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Perspective

Covid-19 Vaccine Injuries — Preventing Inequities in Compensation

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Ordinarily, it takes scientists about 10 years to develop a vaccine. By contrast, the pharmaceutical industry has worked toward emergency approval of Covid-19 vaccines in a matter of months. With 44,000 participants enrolled in clinical trials for the Pfizer–BioNTech vaccine and 30,000 in clinical trials for Moderna's vaccine, common side effects that occur fairly soon after vaccination are likely to be identified. But this abbreviated development timeline provides little opportunity to identify potential adverse events such as joint pain, anaphylaxis, or neurologic conditions such as encephalitis, transverse myelitis, or Guillain–Barré syndrome that might occur in the longer term or that are rare enough that they probably won't be discovered until the vaccine is distributed to a substantial portion of the public. Vaccine-related adverse events would especially burden low-income people, who have limited financial resources to obtain medical care, weather any resulting job loss, and pursue compensation and who are disproportionately non-White.

The United States has developed a robust system for vaccine-injury compensation to alleviate the burdens of adverse medical consequences of vaccines. But this system will be unavailable to people who receive Covid-19 vaccines during the declared public health emergency. All potential vaccine recipients, and especially people in high-risk communities, therefore face a dilemma: should they risk becoming infected or risk having a vaccine injury without sufficient access to compensation?

Normally, once the Food and Drug Administration (FDA) approves a vaccine and the Centers for Disease Control and Prevention (CDC) recommends it for children or pregnant women, injury compensation is available for any recipient through the National Vaccine Injury Compensation Program (VICP). The VICP covers the majority of vaccines administered in the United States. This no-fault program was created to provide an alternative legal avenue to ensure quick and fair compensation for vaccine injuries and to insulate manufacturers from liability to encourage them to pursue vaccine development. In many cases, claimants who develop recognized symptoms within a certain time frame after vaccination don't need to prove that the injuries were caused by the vaccine, which leaves in question only the extent of damages. Successful claims and attorneys' fees are paid out of the Vaccine Injury Compensation Trust Fund, and they have exceeded $4 billion to date.[1] Since 2015,

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the fund has paid out an average total of $216 million to an average of 615 claimants each year.

The declaration of a public health emergency by the Department of Health and Human Services in March 2020, however, resulted in exclusion of Covid-19 vaccine injuries from the VICP. This declaration triggered the Public Readiness and Emergency Preparedness (PREP) Act, a federal law that requires that all people injured by vaccines given as countermeasures during a declared emergency bring claims under only the Countermeasures Injury Compensation Program (CICP). The CICP is far less generous and less accessible than the VICP. It compensates people for only the most serious injuries, has a higher burden of proof than the VICP, has a 1-year statute of limitations after the date of vaccination, and limits awards for damages. For example, the CICP limits lost-income recovery to $50,000 for each year out of work and doesn't include compensation for pain, suffering, or emotional distress.

As a result, people who are vaccinated during the declared public health emergency will be less likely to obtain compensation for injuries associated with Covid-19 vaccines than they would be for injuries from vaccines included in the VICP. Furthermore, the process for pursuing compensation will be lengthier, more difficult, and more expensive because reimbursement for attorneys' fees is unavailable. People vaccinated during a declared public health emergency can never pursue injury claims under the VICP, even if their symptoms manifest or are linked to the vaccine after the declaration is lifted.

Low-income people and people of color typically shoulder the greatest burden during public health disasters and their aftermath, and the Covid-19 pandemic has been no different. Racial and ethnic minorities are more than twice as likely to die from Covid-19 as White people, and mortality is much higher in high-poverty areas than in wealthier ones.[2] It will therefore be acutely important to rapidly vaccinate members of minority and low-income populations.

There are also high levels of vaccine skepticism and reluctance in these communities, often stemming from long-standing inequities in medical treatment and from abuses, such as those that occurred during the infamous Tuskegee syphilis study. In a Kaiser Family Foundation poll conducted in August and September 2020, it was found that 49% of Black respondents would probably not or definitely not take a Covid-19 vaccine, as compared with 33% of White respondents.[3] Similarly, a Pew Research Center poll from November found that although 71% of Black respondents knew someone who had been hospitalized or died from Covid-19, only 42% intended to get a Covid-19 vaccine when it became available.[4] These findings indicate a need to provide strong safety nets and supports to encourage Covid-19 vaccine adoption in vulnerable communities, including adequate injury compensation.

Current projections suggest that the United States will achieve sufficient herd immunity to lift the emergency declaration by the fall of 2021. This development may well allow Covid-19 vaccine-injury claimants who delay vaccination to file under the VICP as long as the CDC has recommended the vaccine for children or pregnant women (the CDC already recommends the Pfizer-BioNTech vaccine for children 16 years of age or older). For lower-income workers, including many "essential workers," however, delaying vaccination until the end of the declared public health emergency would be especially dangerous. These workers are often at high risk for infection because of their close contact with other people at their workplaces. At the same time, low-income people who most need to be vaccinated are also least able to weather the health and financial outcomes of a serious vaccine injury, especially if the CICP is their only option for compensation.

Only people who can afford to wait for Covid-19 vaccination until the emergency declaration has ended and the CDC acts will be able to file injury claims under the VICP. This group will probably consist largely of people who can continue working remotely and socially isolating until they feel adequately assured of the vaccine's safety profile. As compared with people who must work in person, people who can work remotely are disproportionately well educated, high earning, and White.[5] This disparity may translate into substantially unequal compensation for the same types of vaccine injuries between lower-income workers and people who have the privilege of waiting to be vaccinated. Differences in ease of access to compensation and amount of compensation between the VICP and CICP will therefore reinforce long-standing inequities based on income and race and ethnic group.

We believe that any FDA-approved Covid-19 vaccine (includ-

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ing vaccines approved under emergency use authorizations) should fall under the VICP immediately, as should all future vaccines targeting active pandemics. Disadvantaged people who have the greatest need for vaccination, while also being the most vulnerable to financial harm, should have access to a quick and fair system of injury compensation. Moreover, penalizing early recipients of Covid-19 vaccines undermines the important public health goal of vaccinating as many people as possible as quickly as possible to achieve herd immunity.

To rectify the inequities propagated by the CICP, Congress could amend the PREP Act in two ways. First, lawmakers could establish that all vaccines recommended by the CDC to ameliorate a public health emergency must be immediately added to the VICP, regardless of whether they are recommended for pregnant women or children. Second, Congress could require that a 75-cent excise tax be applied to all vaccines for pandemic viruses in the United States — which is already done for childhood vaccines — to finance the Vaccine Injury Compensation Trust Fund. Allowing injured people, including members of vulnerable communities, to obtain compensation by means of the VICP will promote public health goals and enhanced equity while ensuring that anyone who has a vaccine-related injury receives adequate compensation.

Disclosure forms provided by the authors are available at NEJM.org.

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