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# COVID-19 Vaccinations

## Liability and Compensation Considerations Critical for a Successful Campaign

Each week seems to bring welcome news of advances in the search for an effective vaccine to combat the spread of COVID-19. Research in this area has been accelerated by an unprecedented, massively funded global effort that has marshaled the world's best scientific minds to find the solution to a single daunting problem. Although significant work and testing still remain, that the search for vaccines to combat the virulent SARS-CoV-2 virus has moved from its initial discovery to the clinical trial stage in less than six months is both a remarkable story and a testimony to human resilience.

But vaccine development is only one component of the three-part challenge in creating a comprehensive immunization campaign to stop the pandemic. The second critical task is to implement a viable deployment strategy. Success in a laboratory means little if the resources needed for mass production and distribution of the vaccine are lacking and widespread inoculations cannot begin soon after clinical testing has been completed. As past experience has shown, concerns over the potential legal liability for any adverse effects of a vaccine can have a

disruptive effect on the willingness of manufacturers and others in the vaccine supply chain to participate widely in a vaccination campaign. The third task needed for a successful and rapid uptake of a COVID-19 vaccine in the United States is to maximize the target population's willingness to be inoculated despite the possibility, however slight, of significant side effects. That willingness is influenced by many factors, but the historical record suggests that some people who are asked to volunteer for vaccinations may decline to do so over concerns that, if they incur health problems from the vaccine, they may not be fully compensated for the related financial and personal consequences.

In this RAND Corporation Perspective, we examine selected liability and compensation issues as they relate to the future distribution and administration of COVID-19 vaccines. We provide a brief history of how the U.S. government has addressed such issues in previous public health threats—specifically by providing liability immunity to manufacturers and distributors of vaccines should lawsuits arise as the result of serious side effects,

as well as by setting up compensation systems to pay for some of the medical expenses, lost income, and other losses that can result from the adverse effects of vaccination. We draw from that history to better understand some of the challenges that policymakers may face in regard to facilitating the global distribution of COVID-19 vaccines and preventing concerns over compensation from affecting the vaccine's uptake by the public.

## **The Role of Liability in Implementing a Viable Deployment Strategy**

Liability will play an important role in beating COVID-19. Historically, similar fast-moving, large-scale vaccination programs in the United States could have stalled when pharmaceutical companies were reluctant to begin production because of what they perceived as the risks of lawsuits over side effects and other adverse medical consequences of vaccinations.<sup>1</sup> In 1976, when an influenza outbreak in New Jersey was determined to have been

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caused by a virus related to the one responsible for possibly 675,000 deaths in the United States during the 1918–1919 worldwide pandemic, President Gerald Ford quickly announced a plan to “inoculate every man, woman and child in the United States” with a vaccine against the newly discovered strain (popularly referred to as the *swine flu*).<sup>2</sup> But there was immediate pushback from vaccine manufacturers over their potential liability exposure, and when their insurers began to refuse to provide policies that included coverage for such losses, large-scale production of the vaccine was placed in significant jeopardy.<sup>3</sup>

In response, Congress rushed through legislation that substituted the United States as the defendant in any lawsuit filed against a vaccine manufacturer, a vaccine distributor, or any entity providing free vaccinations. In effect, a person who believed that he or she had been harmed by a swine flu vaccination could sue to recover losses (e.g., medical expenses, lost income, loss of financial support as a result of death, compensation for pain and suffering), but the federal government would defend such suits and pay any resulting verdicts or settlements.<sup>4</sup> With these liability protections in place, the stream of vaccine production moved forward as hoped, although the planned campaign flagged after about 45 million vaccinations, when fears of a national pandemic never materialized.<sup>5</sup>

Liability concerns also were at the center of a vaccination campaign first proposed in 2001. Spurred by the potential threat of a bioterrorism event involving the release of smallpox virus, the federal government began to contract with manufacturers to stockpile enough vaccines to inoculate every American if necessary.<sup>6</sup> The initial rollout would provide vaccines to about 500,000 military personnel and 400,000 civilian doctors, nurses,

and first responders to protect against future attacks.<sup>7</sup> Once these target populations were immunized, vaccines would be made available to as many as 10 million more civilian health care and emergency workers. To address the concerns that manufacturers and those administering the vaccine had about potential legal exposure arising from such a large-scale federal campaign, Congress again fast-tracked legislation that provided sweeping liability protections.<sup>8</sup> In a section inserted into the Homeland Security Act of 2002 (HSA) just before final consideration, every smallpox vaccine manufacturer or distributor, health care entity providing the vaccine, and health care professional or other individual authorized to perform the vaccination would be deemed “an employee of the [federal] Public Health Service with respect to liability” arising from the administration of the vaccine.<sup>9</sup> As a result, someone suing a pharmaceutical company for damages related to the vaccine’s side effects would essentially be suing a federal “employee,” and, accordingly, the matter would then be handled in the same manner as any tort suit against the federal government, with the United States covering the costs of defending the litigation and paying for any compensation awards or settlements. As was true with the swine flu program, a sufficiently large stockpile of vaccines was amassed in the aftermath of these liability protections to address the perceived threat, although the campaign was essentially halted after military personnel had been immunized.<sup>10</sup>

Unlike the situation involving the swine flu and smallpox campaigns, liability protections are already in place for all vaccines developed in response to COVID-19. As a result of the Public Readiness and Emergency Preparedness Act of 2005 (PREP), manufacturers,

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distributors, and other actors can be provided tort immunity related to the development, manufacturing, testing, distribution, administration, and use of certain countermeasures against epidemics, pandemics, and acts of bioterrorism.<sup>11</sup> Under PREP, the Secretary of the U.S. Department of Health and Human Services (HHS) must issue a declaration determining that a public health emergency exists (or that there is a credible risk of one) and describe the countermeasures and “persons” (e.g., pharmaceutical companies producing the vaccine) covered by the declaration in order for the immunity to apply. Previous declarations have covered vaccines for the 2009 H1N1 pandemic flu, Ebola virus, and Zika virus.<sup>12</sup>

On March 17, 2020, the HHS secretary issued the required liability protection declaration, which covered any antiviral, drug, biologic, diagnostic, device, or vaccine “used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of

any such product, and all components and constituent materials of any such product.”<sup>13</sup> The only meaningful exception to that immunity would be for acts or failures to act that constitute “willful misconduct” on the part of the covered entity or person—an extremely rare event in the context of vaccine side-effect litigation.<sup>14</sup> In addition, the exception requires that the harm caused constituted either a “serious physical injury” (i.e., was life-threatening or permanently impaired a body function) or death. Therefore, a claim involving a modest adverse reaction that causes an individual to lose a week of work would not be allowed.

As a result of PREP, there should be few concerns on the part of manufacturers, distributors, and others regarding the possibility of being sued in an American courtroom for claims related to personal injuries or deaths arising from producing or administering COVID-19 vaccines when they finally become available. Because the HHS secretary declared that the coverage

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would be “without geographic limitation,” immunity from suits in state and federal courts would be possible even if vaccinations were administered outside the United States. And because PREP makes no reference to the residence or citizenship of a covered person, its protection against suits in federal and state courts is equally available to foreign vaccine producers and others for activities within the United States as long as their actions are within the scope of the HHS secretary’s declaration.

Such protections do not, however, apply to claims against covered persons defined by PREP that are advanced in the civil justice systems of *other* countries. A U.S. vaccine manufacturer might be confident of its liability position within the United States, but should those vaccines be administered elsewhere, the company could be subject to suit in a foreign court for injuries occurring in those locations. In the context of the vaccination campaigns for swine flu and smallpox, the likelihood of foreign litigation was miniscule because the programs were, with few exceptions, solely intended for U.S. residents and vaccine administration was unlikely to take place

in locations not subject to U.S. legal jurisdiction. But the COVID-19 pandemic is a global crisis, not simply a localized outbreak or a bioterrorism threat targeting only Americans. There now appears to be a widely held belief (*hope* might be a better word) that those among the first to market a successful COVID-19 vaccine or treatment will share the science behind its development with others and distribution of the vaccine will be worldwide to the extent practical.<sup>15</sup> This concept of a vaccine as a *global public good* rather than a scarce resource under the sole control of its developers has important liability ramifications. It suggests that manufacturers, distributors, and other entities here in the United States are very likely to find their COVID-19 products and services moving across borders and, as a result, they will be facing uncertain futures in terms of legal exposure in foreign courts. Compounding that uncertainty is the fact that, as these new vaccines are brought to market after accelerated testing phases, there will be relatively little information available initially to help accurately predict the types, frequencies, and severities of all possible side effects caused by their administration.

Therefore, there will also be relatively little information available to accurately predict the financial risk that will be incurred by these companies as their products move around the world.

One potential concern here is that such uncertainty may adversely impact global production and distribution of COVID-19 vaccines in a manner similar to, for example, the initial reluctance of swine flu vaccine manufacturers and their insurers to commit to a large-scale campaign without near total liability protection. Although some countries have legal processes through which vaccine-injury claims can be addressed outside traditional litigation, few countries provide any level of immunity to entities and individuals within the supply chain that compares with the sweeping protections available under PREP.<sup>16</sup> But addressing the problem of a patchwork of liability rules will be difficult: Global lawsuit immunity cannot be granted simply by an act of Congress and the signature of a U.S. president, so some other approach would be needed.

One vehicle for achieving a type of multicountry liability shield was used by the World Health Organization (WHO) in its 2009 international fight against the H1N1 virus pandemic. Countries wishing to accept donations of H1N1 vaccines from WHO and its partners were required to sign “Letters of Agreement” in which they agreed to indemnify donors (e.g., manufacturers, philanthropic agencies, other governments) or discharge them from liability as long as the adverse event (e.g., a side effect that caused substantial suffering to the vaccine’s recipient) was not the result of a failure to comply with WHO’s most recent standards for pharmaceutical manufacturing or a failure to meet agreed-to specifications for the vaccines.<sup>17</sup>

But although 87 mostly developing countries that sought the vaccines signed onto the liability limitations, the experience with COVID-19 vaccines may be quite different. It may be more difficult in the context of the present crisis to reach similar agreements with countries outside the developing world with relatively more-adversarial legal systems or those demanding to include localized exceptions to the proposed liability shields. The bargaining position of the vaccine providers may be less strong when the transfers involve large-scale purchases rather than charitable donations. Some components of the vaccine supply chain may be reluctant to rely solely on the letters of agreement approach if only indemnification rather than complete protection from liability is offered. Although indemnification removes most of the risk of having to pay compensation to those experiencing adverse events, it does not remove the risk of being sued and having to defend claims in local courts (the transactional expenses associated with litigation, even if the defense is successful, can be significant). And unless the negotiation of letters of agreement with individual governments around the world achieves near universal coverage, the millions of vaccinations likely to take place in nonsigning countries might continue to present substantial liability exposure.

An alternative approach would involve the convening of an international convention with the purpose of drafting a treaty, similar to the Montreal Convention that standardized the rules related to international aviation liability.<sup>18</sup> Such an agreement would have the advantage of fostering a uniform approach to the scope and application of liability protections in contrast to an individual letter of agreement approach, which might result in intercountry variation on the conferred immunities. The problem is that

such treaties can take years to negotiate and ratify, and, given the urgency of the current pandemic, the luxury of time may not be present. Nevertheless, if members of the vaccine supply chain perceive that rapid globalization of its much-needed COVID-19 products and services could incur substantial legal risks, it is possible that production and distribution could be limited to just those countries where liability protections are already in place. If that scenario unfolds, then the profound intercountry health disparities that already existed prior to this pandemic will be exacerbated despite the existence of one or more COVID-19 vaccines.

## **The Role of Compensation in Willingness to Be Inoculated**

One benchmark for declaring victory over COVID-19 is when *herd immunity* is achieved, the point at which a sufficiently high percentage of the population is resistant to the disease, thus making its further spread from person to person less likely. Although such resistance can be obtained naturally (e.g., those who survive a bout of COVID-19 may be less susceptible to future infection), the fastest and least disruptive way would be to administer effective vaccines to most of the population. It might be assumed that most people will be incentivized to be vaccinated by the desire to avoid being infected themselves, as well as the hope that, by doing so, family, friends, and coworkers would also be protected. A desire to be a part of a solution that helps return society to some measure of pre-pandemic normality would be in play as well. But a widespread perception that the risks of an adverse outcome from an inoculation are neither theoretical nor trivial

could undercut the vaccination program. Such perceptions would not be unfounded, given that still-in-development COVID-19 vaccines will lack the many decades of data about the rates and types of side effects that are already available for seasonal flu shots, routine childhood immunizations, and even smallpox vaccinations. Adding to those concerns could be a belief that, in the event of a vaccine-caused illness, the person receiving the vaccination could experience complications for which he or she would be financially responsible for related health care costs or income losses, even though he or she played no role in how the condition developed.

The possibility that recipients would be disinclined to roll up their sleeves and offer their arms to a needle because of worries over difficulties in obtaining adequate compensation for serious side effects became central to a heated debate over the original version of the smallpox liability provisions contained in the HSA.<sup>19</sup> As written, the law states that someone incurring serious side effects as a result of a smallpox vaccination would have to sue the federal government under the Federal Tort Claims Act and essentially prove that the specific vaccine they received was negligently manufactured, stored, or administered before any compensation could be awarded. Under this rule, compensation would not be available to those who were able to convince a jury or judge only that the side effects experienced were well-known consequences of the vaccine and that the illnesses first began shortly after the vaccination. Instead, the victims would have to show that something wrong happened somewhere between the production line and the injection, an extremely unlikely event in light of modern pharmaceutical manufacturing processes and distribution systems. This requirement of

proof of negligence meant that very few vaccine recipients who presented serious side effects soon after vaccination would be able to advance a successful lawsuit.

In the runup to the invasion of Iraq, when concerns abounded about how Saddam Hussein's regime might respond, the U.S. government asked civilian health care providers to volunteer to be inoculated against smallpox. This request was done not solely because policymakers wished to spare doctors and nurses the pain and suffering associated with the viral disease, but because these individuals would be needed to care for others in the aftermath of a bioweapon attack. In reviewing the smallpox provisions in the HSA, the Institute of Medicine noted the irony involved with providing protections to those manufacturing or administering the vaccinations but none to those who were volunteering to be the first line of defense against bioterrorism, suggesting that health care workers' "concerns about the financial burden for caring for the adverse reactions of the smallpox vaccine . . . could greatly decrease the number of people who volunteer for smallpox vaccination."<sup>20</sup> There was also pushback from influential organizations, such as health care professional associations and unions, that asked that the vaccination campaign be delayed until various issues were addressed, including concerns about compensation for lost time at work and coverage of medical expenses as a result of any adverse effects.<sup>21</sup>

To address such concerns, Congress passed legislation creating the Smallpox Vaccine Injury Compensation Program (SVICP) about six months after the HSA was enacted in November 2002.<sup>22</sup> To implement the law, HHS developed a table that listed the known adverse effects of the vaccine and the known time frames for the onset of

those conditions following the vaccination.<sup>23</sup> A vaccine recipient would have up to a year to file a claim and provide medical documentation to support his or her belief that the side effect experienced was one listed in the table and that the first symptom or manifestation of the condition arose within the table's time period.

The smallpox compensation program could be characterized as a "no-fault" approach in that the claimant would not be required to prove liability on the part of the manufacturer or any other party to recover any losses, but *only* if the condition met all of the requirements stated on the vaccine table. If HHS decided that the claim was valid, "reasonable and necessary" medical services and products would be paid for or reimbursed.<sup>24</sup> Lost earnings claims could also be compensated, although such claims were capped at two-thirds of the claimant's income at the time of the injury and limited to \$50,000 per year. Death claims from surviving family members would be paid at a rate similar to that provided by the federal Public Safety Officers' Benefits program for first responders killed in the line of duty.<sup>25</sup> Notably, the SVICP provided no compensation for pain and suffering, regardless of the severity of the adverse side effects (this type of loss would have been recoverable if a claimant successfully sued under the ordinary rules of tort litigation). Claimants who were unhappy with the HHS decision or who had medical problems that they believed were caused by the vaccination but nevertheless involved conditions or time periods outside those listed in the table could still file a lawsuit, although to be successful they would have to prove that there was negligence in the supply chain, a very difficult burden to overcome at trial.

Once legislation establishing the SVICP was enacted, organized opposition to the campaign related to concerns that volunteers for the civilian smallpox vaccination program would be left without any meaningful recourse receded. That said, a survey of health care workers who had been asked to volunteer for the vaccination, conducted after the SVICP was in place, found that 49 percent of those who declined felt that their chances of being compensated for a severe reaction were low or very low, compared with 23 percent of those who agreed to participate.<sup>26</sup> A related analysis that focused on those who had refused concluded that, where the risk-benefit balance “does not clearly favor vaccination, other factors such as compensation and liability policies, and potentially even convenience and costs incurred may influence” the decisionmaking of potential vaccinees.<sup>27</sup>

To avoid triggering a compensation controversy similar to what arose with HSA’s smallpox vaccine provisions, the drafters of PREP included a plan for a Countermeasures Injury Compensation Program (CICP) in the legislation

rather than as an afterthought. The CICP is essentially the same as the earlier smallpox compensation plan in terms of process and benefits, and, in fact, PREP and the CICP are now the primary legal vehicles for both the liability protections and the compensation benefits originally legislated for smallpox vaccinations.<sup>28</sup> As was the case with the SVICP, the CICP would rely on an HHS-determined table of known side effects and time frames as the basis for deciding whether a claimed injury would be presumed to have been a consequence of a covered vaccination. CICP claimants who are unsatisfied with the results of that process and have not accepted any compensation from the program can still file suit against the parties believed to be responsible for the injuries and, if successful, be able to recover a wide range of losses (including noneconomic damages, such as pain and suffering), but *only* if willful misconduct is successfully proven by a heightened standard of clear and convincing evidence.<sup>29</sup> As indicated previously, a successful suit for side effects under such a theory would

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be unlikely, even if the injury was clearly shown to be linked to the vaccine.

The documented experience with the way the CICIP has processed requests for compensation is scant, in part because few claims have been received by the program since its inception (most of these involved vaccinations for the 2009 H1N1 outbreak) but primarily because the CICIP, which has been characterized by some as “secretive,” does not publicize its decisions.<sup>30</sup> As of this writing, no table listing any covered COVID-19 countermeasure side effects or onset times has been created, and although it is possible that HHS will make special rules for processing COVID-19 vaccine claims that are different from those currently in place for other countermeasures, it is unknown whether such rules will facilitate the delivery of compensation or present additional barriers. Release of information about individual claim decisions would be extremely helpful in determining whether the program is working as it should.<sup>31</sup>

There are two areas of concern here. One is the question of whether people asked to volunteer for COVID-19 vaccination may be less inclined to do so if they realize that compensation for likely side effects will be reduced from what they might be able to receive through ordinary civil litigation. Although concerns about the safety, effectiveness, and health benefits of a COVID-19 vaccination are likely to loom large in one’s decision to be inoculated, the early pushback to the planned smallpox campaign shows that issues related to compensation for adverse events do matter to some people.<sup>32</sup> Support for this comes from the fact that health care workers who declined to receive a smallpox vaccination were far more likely to be pessimistic about their ability to be compensated for experiencing side effects than were those

who volunteered, despite the existence at the time of a compensation program essentially the same as today’s CICIP. This suggests that an inability to recover from pain, suffering, and other noneconomic damages related to side effects might play a role in some COVID-19 vaccination decisions, as could the CICIP’s limitations on lost-income claims. Currently, there is little public information about the CICIP’s decisionmaking history, so it is not possible to know whether program administrators have been relatively accommodating when considering benefit claims or reluctant to compensate unless faced with uncontroverted evidence of the relationship between the vaccination and the claimant’s medical condition and financial losses. Uncertainty about the likelihood of adequate compensation if an inoculation triggers an adverse side effect may well cause some to decline a free vaccination—a scenario that appeared to have unfolded to some degree with the smallpox campaign.

The other area of concern is an increase in the rate of refusal based not on an expectation of insufficient compensation but on reports that it could take months or years before a claimant would receive any money at all. One source for that concern relates to the priorities that HHS might give to the rulemaking needed to get the CICIP related to COVID-19 vaccinations fully underway in a timely manner. The 2009 H1N1 virus was first detected in the United States in early April 2009, and, by mid-June, the HHS secretary issued a PREP declaration that provided liability protections to manufacturers and others for pandemic countermeasures related to the virus, both for those currently in use and those that might be developed in the future.<sup>33</sup> In addition to employing existing treatments, a major H1N1 vaccination campaign began in fall 2009.

Nevertheless, it was not until October 2010 that rules were published describing the procedures for navigating the claiming process, and the necessary vaccine table for determining whether a claimed injury related to the H1N1 vaccine was eligible for the CICIP's no-fault compensation provisions was not developed until later.<sup>34</sup> As a result, if someone suffered an adverse reaction to an H1N1 vaccine when the campaign first began, that person would have had to wait more than a year before their claim could be reviewed and perhaps much longer before any benefits were awarded.<sup>35</sup>

A related issue involves the claim review process itself. Although up-to-date statistics are not available without a Freedom of Information Act request, a reasonable assumption is that the CICIP has processed no more than 3,000 claims during its 15 years in existence.<sup>36</sup> But a COVID-19 vaccination campaign that could conceivably target 328 million Americans in a relatively short period of time is likely to generate far more than just 200 adverse effect claims each year, even if the vaccine is reasonably safe. Unless HHS is adequately prepared for the possibility of an avalanche of claims on day one of the campaign, there is a very real risk that the review process would be overwhelmed and a backlog created that would trigger widespread frustration for claimants. It is difficult to imagine such frustration not being widely reported and then negatively impacting the decisionmaking of those still weighing the risks and benefits of being vaccinated.

## Concluding Thoughts

The history of vaccination campaigns in the United States has much to offer in the form of guidance as the country prepares for the next phase in the war against COVID-19, as well as against future pandemics. We know from the past that the production of critical vaccines can stall if private manufacturers and their insurers are not willing to take on the legal exposure associated with moving forward. We also know that, even when provided with a remarkable level of immunity against suit in the United States, American companies in the vaccine supply chain still face litigation risks in *other* countries. How that risk will affect production and distribution of these important global public goods is yet to be determined, but the potential for disrupting the flow of vaccines to places where they might be needed most should merit further discussion on how to achieve international agreement on the liability question.

Another important lesson is that voluntary vaccination programs could be impacted to some degree if people believe that they will be shouldering the full financial and personal risks of adverse side effects. Creation of a compensation program can help counter that belief, but only if the claiming process is perceived to be just, adequate, easy to navigate, and not subject to intolerable delay. In the campaign that will soon unfold, Americans will be asked to volunteer their immune systems not simply for their own health but also for the welfare of the larger community, despite the knowledge that some people will be harmed when doing so. With such risks in play, the least that policymakers and the public can do is carefully consider what types and levels of compensation for any adverse effects of vaccination are truly fair and appropriate.

## Notes

<sup>1</sup> Much of the discussion herein regarding prior vaccination programs and related legislation is drawn from Chapter Seven in Nicholas M. Pace and Lloyd Dixon, *Assigning Responsibility Following a Catastrophe: Alternatives to Relying Solely on Traditional Civil Litigation*, Santa Monica, Calif.: RAND Corporation, RR-1597-RC, 2017.

<sup>2</sup> Comptroller General of the United States, *The Swine Flu Program: An Unprecedented Venture in Preventative Medicine*, Washington, D.C.: U.S. General Accounting Office, HRD-77-115, June 27, 1977; Gerald R. Ford, “President Gerald R. Ford’s Remarks Announcing the National Swine Flu Immunization Program,” White House Briefing Room, Washington, D.C., March 24, 1976; and Richard E. Neustadt and Harvey V. Fineberg, *The Swine Flu Affair: Decision-Making on a Slippery Disease*, Washington, D.C.: National Academies Press, 1978.

<sup>3</sup> Neustadt and Fineberg, 1978, pp. 41–48, and Appendix C (“Swine Flu Chronology”).

<sup>4</sup> National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380 (1976).

<sup>5</sup> Comptroller General of the United States, 1977, p. 55.

<sup>6</sup> Some scenarios suggested that a successful, multicity coordinated attack could kill as many as one million people. Melody Petersen, “Shares of Tiny Vaccine Maker Soar,” *New York Times*, November 30, 2001; Chuck Staresinic, “Lessons from a Dark Winter,” *Pitt Med*, spring 2014; and Richard W. Stevenson and Sheryl Gay Stolberg, “Threats and Responses: Vaccinations; Bush Lays Out Plan on Smallpox Shots; Military Is First,” *New York Times*, December 14, 2002.

<sup>7</sup> See Richard W. Stevenson and Sheryl Gay Stolberg, “Threats and Responses: Vaccinations; Bush Lays Out Plan on Smallpox Shots; Military Is First,” *New York Times*, December 14, 2002.

<sup>8</sup> As the Centers for Disease Control and Prevention (CDC) explained at the time,

Manufacturers of smallpox vaccine and those healthcare entities that would administer the vaccine have raised concerns about their potential liability for involvement in a federal smallpox vaccination campaign. Section 304 of the Homeland Security Act is intended to alleviate these liability concerns and therefore ensure that vaccine is available and can be administered, particularly in the event of a smallpox-related actual or potential public health emergency such as a bioterrorist incident (CDC,

“Smallpox Questions and Answers: Section 304 of the Homeland Security Act,” January 17, 2003).

See also comments of Rep. Henry Waxman in 146 Cong. Rec. H8700, November 13, 2002, and Petersen, 2001. Interestingly, contracts were already in place to produce sufficient supplies of the vaccine even before the liability protections were granted, though it is not clear whether production goals would have been achieved without the legislation.

<sup>9</sup> See Homeland Security Act of 2002, Pub. L. No. 107-296 (2002), Sec. 304 (Conduct of Certain Public Health-Related Activities).

<sup>10</sup> U.S. General Accounting Office, *Smallpox Vaccination: Implementation of National Program Faces Challenges*, Washington, D.C., GAO-03-578, April 30, 2003, p. 4; John D. Grabenstein and William Winkenwerder, Jr., “U.S. Military Smallpox Vaccination Program Experience,” *Journal of the American Medical Association*, Vol. 289, No. 24, June 25, 2003.

<sup>11</sup> Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L. 109-148 (2006), Division C.

<sup>12</sup> Health Resources and Services Administration, “Covered Countermeasures,” webpage, March 2017.

<sup>13</sup> “Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,” 85 Fed. Reg. 15198 (Mar. 17, 2020).

<sup>14</sup> Far more likely are claims involving design defects and failures to warn of known shortcomings, but such theories of recovery are clearly blocked by PREP’s blanket immunity.

<sup>15</sup> See Ivan Couronne, “Virus Vaccine Will Be ‘Global Public Good’: Top US Official,” *Barron’s*, May 20, 2020; and Priti Patnaik, “A Strong Call for COVID-19 Treatments and Vaccines to Be Global Public Goods—World Health Assembly,” *International Health Policies* blog, May 20, 2020.

<sup>16</sup> See Claire Looker and Heath Kelly, “No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programs,” *Bulletin of the World Health Organization*, Vol. 89, No. 5, May 1, 2011; and Randy G. Mungwira, Christine Guillard, Adiel Saldaña, Nobuhiko Okabe, Helen Petousis-Harris, Edinam Agbenu, Lance Rodewald, and Patrick L. F. Zuber, “Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries:

A Review and Survey of Implementing Countries,” *PLoS ONE*, Vol. 15, No. 5, May 21, 2020.

<sup>17</sup> World Health Organization, *Report of the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative*, Geneva, 2012.

<sup>18</sup> See John D. Winter, Cassye Cole, and Jonah Wacholder, “Toward a Global Solution on Vaccine Liability and Compensation,” *Food and Drug Law Journal*, Vol. 74, No. 1, March 28, 2019. The authors describe a suggested approach for achieving “globally-coordinated treaty-based immunity” (p. 13).

<sup>19</sup> Committee on Smallpox Vaccination Program Implementation, Board on Health Promotion and Disease Prevention, Institute of Medicine of the National Academies, “Review of the Centers for Disease Control and Prevention’s Smallpox Vaccination Program Implementation, Letter Report 1,” letter to Julie Gerberding, director, Centers for Disease Control and Prevention, January 16, 2003, reprinted in Alina Baciu, Andrea Pernack Anason, Kathleen Stratton, and Brian Strom, eds., *The Smallpox Vaccination Program: Public Health in an Age of Terrorism*, Washington, D.C.: The National Academies Press, 2005; and Robert Pear, “Threats and Responses: Legal Risks; For Victims of Vaccine, Winning Case Will Be Hard,” *New York Times*, December 14, 2002; 20 Committee on Smallpox Vaccination Program Implementation, Board on Health Promotion and Disease Prevention, Institute of Medicine of the National Academies, 2005, p. 133.

<sup>21</sup> See, for example, American Federation of State, County and Municipal Employees, “AFSCME Urges Administration to Take Necessary Vaccination Precautions to Save Lives,” press release, January 24, 2003; and American Nurses Association, “American Nurses Association Asks President to Delay Smallpox Vaccination Plans,” press release, Washington, D.C., 2003.

<sup>22</sup> Smallpox Emergency Personnel Protection Act of 2003, Pub. L. 108-20 (2003).

<sup>23</sup> “Declaration Regarding Administration of Smallpox Countermeasures,” 68 Fed. Reg. 4212 (Jan. 28, 2003); “Smallpox Vaccine Injury Compensation Program: Smallpox (Vaccinia) Vaccine Injury Table,” 68 Fed. Reg. 51492 (Aug. 27, 2003).

<sup>24</sup> “Smallpox Vaccine Injury Compensation Program: Administrative Implementation,” 68 Fed. Reg. 70079 (Dec. 16, 2003).

<sup>25</sup> See, for example, Bureau of Justice Assistance, “Benefits by Year,” webpage, undated.

<sup>26</sup> Pascale M. Wortley, Paul S. Levy, Linda Quick, Trevor R. Shoemaker, Melissa A. Dahlke, Brian Evans, Brian Burke, and Benjamin Schwartz, “Predictors of Smallpox Vaccination Among Healthcare Workers and Other First Responders,” *American Journal of Preventive Medicine*, Vol. 32, No. 6, June 1, 2007.

<sup>27</sup> Pascale M. Wortley, Benjamin Schwartz, Paul S. Levy, Linda M. Quick, Brian Evans, and Brian Burke, “Healthcare Workers Who Elected Not to Receive Smallpox Vaccination,” *American Journal of Preventive Medicine*, Vol. 30, No. 3, March 2006, p. 264.

<sup>28</sup> Regulations covering the CICIP can be found at 42 C.F.R. §§ 110.1–110.100.

<sup>29</sup> Most civil suits in the United States are decided using a “preponderance of evidence” standard in which a defendant’s liability can be established if the jury or judge believes that the proof offered by the plaintiff is simply more probable to be true than not. A “clear and convincing evidence” standard requires that the proof must be highly and substantially more probable to be true than not.

<sup>30</sup> Robert Roos, “HHS: 386 Injury Claims Filed over H1N1 Countermeasures,” Center for Infectious Disease Research and Policy webpage, March 16, 2011; and Elaine Silvestrini, “Americans Hurt by Coronavirus Treatments Will Have Few Legal Options,” *Legal Examiner*, June 16, 2020.

<sup>31</sup> In contrast, information about claims for childhood and seasonal vaccination injuries is routinely made available to the public by the National Vaccine Injury Compensation Program.

<sup>32</sup> For an analysis of reasons for declining to receive a seasonal flu vaccination, see Glen J. Nowak, Michael A. Cacciatore, and Maria E. Len-Ríos, “Understanding and Increasing Influenza Vaccination Acceptance: Insights from a 2016 National Survey of U.S. Adults,” *International Journal of Environmental Research and Public Health*, Vol. 15, No. 4, April 2010.

<sup>33</sup> CDC, “The 2009 H1N1 Pandemic: Summary Highlights, April 2009–April 2010,” webpage, June 16, 2010; and “Pandemic Influenza Antivirals-Amendment,” 74 Fed. Reg. 29213 (June 19, 2009).

<sup>34</sup> “Countermeasures Injury Compensation Program (CICIP): Administrative Implementation, Interim Final Rule,” 75 Fed. Reg. 63656 (Oct. 15, 2010).

<sup>35</sup> Those seeking compensation prior to the adoption of program regulations could submit a letter to HHS indicating an intent to

formally claim once rules were adopted. Interestingly, the first vaccine countermeasure table covering pandemic influenza does not appear to have been adopted until 2014, suggesting that H1N1 claims considered prior to that time would not have benefited from the claimant-friendly rebuttable presumption available under the CICP that the vaccine was the cause of the injury when the condition occurred within the listed time period and at the level of severity described in the table. “Countermeasures Injury Compensation Program: Pandemic Influenza Countermeasures Injury Table,” 79 Fed. Reg. 17973 (Mar. 31, 2014).

<sup>36</sup>From June 2009 (when the HHS secretary issued a PREP declaration addressing the 2009 H1N1 pandemic) through March 2011, the CICP received 386 injury claims arising from the monovalent version of the H1N1 vaccine and related countermeasures (Roos, 2011). An additional eight claims arose from other covered countermeasures. Assuming that this period was the high watermark for CICP claims following the program’s inception in 2005, it is unlikely that the average number of claims received annually exceeds 200.

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## About This Perspective

The authors of this Perspective examine liability and compensation issues as they relate to the future distribution and administration of the COVID-19 vaccine. They provide a brief history of how the U.S. government has addressed liability and compensation concerns in previous public health threats—specifically by providing liability immunity to manufacturers and distributors of vaccines should lawsuits arise as the result of serious side effects, as well as setting up compensation systems that provide some, but not all, benefits of traditional tort litigation. That the COVID-19 pandemic is global complicates issues of liability outside the United States because an act of Congress cannot determine legal procedure in other countries. The authors also consider the possibility that volunteers for vaccination campaigns may be hesitant and suggest consideration of appropriate compensation for any adverse effects.

RAND Social and Economic Well-Being is a division of the RAND Corporation that seeks to actively improve the health and social and economic well-being of populations and communities throughout the world. This research was conducted in the Justice Policy Program within RAND Social and Economic Well-Being. The program focuses on such topics as access to justice, policing, corrections, drug policy, and court system reform, as well as other policy concerns pertaining to public safety and criminal and civil justice. For more information, email [justicepolicy@rand.org](mailto:justicepolicy@rand.org).

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