-to-the-declaration-under-the-public-readiness-and-emergency-preparedness-act-for>
- Food and Drug Administration. Medical Countermeasures Initiative. Accessed December 22, 2020. <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/medical-countermeasures-initiative-mcmi>
- Health Resources & Services Administration. Comparison of Countermeasures Injury Compensation Program (CICIP) to the National Injury Compensation Program (VICP). Accessed December 12, 2020. <https://www.hrsa.gov/cicp/cicp-vicp>
- Health Resources & Services Administration. Countermeasures Injury Compensation Program (CICIP) data. Accessed December 23, 2020. <https://www.hrsa.gov/cicp/cicp-data>
- Meissner HC, Plotkin SA. The facts about vaccine safety. *Clin Infect Dis.* 2020;ciaa697. doi:10.1093/cid/ciaa697
- Health Resources & Services Administration. Countermeasures Injury Compensation Program (CICIP). November 2020. Accessed January 31, 2021. <https://www.hrsa.gov/cicp/>