

From: Theresa Wrangham <tkw@nvic.org>

Sent: Tuesday, August 24, 2021 3:06 PM

To: HRSA HSB CICP <CICP@hrsa.gov>

Subject: Pfizer COVID-19 Vaccine

Importance: High

To whom it may concern,

I am seeking clarification on the newly licensed Pfizer COVID-19 vaccine. It is my impression that with the FDA reissuing the EUA status to the newly licensed vaccine that it will continue to be considered a countermeasure under the PREP Act and that any injuries resulting from the vaccine will be processed by the CICP.

On the whole from a mile-high view, while the PREP Act is in effect, all EUA products, etc. that cause harm will be processed by the CICP. Additionally, when the emergency is declared over by DHHS, then licensed vaccines that were covered by the PREP Act, and which cause harm, will then be compensated via the VICP.

Can you confirm these understandings, and/or correct them?

Many thanks,

Theresa Wrangham, Executive Director

National Vaccine Information Center - NVIC.org

Founded in 1982 by parents of vaccine-injured children, the National Vaccine Information Center (NVIC) is a charitable non-profit dedicated to preventing vaccine injuries and deaths through public education. NVIC defends the human right to autonomy and freedom of thought, speech, conscience, religious belief and informed consent to medical risk taking. NVIC opposes "no exceptions" mandatory vaccination laws and advocates for the inclusion of flexible medical, religious and conscientious belief vaccine exemptions in public health policies and laws. NVIC does not offer medical or legal advice, and supports the availability of all preventive health care options, including vaccines.

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---- On Thu, 26 Aug 2021 11:45:33 -0600 **Mishler, Dale (HRSA)** <DMishler@hrsa.gov> wrote ----

Ms. Wrangham,

Thank you for your inquiry to the Health Resources and Services Administration, Healthcare Systems Bureau, Countermeasures Injury Compensation Program (CICP). Your question relates to which Program provides coverage, the CICP or the Vaccine Injury Compensation Program (VICP), for injuries alleged to have been caused by the newly licensed Pfizer COVID-19 vaccine.

As noted, the COVID-19 vaccines currently authorized through Food and Drug Administration (FDA) Emergency Use Authorizations or approved by the FDA are covered countermeasures under the Public Readiness and Emergency Preparedness Act and, therefore, individuals who allege injury as a result of the administration or use of such vaccines are eligible to apply for benefits under the CICP. Full FDA approval of the Pfizer COVID-19 vaccine does not remove its coverage from the CICP or provide coverage under the VICP. In order to add a new vaccine to the VICP, the following actions must occur: (1) the vaccine must be recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children and/or pregnant women; (2) Congress must enact an excise tax on the vaccine; and (3) the U.S. Department of Health and Human Services (HHS) must add the vaccine to the Vaccine Injury Table through publication of a notice of coverage in the Federal Register.

No COVID-19 vaccine currently meets the above criteria for coverage under the VICP because no COVID-19 vaccine at this time is subject to an excise tax by federal law. Only once the first two criteria are met can HHS add a new vaccine or class of vaccines to the Vaccine Injury Table.

Respectfully;

Dale Mishler, DHSc, MS, APRN
Captain, United States Public Health Service
Branch Chief – CRPB
Acting Branch Chief – VICP-POB
Division of Injury Compensation Programs
Healthcare Systems Bureau
Phone: (301) 443-1413
Cell: (240) 460-6780



From: Theresa Wrangham <tkw@nvic.org>
Sent: Thursday, August 26, 2021 5:17 PM
To: Mishler, Dale (HRSA) <DMishler@hrsa.gov>
Subject: Re: FW: Pfizer COVID-19 Vaccine

Dear Captain Mishler,

Thank you for your prompt response. I believe you addressed all my questions, except for one. My struggle is understanding any intersection between the law governing the VICP and the PREP Act.

While the PREP Act remains in effect, can the three criteria you noted for addition to the VICP be accomplished to transfer an active countermeasure vaccine from the CICIP to the VICP? I believe the answer is no, as these vaccines remain as "countermeasures" while the PREP Act is in effect. Further, I believe that their status as a "countermeasure" would only end when 1) there is a declaration to end the state of emergency, or 2) that the original declaration of the emergency that triggered the PREP Act expires.

In essence, I believe that a vaccine that is actively identified as a "countermeasure" while the PREP Act is in effect cannot complete the VICP criteria because it seems clear under the PREP Act that any injury associated with an active "countermeasure" falls to the CICIP to resolve. However, once the PREP Act is no longer in effect, then the former "countermeasure" can complete the process you identified that is typical its addition to the VICP.

Could you confirm or correct my understanding in this regard?

Many thanks,

Theresa Wrangham, Executive Director
National Vaccine Information Center - NVIC.org

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---- On Mon, 30 Aug 2021 13:38:24 -0600 **Mishler, Dale (HRSA)** <DMishler@hrsa.gov> wrote ----

Dear Ms. Wrangham,

The question you ask seeks a legal opinion regarding a speculative future event. Our office is not able to provide such legal advice.

Respectfully;

Dale Mishler, DHSc, MS, APRN
Captain, United States Public Health Service
Branch Chief – CRPB
Acting Branch Chief – VICP-POB
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