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The Prep Act and the Countermeasures Injury Compensation Program: Past, Present, and Future

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THE PREP ACT AND THE COUNTERMEASURES INJURY COMPENSATION PROGRAM: PAST, PRESENT, AND FUTURE

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The terrorist attacks of September 11, 2001, ushered in an era of legislative reform to bolster the United States' ability to prepare for and respond to public health emergencies, including pandemics and acts of

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bioterrorism. As part of its post-9/11 response, Congress enacted broad liability protections for, among others, manufacturers of medical countermeasures, along with a corresponding no-fault compensation program for individuals injured by such countermeasures. During public health emergencies like the COVID-19 pandemic, these liability protections play a critical role in encouraging the development and use of medical countermeasures. The no-fault compensation program, however, leaves much to be desired by individuals harmed by countermeasures. The COVID-19 pandemic provides an opportune time to take a fresh look at the compensation program and to consider needed reforms. After describing the liability protections and the corresponding compensation program, this Article unpacks the compensation program's deficiencies and proposes reforms that recognize that liability protections must go hand-in-hand with a robust no-fault injury compensation program.

Introduction

Following the September 11, 2001, terrorist attacks on the United States and the coinciding delivery of anthrax through the U.S. mail,[1] Congress passed several laws to strengthen the nation's ability to prepare for and respond to public health emergencies involving chemical, biological, radiological, or nuclear (CBRN) agents, including emerging infectious diseases.[2] Nearly one dozen laws fell within this congressional effort. These laws amended provisions of the Public Health Service Act (PHSA)[3] and the Food, Drug, and Cosmetic Act (FDCA).[4] They included, among others, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,[5] the Project BioShield Act of 2004,[6] the Public Readiness and Emergency Preparedness Act (PREP Act),[7] the Pandemic and All-Hazards

1. These two events appear to be unrelated. *See* S. Rep. No. 107-351 & H. Rep. No. 107-792, at 394 (J. Rep. 2002) ("To date, no connection has been established between the anthrax attacks and the terrorist attacks of September 11."); Dep't of Justice, Amerithrax Investigative Summary 1 (2010), https://www.justice.gov/archive/amerithrax/docs/amx-investigative-summary2.pdf (concluding that Dr. Bruce E. Ivins of the U.S. Army Medical Research Institute of Infectious Diseases acted alone in mailing the anthrax letters).

2. *See MCM-Related Counterterrorism Legislation*, U.S. Food & Drug Admin. (Sept. 2, 2021), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation; *see also infra* notes 5–12.

3. 42 U.S.C. §§ 201–300mm-61 (2022).

4. 21 U.S.C. §§ 301–399i (2022).

5. Pub. L. No. 107-188, 116 Stat. 594 (2002).

6. Pub. L. No. 108-276, 118 Stat. 835 (2004).

7. Pub. L. No. 109-148, 119 Stat. 2818 (2005).

Preparedness Act,[8] the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013,[9] various provisions of the 21st Century Cures Act,[10] Public Law 115-92,[11] and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019.[12]

Among these laws, the PREP Act sought to address liability concerns raised by the research, development, manufacture, distribution, and use of medical countermeasures against pathogens that may give rise to epidemics or pandemics, such as COVID-19, or that may be used as CBRN agents, such as anthrax. The PREP Act provides certain "covered persons" with broad immunity from federal and state claims for losses relating to specified "covered countermeasures" administered or used during a public health emergency.[13] Liability protections represent a critical component of public health preparedness and response efforts, as they help encourage the development and use of medical countermeasures prior to and during public health emergencies.[14] Yet, there are tradeoffs.

For example, with few exceptions, individuals who believe they have been injured by a covered countermeasure cannot seek recourse by filing suit against a covered person. Instead, they must seek compensation through the Countermeasures Injury Compensation Program (CICP), a no-fault compensation program available to eligible individuals who suffer serious physical injuries or death directly caused by the administration or use of a covered countermeasure. Serious medical, legal, and social concerns have surfaced as a result, given the CICP's numerous inadequacies.

This Article addresses the tort law gap in an age of pandemic and bioterrorism threats. It proceeds with a narrow scope. That is, even though the PREP Act can apply to claims related to a broad array of

8. Pub. L. No. 109-417, 120 Stat. 2831 (2006).

9. Pub. L. No. 113-5, 127 Stat. 161 (2013).

10. Pub. L. No. 114-255, §§ 3081–88, 130 Stat. 1033, 1140–49 (2016).

11. Pub. L. No. 115-92, 131 Stat. 2023 (2017).

12. Pub. L. No. 116-22, 133 Stat. 905 (2019).

13. Important terms are defined in Part I.A.

14. As stated by then-Senate Majority Leader Bill Frist, co-sponsor of the bill that included the PREP Act:

> The real and imminent dangers posed by diseases like avian influenza underscore the serious need to bolster America's preparedness by enacting meaningful liability reform. These sensible and measured reforms will encourage manufacturers, distributors, and first responders to keep Americans safe once disaster strikes. The bill strikes a reasonable balance where those who are harmed will be fairly compensated and life-saving products will be available in ample supply to protect and treat as many Americans as possible.

B. Kurt Copper, *"High and Dry?" The Public Readiness and Emergency Preparedness Act and Liability Protection for Pharmaceutical Manufacturers*, J. HEALTH L., Winter 2007, at 65, 67–68.

covered countermeasures and covered persons, this Article centers on the liability protections provided to manufacturers of therapeutics and vaccines. As an important case study, it focuses particularly on vaccines, given the vast number of individuals who have received or will receive a COVID-19 vaccine and thus potentially make claims for compensation through the CICP for injuries related to COVID-19 vaccines. Importantly, however, this Article does not lose sight of the need to provide an adequate compensation system for individuals injured by all covered countermeasures.

Two important points ground this Article. First, the immunity protections provided by the PREP Act serve an important purpose during public health emergencies and should be retained. Second, the safety and efficacy of COVID-19 vaccines and therapeutics available in the United States are supported by ongoing studies and robust post-authorization monitoring. This Article recognizes, however, that no medical product is one-hundred percent safe. The problems with the PREP Act stem not from the breadth of its liability protections, but rather its inadequate compensation program that lacks transparency and is likely unprepared to handle a public health emergency of COVID-19's magnitude.

This Article proceeds in four parts. Part I introduces the PREP Act and related concepts, including a brief overview of Emergency Use Authorizations (EUAs) and the COVID-19 PREP Act Declaration.[15] Part II highlights PREP Act case law, both prior to and during the COVID-19 pandemic.[16] Part III turns to the CICP, examining its scope and limitations and comparing it to another no-fault compensation program, the National Vaccine Injury Compensation Program (VICP).[17] Part IV discusses the importance of a more robust and transparent compensation program and proposes reforms to address the CICP's limitations.[18] The Article concludes by urging further discussion and consideration of legislative and policy changes to ensure that those injured by covered countermeasures receive adequate compensation through a fair, transparent, and accessible process.[19]

15. *See infra* Part I.
16. *See infra* Part II.
17. *See infra* Part III.
18. *See infra* Part IV.
19. *See infra* Conclusion.

I. The PREP Act: Then and Now

This Part opens with a descriptive account of the PREP Act.[20] It unpacks the essential elements of the law that lay the foundation for the analysis and normative conclusions developed in this Article. It then turns to the current COVID-19 PREP Act Declaration to describe the scope of the protections provided by that Declaration and its amendments.

A. The PREP Act

Congress enacted the PREP Act in 2005 to address liability concerns raised by the research, development, manufacture, distribution, and use of medical countermeasures against pathogens that can give rise to epidemics or pandemics, such as COVID-19, or that may be used as CBRN agents, such as anthrax.[21] The PREP Act encourages the expeditious development and deployment of certain "covered countermeasures" (e.g., diagnostics, devices, therapeutics, and vaccines) during a public health emergency by limiting legal liability for losses relating to the use or administration of such products.[22] The Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) must first make a determination that a disease or other threat to health constitutes a public health emergency or a credible risk of such emergency.[23] Following such determination, the PREP Act authorizes the Secretary to issue a PREP Act declaration that provides certain "covered persons" with immunity from suit and liability under federal and state law for "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of" a covered countermeasure.[24]

The following terms are important for understanding the PREP Act and its scope:

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20. For additional background on the lead-up to the PREP Act, see Lincoln Mayer, *Immunity for Immunizations: Tort Liability, Biodefense, and Bioshield II*, 59 Stan. L. Rev. 1753, 1757–61 (2007).

21. *See* U.S. Dep't of Health & Human Servs., Pandemic Planning Update: A Report from Secretary Michael O. Leavitt 6 (2006) ("The threat of liability has been a major obstacle to developing a strong domestic vaccine industry. . . . As a result, Congress adopted legislation (PREP Act) providing industry with limited liability when meeting a declared public health emergency.").

22. *See* 42 U.S.C. § 247d-6d (2020).

23. *Id.* § 247d-6d(b).

24. *Id.* § 247d-6d(a).

- "Covered countermeasure"[25] has a complex statutory definition, but it is essentially a drug, biologic (including vaccines), device, or diagnostic used to treat, diagnose, cure, prevent, or mitigate a pandemic/epidemic or threat to public health (or "limit the harm such pandemic or epidemic might otherwise cause"[26]) that is: (1) approved, licensed, or cleared under the FDCA or PHSA; (2) authorized for investigational use; or (3) authorized for emergency use.[27] It also includes certain respiratory protective devices approved by the National Institute for Occupational Safety and Health that the Secretary has determined to be a priority for use during a declared public health emergency.[28]
- A "covered person" includes the United States; manufacturers, distributors, and program planners[29] of covered countermeasures; qualified persons (defined below) who prescribe, administer, or dispense covered countermeasures; and officials, agents, or employees of any of the previously listed persons.[30]
- "Qualified persons," with respect to the administration or use of a covered countermeasure, include (1) licensed health profes-

25. *Id.* § 247d-6d(i)(1); *see also id.* § 247d-6d(i)(7) (defining "qualified pandemic or epidemic product"); *see also id.* § 247d-6b(c)(1)(B) (defining "security countermeasure"). In addition to falling under one of the enumerated categories, a declaration must be issued with respect to the countermeasure. *Id.* § 247d-6d(a)(1).

26. *Id.* § 247d-6d(i)(7)(A)(II).

27. This includes products authorized under an Emergency Use Authorization (EUA) pursuant to section 564 of the FDCA, described in Emergency Use Instructions (EUIs) issued by the Centers for Disease Control and Prevention (CDC) pursuant to section 564A of the FDCA, or held for emergency use pursuant to section 564B of the FDCA. 21 U.S.C. §§ 360bbb-3–360bbb-3b (2019).

28. Section 3103 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act amended the PREP Act to add this category of respiratory protective devices to the definition of covered countermeasure. Pub. L. No. 116-136, § 3103, 134 Stat. 281, 361 (2020) (codified as amended at 42 U.S.C. § 247d-6d(i)(1)(D) (2020)).

29. Program planners include state/local governments, Native American tribes, or other persons who supervise/administer programs. 42 U.S.C. § 247d-6d(i)(6). Such programs include those relating to the administration, dispensing, distribution, provision, or use of a countermeasure, including "a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a [PREP Act declaration]." *Id.* HHS adopted a broad interpretation of the term "program planner" for purposes of the COVID-19 PREP Act Declaration. U.S. DEP'T OF HEALTH & HUMAN SERVS., ADVISORY OPINION 20-04 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE SECRETARY'S DECLARATION UNDER THE ACT 2–3 (2020), https://www.hhs.gov/sites/default/files/advisory-opinion-20-04-hhs-ogc-public-readiness-emergency-preparedness-act.pdf [hereinafter ADVISORY OPINION NO. 20-04] ("[A]ny individual or organization can potentially be a program planner and receive PREP Act coverage . . . [including] private businesses, public and private transportation providers, public and private schools, and religious organizations are all eligible for PREP Act coverage when they act in accordance with the PREP Act and the Declaration.").

30. 42 U.S.C. § 247d-6d(i)(2).

sionals or other individuals authorized to prescribe, administer, or dispense covered countermeasures under applicable state law; or (2) other categories of persons identified by the Secretary in a PREP Act declaration.[31]

- A "loss" means "any type of loss," including: (1) death; (2) physical, mental, or emotional injury, illness, disability, or condition (or fear thereof[32]); and (3) loss or damage to property, including business interruption loss.[33] At a minimum, this definition appears to include most state tort law, medical malpractice, and wrongful death claims arising from the use or administration of covered countermeasures.

The Secretary must define the scope of protections afforded by each PREP Act declaration, including the covered countermeasures, geographic areas, subject populations, time periods, and means of distribution covered by the declaration. Since the PREP Act's enactment in 2005, PREP Act declarations have been issued to cover countermeasures for smallpox, botulinum toxin, acute radiation syndrome, anthrax, pandemic influenza, Zika, nerve agents and insecticides, Ebola, Marburgvirus and Marburg Disease, and COVID-19.[34]

The PREP Act permits covered persons to assert immunity from suit rather than litigate entitlement to reimbursement, as may be required under other forms of liability protection.[35] The immunity provided has been described by scholars and courts as "potent,"[36] "unprecedented,"[37] and "sweeping."[38] Indeed, it applies to:

> *Any claim for loss* that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the *design, development, clinical testing or investigation, manufacture, labeling, distribution, formula-*

31. *Id.* § 247d-6d(i)(8).

32. This includes fear of "any need for medical monitoring." *Id.* § 247d-6d(a)(2).

33. *Id.*

34. *See Public Readiness and Emergency Preparedness Act*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx (last visited Mar. 4, 2022) (listing PREP Act declarations).

35. *See* 48 C.F.R. § 52.250-1 (2007) (providing for insurance or indemnification under Pub. L. No. 85-804 for unusually hazardous risks).

36. Mayer, *supra* note 20, at 1762.

37. Samuel C. Bauer, *Ebola and the Public Readiness and Emergency Preparedness Act: Defining the Outer Boundaries of Unreviewable Administrative Action*, 8 NE. U. L.J. 223, 228 (2016); Angela Marino, *The Cost of a Countermeasure: The Expansive Liability Protection of the Public Readiness and Emergency Preparedness Act of 2005*, 20 U. FLA. J.L. & PUB. POL'Y 199, 200 (2009).

38. Parker v. St. Lawrence Cty. Pub. Health Dep't, 954 N.Y.S.2d 259, 262 (App. Div. 2012); *see also* Bauer, *supra* note 37, at 231 (referring to the PREP Act's liability protections as "expansive").

> *tion, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing*, or use of such countermeasure.[39]

The PREP Act also includes a broad preemption provision, which preempts state laws that are different from or that conflict with the PREP Act.[40]

Despite its breadth, the PREP Act includes limitations—even while the law may not go far enough in protecting and compensating harmed individuals. First, it does not provide immunity for death or serious physical injury caused by willful misconduct.[41] This exception, however, establishes a difficult standard for plaintiffs to meet,[42] and the process for filing suit and proving willful misconduct is limited in several ways.

For example, to recover under the willful misconduct standard, an individual must first seek compensation through the CICP.[43] The harmed person(s) cannot sue if they choose to be compensated through the CICP.[44] If a suit is filed, the standards are difficult to

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39. 42 U.S.C. § 247d-6d(a)(2)(B) (emphasis added).

40. *Id.* § 247d-6d(b)(8). The preemption provision provides as follows:

> During the effective period of a declaration . . . or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—(A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the [FDCA].

Id.

41. *Id.* § 247d-6d(d). The PREP Act defines "willful misconduct" as "an act or omission that is taken—(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." *Id.* § 247d-6d(c)(1)(A). The law further states that the criteria for establishing willful misconduct "shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness." *Id.* § 247d-6d(c)(1)(B).

42. *See, e.g.*, Copper, *supra* note 14, at 88 n.123 ("Even if one were able to produce proof of possible willful misconduct on the part of drug companies, a near impossibility, the procedural hurdles of the act would make the cause of action exceedingly difficult to bring."); Mary S. Holland, *Liability for Vaccine Injury: The United States, the European Union, and the Developing World*, 67 EMORY L. J. 415, 449 (2018) (describing the requirements to establish willful misconduct as "almost insurmountable hurdles to justiciability"); Robert Church et al., *COVID-19: Daily Report for Life Sciences and Health Care Companies*, JD SUPRA (Mar. 25, 2020), https://www.jdsupra.com/legalnews/covid-19-daily-report-for-life-sciences-22095/ (describing the willful misconduct standard under the PREP Act as a "high bar").

43. *See infra* Part III; 42 U.S.C. § 247d-6e(d)(1).

44. 42 U.S.C. § 247d-6e(d)(5).

meet. The suit must be filed in the U.S. District Court for the District of Columbia,[45] and a plaintiff must prove willful misconduct by "clear and convincing evidence,"[46] a higher standard than the "preponderance of the evidence" standard typically used in civil court.[47] Such standards very likely enable covered persons to avoid some lawsuits.[48] Furthermore, manufacturers and distributors can defend against such claims if the activity is regulated under the PHSA or FDCA and if (1) the Secretary or Attorney General has not initiated an enforcement action with respect to the activity; or (2) any such enforcement action was terminated or finally resolved without a "covered remedy," such as a conviction, injunction, monetary penalty, recall, or revocation of an EUA and/or approval/clearance.[49]

In addition to the exception for willful misconduct, the PREP Act "does not provide immunity against federal enforcement actions brought by the federal government—civil, criminal, or administrative. Nor does the PREP Act provide immunity against suit and liability for claims under federal law for equitable relief."[50] The PREP Act also does not apply to claims brought in non-U.S. tribunals or under non-U.S. law.[51] Further, although the Secretary cannot retroactively limit protections provided to covered countermeasures that are used prior to the amendment or withdrawal of a declaration, countermeasures that are distributed while a declaration remains in effect are at risk of losing protection in the event the Secretary amends or withdraws a declaration after their distribution but before their use.[52] Lastly, PREP Act declarations frequently limit the potential scope of protection by covering the administration or use of covered countermeasures only when they are distributed in connection with a federal contract, grant, or other agreement.[53]

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45. *Id.* § 247d-6d(e)(1).

46. *Id.* § 247d-6d(c)(3). Additionally, the plaintiff must plead each element with particularity, and the complaint must be verified and supported by certified medical records and an affidavit from a physician who did not treat the patient. *Id.* § 247d-6d(e).

47. *See id.* § 300aa-13(a)(1) (1992); Holland, *supra* note 42, at 449.

48. A letter from Senator Ted Kennedy and twenty colleagues to the Speaker of the House and majority leader urged the repeal of the PREP Act, arguing that it could "be used to allow manufacturers of virtually any drug or vaccine to escape responsibility for gross negligence or even criminal acts." Holland, *supra* note 42, at 449–50 (quoting Sen. Kennedy's letter).

49. 42 U.S.C. § 247d-6d(c)(5)(A), (B)(ii).

50. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., ADVISORY OPINION ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE MARCH 10, 2020 DECLARATION UNDER THE ACT 2 (2020), https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf.

51. 42 U.S.C. § 247d-6d(d)–(e).

52. *See id.* § 247d-6d(a)(3)(A), (b)(4).

53. *See, e.g.*, Ebola Virus Disease Vaccines–Amendment, 84 Fed. Reg. 764, 766 (Jan. 31, 2019). A relevant provision in the PREP Act declaration for Ebola, for example, states:

B. Emergency Use Authorizations

To understand the PREP Act, EUAs must be explained. Section 564 of the FDCA provides the U.S. Food and Drug Administration (FDA) the authority to authorize the use of an unapproved medical product (e.g., drug, biologic (including vaccines), device, or diagnostic) or an unapproved use of an approved medical product in the context of a public health emergency such as the COVID-19 pandemic.[54] The FDA may issue an EUA following a determination of a particular type of threat or public health emergency. The types of emergencies that trigger these authorities include (1) public health emergencies announced by the Secretary of HHS; (2) military emergencies announced by the Secretary of Defense; (3) domestic emergencies announced by the Secretary of Homeland Security; and (4) the identification of a "material threat" pursuant to section 319F-2 of the PHSA that is sufficient to affect national security or the health and security of U.S. citizens living abroad.[55]

Following such a determination, the Secretary of HHS can make a declaration that the circumstances exist to justify an EUA.[56] During the effective period of the Secretary's declaration, the FDA may then issue EUAs for products intended for use during that period to address the actual or potential threat. The FDA may issue an EUA only if the following criteria are met:[57]

1. The CBRN agent(s) referred to in the Secretary's EUA declaration (e.g., SARS-CoV-2, the virus that causes COVID-19) is capable of causing a serious or life-threatening disease or condition;
2. Based on the totality of scientific evidence available, it is reasonable to believe that (a) the product "may be effective" in

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> [L]iability immunity is afforded to Covered Persons for Recommended Activities involving Covered Countermeasures that are directly supported by the U.S. Federal Government through past, present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or arrangements. The Secretary specifies that the term "directly supported" in this Declaration means that the U.S. has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing.

Id.

54. 21 U.S.C. § 360bbb-3.

55. *Id.* § 360bbb-3(b).

56. *Id.* § 360bbb-3(b)(1). A determination under section 319 or section 319F-3 of the PHSA does not enable the FDA to issue EUAs. *Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited Mar. 2, 2022). The determination must be made pursuant to section 564 of FDCA. *Id.*

57. 21 U.S.C. § 360bbb-3(c).

preventing, diagnosing, or treating the disease or condition caused by the pathogen (e.g., COVID-19) and (b) the known and potential benefits of the product, when used to prevent, diagnose, or treat the disease or condition, outweigh the known and potential risks of the product; and

3. There are "no adequate, approved, and available" alternatives to the emergency use of the product.

Importantly, an EUA does not represent a full approval or license. Rather, it provides an authorization to distribute and use the product, subject to the terms and conditions of the EUA, during the effective period of the Secretary's declaration.

On February 4, 2020, then-Secretary Alex Azar determined, pursuant to section 564 of the FDCA, that a public health emergency existed involving COVID-19.[58] The Secretary subsequently issued declarations that the circumstances existed justifying EUAs for particular types of medical products for COVID-19, including in vitro diagnostics,[59] medical devices,[60] and drugs and biologics (including vaccines).[61] In turn, the FDA issued a number of EUAs for COVID-19 vaccines, therapeutics, devices, and diagnostics.[62] Each of these EUA products represents a covered countermeasure for purposes of the PREP Act.

C. COVID-19 PREP Act Declaration

Secretary Azar first issued a PREP Act declaration for COVID-19 (COVID-19 PREP Act Declaration) on March 10, 2020, with an effective date of February 4, 2020, through October 1, 2024 (plus an additional twelve months for disposition of covered countermeasures).[63] Under the COVID-19 PREP Act Declaration, a covered countermeasure includes "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19."[64]

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58. Determination of Public Health Emergency, 85 Fed. Reg. 7316, 7316 (Feb. 7, 2020).

59. *Id.* at 7316–17.

60. Emergency Use Authorization Declaration, 85 Fed. Reg. 17,335, 17,336 (Mar. 27, 2020).

61. Emergency Use Authorization Declaration, 85 Fed. Reg. 18,250, 18,250 (Apr. 1, 2020).

62. *See Emergency Use Authorization*, *supra* note 56 (compiling COVID-19 and other current EUAs).

63. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020).

64. *Id.*

The Secretary amended the COVID-19 PREP Act Declaration multiple times to expand the scope of immunity.[65] Among other things, these amendments broadened the definition of "covered countermeasures" under the COVID-19 PREP Act Declaration;[66] added additional categories of qualified persons authorized to prescribe, dispense, and administer covered countermeasures;[67] provided immunity for *not* administering a covered countermeasure in certain situations;[68] and added a method of distribution to provide liability

65. As of March 4, 2022, the COVID-19 PREP Act Declaration has been amended ten times. *See* Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982 (Jan. 7, 2022); Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 51,160 (Sept. 14, 2021); Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 41,977 (Aug. 4, 2021); Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 14,462 (Mar. 16, 2021); Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 9516 (Feb. 16, 2021); Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 7872 (Feb. 2, 2021); Fourth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 79,190 (Dec. 9, 2020); Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 52,136 (Aug. 24, 2020); Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 35,100 (June 8, 2020); Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21,012 (Apr. 15, 2020). For a brief description of most of the amendments, see KEVIN J. HICKEY, THE PREP ACT AND COVID-19: LIMITING LIABILITY FOR MEDICAL COUNTERMEASURES 5 (2022), https://crsreports.congress.gov/product/pdf/LSB/LSB10443.

66. *See* Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. at 21,014.

67. *See* Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. at 51,161; Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. at 41,978; Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. at 14,463–64; Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. at 9517–19; Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. at 7873.

68. Fourth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. at 79,197 ("Prioritization or purposeful allocation of a Covered Countermeasure [which may result in use of a Covered Countermeasure for one individual over another], particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections."); *see also* U.S. DEP'T OF HEALTH & HUMAN SERVS., ADVISORY OPINION NO. 21-01 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT SCOPE OF

protections for private distribution channels.[69] Many of the later amendments continued to expand the COVID-19 PREP Act Declaration in an effort to facilitate vaccination efforts.[70]

II. PREP Act Case Law

There is limited case law addressing the merits of a PREP Act immunity defense based on the use of a covered countermeasure, particularly with respect to claims against manufacturers of covered countermeasures. Most cases, both prior to and during the COVID-19 pandemic, involved claims against healthcare providers and healthcare facilities. This Part highlights some of those cases.

A. Pre-COVID-19 Case Law

Prior to COVID-19, three primary PREP Act cases included *Kehler v. Hood*,[71] *Parker v. St. Lawrence County Public Health Department*,[72] and *Casabianca v. Mount Sinai Medical Center*.[73] Of these, *Kehler* is the only case involving a manufacturer of a covered countermeasure.

In *Kehler*, Larry and Ann Kehler filed suit against a healthcare provider and hospital for failing to obtain informed consent prior to administering the H1N1 vaccine to Mr. Kehler, which the plaintiffs alleged resulted in an injury to Mr. Kehler.[74] The defendants thereafter brought third-party product liability claims against the manufacturer of the vaccine.[75] The federal district court concluded that the PREP Act barred the claim against the manufacturer, stating:

> The parties do not dispute that third party defendant . . . the alleged manufacturer of the H1N1 vaccine at issue here, is protected by the PREP Act and is *absolutely immune* from liability for any type of

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Preemption Provision 3–4 (2021), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf [hereinafter Advisory Opinion No. 21-01].

69. *See* Fourth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. at 79,194.

70. *See, e.g.*, Press Release, U.S. Dep't of Health & Human Servs., Biden Administration Takes Action Through HHS to Increase Number of Vaccinators (Mar. 12, 2021), https://www.hhs.gov/about/news/2021/03/12/biden-administration-takes-action-through-hhs-increase-number-vaccinators.html ("As part of President Biden's national strategy to defeat the pandemic . . . HHS has used its authority under the Public Readiness and Emergency Preparedness Act (PREP Act) to add additional categories of qualified people authorized to prescribe, dispense, and administer COVID-19 vaccines.").

71. Kehler v. Hood, No. 4:11CV1416, 2012 WL 1945952 (E.D. Mo. May 30, 2012).

72. Parker v. St. Lawrence Cty. Pub. Health Dep't, 954 N.Y.S.2d 259 (App. Div. 2012).

73. Casabianca v. Mt. Sinai Med. Ctr., No. 112790/10, 2014 WL 10413521 (N.Y. Sup. Ct. Dec. 2, 2014).

74. *Kehler*, 2012 WL 1945952, at *1.

75. *Id.*

> loss caused by the vaccine. Further, no injured party here has alleged that [the manufacturer] engaged in willful misconduct so as to bring its claim within the statute's only recognized exception to immunity.[76]

The state law claims against the healthcare provider and hospital were remanded to state court, and the district court did not rule on whether the PREP Act's immunity defense was applicable to the state law claims brought against the healthcare provider and hospital.[77]

In *Parker*, the plaintiffs sued the county health department, alleging that the administration of the H1N1 vaccine to their daughter without their consent constituted negligence and resulted in a battery upon their daughter.[78] The New York Supreme Court, Appellate Division, dismissed the plaintiffs' state law negligence and battery claims, concluding that the state law claims were "preempted by the PREP Act and, inasmuch as the exclusive remedy under the statute is a federal cause of action to be brought in federal court, the complaint must be dismissed for lack of subject matter jurisdiction."[79] The court noted the PREP Act's broad preemption clause and its "sweeping" immunity provision, concluding that "Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary, including one based upon a defendant's failure to obtain consent."[80]

A third case, *Casabianca*, did not involve the use or administration of a covered countermeasure under the PREP Act.[81] Rather, the plaintiff alleged malpractice for *failure* to administer a covered countermeasure—the H1N1 vaccine—a failure alleged to have caused the death of the plaintiff's husband.[82] The New York Supreme Court denied the defendant's motion to dismiss, concluding that malpractice claims arising from the failure to administer a covered countermea-

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76. *Id.* at *3 (emphasis added).

77. *Id.* at *4. Essentially, the court appeared to treat the state medical negligence claims as based on the healthcare provider's and hospital's actions *prior* to the administration of the vaccine and thus not actually "relating to" the administration of the vaccine, which could bring it under the PREP Act. *See id.* "Plaintiffs raise State law claims of medical negligence based on the conduct of defendants Dr. Hood and St. Luke's which occurred prior to the administration of the H1N1 vaccine." *Id.*

78. Parker v. St. Lawrence Cty. Pub. Health Dep't, 954 N.Y.S.2d 259, 261 (App. Div. 2012).

79. *Id.* at 263.

80. *Id.* at 262.

81. Casabianca v. Mt. Sinai Med. Ctr., No. 112790/10, 2014 WL 10413521, at *1 (N.Y. Sup. Ct. Dec. 2, 2014).

82. *Id.* at *1.

sure vaccine were outside the scope of the PREP Act's immunity provisions for the H1N1 vaccine.[83]

In its decision, the court noted that the vaccine was in short supply and that the hospital was selectively administering it to high-risk patients in accordance with guidelines from states and the Centers for Disease Control and Prevention (CDC).[84] The decedent did not meet the eligibility criteria and therefore was not administered the vaccine.[85] Given the facts of *Casabianca*, it is not clear whether such a claim could be pursued under the COVID-19 PREP Act Declaration. As noted above, the COVID-19 PREP Act Declaration was amended to clarify that the PREP Act may provide immunity for *failing* to administer a covered countermeasure, when such failure results from prioritizing or purposefully allocating a covered countermeasure in limited supply, "particularly if done in accordance with a public health authority's directive," such as the CDC, which was the case in *Casabianca*.[86]

B. COVID-19 Case Law

In the context of COVID-19, most publicly available court decisions citing the PREP Act as of February 2022 involved nursing homes/long-term care facilities.[87] Many were filed initially in state courts and typically alleged claims such as medical malpractice and wrongful death arising from the facilities' failures to take appropriate actions and follow certain policies, procedures, and guidelines to prevent the

83. *Id.* at *4–5.

84. *Id.* at *1.

85. *Id.*

86. Fourth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 79,190, 79,197 (Dec. 9, 2020). An advisory opinion issued by the HHS Office of General Counsel on January 8, 2021, affirmed that the PREP Act may apply in such a situation, as the failure to use the countermeasure would "relate to" the administration of a covered countermeasure to another person because that other person "was able to receive the [covered countermeasure] only because it was not administered to the [other person]." ADVISORY OPINION NO. 21-01, *supra* note 68, at 3. "In contrast, the failure to purchase *any* PPE [personal protective equipment], if not the outcome of some form of decision-making process may not be sufficient to trigger the PREP Act." *Id.* (emphasis added).

87. *But see, e.g.*, Tonkinson v. Walmart, Inc., No. 21-2588, 2022 WL 425868, at *1 (D. Kan. Feb. 11, 2022) (alleging, *inter alia*, "that Walmart made material misstatements of fact and law to obtain signatures and induce [a minor] to be 'vaccine injected without parental consent, and to conspire with [the minor] to keep what Walmart had done to [the minor] a secret'"); Ruiz v. ConAgra Foods Packaged Foods, LLC, No. 21-CV-387, 2021 WL 3056275, at *1 (E.D. Wis. July 20, 2021) (alleging that plaintiff contracted COVID-19 while working at ConAgra under unsafe working conditions and that plaintiff transmitted the disease to his wife, who died).

spread of COVID-19 among the facilities' residents.[88] That is, they typically did not allege an injury relating to the use or administration of a covered countermeasure or bring claims against a manufacturer of a covered countermeasure.

At least one case, brought against the owners of a senior living community, involved claims relating to the use of hydroxychloroquine sulfate, which was authorized for emergency use at the time it was used.[89] The suit was filed after Anne Jean Cannon, a resident of the senior living community diagnosed with COVID-19, died after receiving the treatment.[90] When Ms. Cannon received the drug, the hydroxychloroquine EUA applied only to the treatment of adults and adolescent patients hospitalized with COVID-19.[91] The defendants filed a motion to dismiss, arguing that hydroxychloroquine was a covered countermeasure, and thus its use to treat Ms. Cannon was covered by the PREP Act.[92] The court denied the motion because, among other reasons, the plaintiffs alleged that the drug was used to treat Ms. Cannon at the senior living community, rather than in a hospital setting as required by the terms of the EUA.[93] The court stated:

> Accepting Plaintiffs' allegations as true, as this Court must at this motion to dismiss stage of the proceedings, Defendants' administration of hydroxychloroquine sulfate does not fall within the clear,

88. *See, e.g.*, Baskin v. Big Blue Healthcare, Inc., No. 2:20-cv-2267, 2020 WL 4815074, at *1 (D. Kan. Aug. 19, 2020) (holding that the court lacked subject matter jurisdiction and remanding to state court after concluding that the PREP Act does not apply to claims alleging negligence for failure to follow certain policies, procedures, and guidelines regarding COVID-19); Estate of Maglioli v. Andover Subacute Rehab. Ctr. I, 478 F. Supp. 3d 518, 531 (D. N.J. 2020) (concluding, *inter alia*, that the action could not be removed to federal court under the PREP Act because state claims relating to the failure to use countermeasures fall outside the PREP Act, "which is designed to protect those who employ countermeasures [e.g., PPE], not those who decline to employ them"). Because some of these cases were filed and decided prior to the Fourth Amendment to the COVID-19 PREP Act Declaration in December 2020, which made clear that the PREP Act can apply to the failure to administer a covered countermeasure when such failure is the result of prioritizing or purposefully allocating a covered countermeasure that is in limited supply, it is not clear whether the courts would reach the same conclusions in all of these cases. *See* Fourth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. at 79,197.

89. The FDA issued an EUA for hydroxychloroquine sulfate and chloroquine phosphate on March 28, 2020. Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19 Update): FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine (June 15, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and. Based on the Agency's ongoing analysis of the EUA and emerging scientific data, the FDA revoked the EUA on June 15, 2020, after concluding that the statutory criteria for an EUA were no longer met. *Id.*

90. Cannon v. Watermark Retirement Cmtys., Inc., No. 21-1451, 2021 WL 3033762, at *1 (E.D. Pa. July 19, 2021).

91. *Id.* at *3.

92. *Id.* at *1.

93. *Id.* at *3.

> explicit, and limited scope of the drug's FDA emergency use authorization. Therefore, based on these allegations, the administration of the treatment as Defendants used it cannot be considered a covered countermeasure because it was not "authorized for investigational or emergency use, as those terms are defined in the [FDCA,]" as required by the PREP Act . . . . Accordingly, Defendants' motion to dismiss is denied.[94]

The court also rejected the defendant's argument that immunity applies to the misuse of a covered countermeasure because "[d]efendants did not 'misuse' a covered countermeasure because, in order to misuse a covered countermeasure, the treatment in question must first satisfy the definition of a covered countermeasure, which, as explained above, [d]efendants' administration of treatment to Cannon does not."[95] Unlike other cases discussed next, the plaintiffs did not seek to remand this case to a state court.

In many cases, defendants sought to remove the case to federal court claiming, in part, that federal courts have original jurisdiction because the actions are preempted by the PREP Act, a federal statute.[96] The majority of courts addressing the complete preemption question, even after the Secretary issued the January 2021 Advisory Opinion, which stated the PREP Act "is a 'complete preemption' statute,"[97] have held that the PREP Act does not, in fact, trigger complete preemption.[98]

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94. *Id.*

95. *Id.* at *4. The court also held that the defendant's actions did not fall within the PREP Act's "safe harbor" provision, which provides immunity for a covered entity that "reasonably could have believed" that the countermeasure administered "was (1) being administered to and by the proper populations specified in the Secretary's declaration and (2) being administered within a proper geographic area specified in the Secretary's declaration, even if the countermeasure did not actually satisfy those conditions." *Id.*; *see also* 42 U.S.C. § 247d-6d(a)(3)(C). The court held that it was not reasonable for defendants to believe the administration of hydroxychloroquine was proper because the EUA "was unambiguous" as to where the drug needed to be administered and to whom it could be administered. *Cannon*, 2021 WL 3033762, at *4.

96. *See, e.g.*, Dupervil v. Alliance Health Operations, LLC, 516 F. Supp. 3d 238, 248 (E.D.N.Y. 2021); Estate of Maglioli v. Andover Subacute Rehab. Ctr. I, 478 F. Supp. 3d 518, 523–24 (D. N.J. 2020).

97. ADVISORY OPINION NO. 21-01, *supra* note 68, at 2.

98. *See e.g.*, Maglioli v. Alliance HC Holdings LLC, 16 F.4th 393, 407–08 (3d Cir. 2021) (holding that the PREP Act does not completely preempt all state law claims); Leroy v. Hume, No. 20-CV-5325, 2021 WL 4350502, at *3 (E.D.N.Y. Sept. 24, 2021) (collecting cases and stating that "[o]ver the past eighteen months, several dozen district courts have addressed the argument of complete preemption put forth by defendants, and the overwhelming consensus among them is that claims like plaintiffs' are not completely preempted by the PREP Act"); Estate of Jenkins v. Beverly Hills Senior Care Facility, Inc., No. CV-21-4902, 2021 WL 3563545, at *4 (C.D. Cal. Aug. 12, 2021) (collecting cases and stating that "[t]hese cases plainly hold that the PREP Act does not 'wholly displace' state law claims that implicate healthcare entities and COVID-19"); Roebuck v. Mayo Clinic, No. CV-21-00510, 2021 WL 1851414, at *4 (D. Ariz. May 10, 2021) (collecting cases). While most defendants have not succeeded in removing the claims to federal courts

In the cases alleging various failures, the alleged failures are broad and go beyond, or do not even include, failures to use or administer covered countermeasures. As noted, the fourth amendment to the COVID-19 PREP Act Declaration made it clear that claims relating to the failure to use or administer a covered countermeasure may fall within the PREP Act's liability protections if the failure resulted from prioritizing or purposefully allocating covered countermeasures in short supply.[99] Of the cases discussing the fourth amendment and HHS Advisory Opinion 21-01, which added additional clarity on this point, the courts generally held that the specific facts of the case brought it outside the narrow examples of inaction that can fall within the PREP Act.[100] The broader inaction claims in these cases included "fail[ing] to properly implement an effective infection control program (including by failing to properly train staff);"[101] "fail[ing] to maintain sufficient staffing levels [and] fail[ing] to implement any safety measures;"[102] failing to provide adequate supplies of personal protective equipment;[103] and "failing to properly execute existing pro-

based on the PREP Act, at least two courts have held that the PREP Act is a complete preemption statute. *See* Rachal v. Natchitoches Nursing & Rehab. Ctr. LLC, No. 1:21-CV-00334, 2021 WL 5449053, at *2 n.3 (W.D. La. Apr. 30, 2021) ("[T]he Court finds that the PREP Act is a complete preemption statute, thus creating a federal cause of action as specified therein."); Garcia v. Welltower OpCo Grp., 522 F. Supp. 3d 734, 743 (C.D. Cal. 2021) ("[T]he Court finds that the PREP Act provides for complete preemption."). Many courts within the Ninth Circuit—and elsewhere—declined to follow *Garcia*, sometimes citing its failure to apply the proper complete preemption test. *See, e.g.*, Acra v. Cal. Magnolia Convalescent Hosp., Inc., No. 21-898, 2021 WL 2769041, at *6 (C.D. Cal. July 1, 2021) (collecting cases). The question—and answer—of whether the PREP Act is a complete preemption statute is beyond the scope of this Article.

99. *See supra* note 68 and accompanying text.

100. *See, e.g.*, Estate of Costa v. WDW Joint Venture, No. CV-21-05762, 2021 WL 3089332, at *4 (C.D. Cal. July 21, 2021); Jones v. Legacy Mgmt. Grp., No. 6:21-CV-00838, 2021 WL 3416993, at *3–4 (W.D. La. July 7, 2021); Reed v. Sunbridge Hallmark Health Servs., LLC, No. CV-21-3702, 2021 WL 2633156, at *5–6 (C.D. Cal. June 25, 2021); Stone v. Long Beach Healthcare Ctr., LLC, No. CV-21-326, 2021 WL 1163572, at *4–7 (C.D. Cal. Mar. 26, 2021); Anson v. HCP Prairie Village KS OPCO LLC, 523 F. Supp. 3d 1288, 1300 (D. Kan. 2021).

101. *Stone*, 2021 WL 1163572, at *4 (concluding that PREP Act immunity for a failure to act applies only "when the failure to administer a covered countermeasure to one individual has a 'close causal relationship' to the administration of that covered countermeasure to another individual . . . . Other 'inaction claims' may not").

102. Nava v. Parkwest Rehab. Ctr. LLC, No. 2:20-CV-07571, 2021 WL 1253577, at *3 (C.D. Cal. Apr. 5, 2021) (concluding that "state-law claims of negligence and wrongful death brought against a nursing home for failure to protect against the spread of COVID-19 . . . are not properly characterized as federal-law claims under the PREP Act" (quoting Dupervil v. Alliance Health Operations, LLC, 516 F. Supp. 3d 238, 255 (E.D.N.Y. 2021))). *See also* Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC, No. 20cv1198, 2020 WL 6140474, at *2–3 (W.D. Pa. Oct. 16, 2020) (involving "inaction" claims in addition to failure to provide PPE, including failure to provide proper training, failure to follow federal guidance, and failure to implement various safety and preventative policies and procedures).

103. *See, e.g.*, Estate of Jones v. St. Jude Operating Co., 524 F. Supp. 3d 1101, 1104 (D. Or. 2021).

tocols and procedures set in place to prevent the spread of the Covid-19 virus."[104] Plaintiffs generally did not (1) claim that a covered countermeasure itself caused injury or death; (2) claim specifically that a covered countermeasure was *not* used when the covered countermeasure was in short supply and allocated to another individual;[105] or (3) make claims against manufacturers of covered countermeasures.

Notwithstanding the positions taken by courts thus far with respect to the application of the PREP Act during the COVID-19 pandemic, it remains to be seen how a manufacturer of a covered COVID-19 countermeasure would fare in a lawsuit relating to the manufacturer's covered countermeasure(s). That said, because claims against manufacturers are more likely to involve the actual use or administration of a covered countermeasure—which fall more clearly within the PREP Act—manufacturers may not encounter the same problems as the facility defendants in the cases discussed above. Thus, unless plaintiffs can meet the high bar of proving willful misconduct, compensation through the CICP will provide their only recourse.

III. The Countermeasures Injury Compensation Program

When enacting the PREP Act, which can cut off an injured individual's ability to seek recourse through the courts, Congress recognized the need to include an alternative form of relief for individuals injured by covered countermeasures. Thus, Congress also added section 319F-4 to the PHSA, which established the CICP, a no-fault compensation program.[106] This Part describes the CICP and its numerous limitations and inadequacies.

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104. Estate of Maglioli v. Andover Subacute Rehab. Ctr. I, 478 F. Supp. 3d 518, 523 (D. N.J. 2020).

105. Although some claims included the failure to use PPE or failure to test residents and/or staff for COVID-19, both of which could involve covered countermeasures, defendants typically did not argue that these failures were because PPE or tests were in short supply and allocated to others. For example, in *Estate of Jenkins v. Beverly Hills Senior Care Facility, Inc.*, the plaintiffs claimed that the defendants "fail[ed] to test residents and/or staff for COVID-19 *despite the availability and feasibility of regular testing*." Estate of Jenkins v. Beverly Hills Senior Care Facility, Inc., No. CV-21-04902, 2021 WL 3563545, at *1 (C.D. Cal. Aug. 12, 2021) (emphasis added). *See also* cases cited *supra* note 88.

106. 42 U.S.C. § 247d-6e; *see also Countermeasures Injury Compensation Program (CICP)*, Health Resources & Servs. Admin. (Nov. 2020), https://www.hrsa.gov/cicp. Regulations promulgated by HHS govern CICP procedures and eligibility determinations. *See generally* 42 C.F.R. Part 110 (2020).

A. Scope and Limitations of the Countermeasures Injury Compensation Program

The CICP is a no-fault compensation program intended to provide benefits to eligible persons (or their survivors) who sustain serious physical injuries or death as a direct result of the administration or use of a covered countermeasure pursuant to a PREP Act declaration.[107] Eligible individuals may receive reimbursement for reasonable and necessary medical expenses; loss of employment income; and survivor benefits in the case of death if the Secretary determines the death was a direct result of a covered injury.[108] The CICP has a number of important limitations, and it has been criticized as an inadequate mechanism for compensating individuals harmed by covered countermeasures.[109]

First, "eligible individuals" (or their survivors) are those who suffer death or serious physical injury directly caused by the administration of a covered countermeasure pursuant to a PREP Act declaration.[110] A "serious physical injury" is defined as "an injury that (A) is life threatening; (B) results in permanent impairment of a body function or permanent damage to a body structure; or (C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure."[111] The CICP regulations state further that "[a]s a general matter, only injuries that warrant[ ] hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries."[112] Additionally, "[i]njuries resulting from the underlying condition for which the countermeasure was administered or used," such as if the covered countermeasure was ineffective in treat-

107. 42 U.S.C. § 247d-6e(a).

108. 42 C.F.R. §§ 110.2, 110.31, 110.32, 110.33 (2010).

109. *See* Tom Hals, *COVID-19 Era Highlights U.S. 'Black Hole' Compensation Fund for Pandemic Vaccine Injuries*, REUTERS (Aug. 21, 2020, 6:08 AM), https://www.reuters.com/article/us-health-coronavirus-vaccines-liability/covid-19-era-highlights-u-s-black-hole-compensation-fund-for-pandemic-vaccine-injuries-idUSKBN25H1E8; Mary Shinn, *After Suffering COVID-19 Vaccine-Caused Blood Clots, Colorado Springs Woman Sees Problems with Federal Compensation System*, THE GAZETTE (June 19, 2021), https://gazette.com/news/after-suffering-covid-19-vaccine-caused-blood-clots-colorado-springs-woman-sees-problems-with-federal/article_4dff7f24-bf26-11eb-bc0c-2f09adb3f051.html; Jake Daly, *Liability For Injuries Caused by COVID-19 Vaccines*, FREEMAN, MATHIS, & GRAY LLP BLOGLINE (Jan. 7, 2021), https://www.fmglaw.com/FMGBlogLine/business-litigation/liability-for-injuries-caused-by-covid-19-vaccines/.

110. 42 U.S.C. § 247d-6e(e)(5) (defining "eligible individual"); *id.* § 247d-6e(e)(2) (defining "covered individual"); *id.* § 247d-6e(e)(3) (defining "covered injury").

111. *Id.* § 247d-6d(i)(10).

112. 42 C.F.R. § 110.3(z).

ing or preventing the underlying condition or disease, are not considered covered injuries.[113] For example, an individual who receives a COVID-19 vaccine, but is later diagnosed with COVID-19, would not be able to seek compensation for harms caused by the disease itself based on an argument that the vaccine was ineffective.[114]

Second, numerous procedural limitations make it difficult to obtain compensation through the CICP. For example, there is a rebuttable presumption that a covered countermeasure is the cause of an injury only if it is set forth in a Covered Countermeasure Injury Table (Table) and only if the injury occurred within a specified time period and at a specific level of severity.[115] Further, even if a Table's requirements are satisfied, the presumption may be rebutted if the Secretary determines, after reviewing the evidence, that a source other than the countermeasure more likely caused the injury.[116] The Secretary may, but is not required to, obtain the opinions of qualified medical experts in making determinations concerning covered injuries.[117] For injuries not listed in a Table, "the requester must demonstrate that the injury occurred as the *direct result* of the administration or use of a covered countermeasure."[118] This requires proof "based on compelling, reliable, valid, medical and scientific evidence. Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury."[119] As of March 2022, there are two tables: one for pandemic influenza countermeasures and one for smallpox countermeasures.[120] Unless and until a table is created for COVID-19 countermeasures, those seeking compensation must meet the higher "direct result" standard.[121]

Other procedural limitations include a one-year statute of limitations.[122] Specifically, requests "must be filed within one year of the date of the administration or use of a covered countermeasure that is

113. *Id.* § 110.20(d).

114. This limitation, however, is logical and important, given that no medical product can guarantee 100% efficacy.

115. 42 C.F.R. § 110.20(b). Guillain-Barré syndrome, for example, is presumed to be caused by the 2009 H1N1 vaccine if its onset occurs three to forty-two days after administration of the vaccine. *Id.* § 110.100(a).

116. *Id.* § 110.20(b).

117. *Id.* § 110.20(a).

118. *Id.* § 110.20(c) (emphasis added).

119. *Id.*

120. *Id.* § 110.100.

121. *Id.* § 110.3(g).

122. *Id.* § 110.42(a).

alleged to have caused the injury."[123] Further, the process is handled entirely within HHS rather than a court; there is no right to a hearing; and although one step administrative reconsideration is possible, no judicial appeal is permitted.[124]

Third, Congress funds the CICP through emergency appropriations to the Covered Countermeasures Process Fund (Countermeasures Fund).[125] However, the PREP Act does not allocate money to the fund nor does it mandate that the CICP be funded adequately.[126] With respect to COVID-19, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and the Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA) appropriated funds that HHS may, *but is not required to*, use for the Countermeasures Fund. The CPRSA appropriated $3.1 billion to the Secretary to respond to COVID-19, including for the development and purchase of countermeasures, and allows, but does not require, these funds to "be transferred to, and merged with" the Countermeasures Fund.[127] The CARES Act appropriated $27 billion to the Secretary for similar purposes and also allows, but does not require, the Secretary to transfer funds to the Countermeasures Fund.[128] Whether any of the appropriated money is transferred to the Countermeasures Fund thus remains at the discretion of the Secretary.

Along with uncertain funding, awards for damages are limited. For example, the CICP limits lost income recovery to $50,000 for each year of lost work, with no adjustments for inflation, and it does not pay benefits for lost employment income after the individual turns sixty-five years old.[129] The CICP does not compensate for pain, suffering, or emotional distress, nor does it pay attorneys' fees and costs.[130] Additionally, the CICP is the "payer of last resort" and will only cover

123. *Id.* If a new Covered Countermeasure Injury Table is issued or an existing Table is amended, a one-year extension is provided to those requesters who could not establish an injury before the new or amended Table was issued. *Id.* § 110.42(f).

124. *Id.* §§ 110.90–92.

125. 42 U.S.C. § 247d-6e(a).

126. Copper, *supra* note 14, at 91; Marino, *supra* note 37, at 211 (referring to the CICP as an "unfunded compensation scheme").

127. Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 146, 147 (2020).

128. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281, 560–61 (2020).

129. 42 C.F.R. § 110.81(c)(2), (c)(4).

130. KEVIN J. HICKEY & ERIN H. WARD, COMPENSATION PROGRAMS FOR POTENTIAL COVID-19 VACCINE INJURIES 3 (2021), https://crsreports.congress.gov/product/pdf/LSB/LSB10584.

expenses or provide benefits that other third-party payers (e.g., health insurance, workers' compensation, etc.) are not obligated to pay.[131]

Finally, the CICP lacks transparency. Decisions are not made public, and the CICP has been described as "secretive"[132] and "extremely narrow and hard to win."[133] As of February 1, 2022, the CICP had received 7,033 claims since it began in 2010, with 6,940 claims deemed eligible for medical review.[134] Of these, only forty were found eligible for compensation and only twenty-nine received compensation, totaling more than $6 million.[135] One claim was pending as of February 1, 2022, and ten claims did not receive compensation because they did not have any compensable expenses or losses.[136] Of the claims eligible for medical review as of February 1, 2022, 363 had been denied and 6,537 were pending or in review.[137] The full decisions are not made public, but information provided by the Health Resources and Services Administration (HRSA) shows that of the cases found eligible for compensation, most were related to the H1N1 vaccine and Guillain-Barré syndrome, a neurological disorder.[138]

Of the 6,540 COVID-19 countermeasure claims filed as of February 1, 2022, allegations of injury or death due to a COVID-19 vaccine accounted for 3,700 claims, and 2,840 claims alleged injuries or death

131. 42 C.F.R. § 110.3(q) (defining "payer of last resort"); *id.* § 110.3(ee) (defining "third-party payer").

132. Jodie Fleisher et al., *Critics Question Vaccine Injury Compensation Program Readiness as COVID-19 Claims Come In*, NBC MIAMI (Feb. 25, 2021, 7:02 PM), https://www.nbcmiami.com/investigations/critics-question-vaccine-injury-compensation-program-readiness-as-covid-19-claims-come-in/2392118/ ("It's always been so secretive . . . ." (quoting Professor Peter Myers)); *see also* Peter H. Meyers, *The Trump Administration's Flawed Decision on Coronavirus Vaccine Injury Compensation: Recommendations for Changes*, 7 J.L. & THE BIOSCIS. 1, 1 (2020) ("There is a lack of transparency and no meaningful opportunity for petitioners to participate in the administrative proceedings within [HHS] in which their claims for compensation are decided."); Hals, *supra* note 109 (referencing Professor Meyers's description of the CICP as a "'black hole' process").

133. Dorit Rubinstein Reiss, *Congress Should Enact No-Fault Compensation for COVID-19 Vaccine Injuries*, BILL OF HEALTH (Jan. 5, 2021), https://blog.petrieflom.law.harvard.edu/2021/01/05/covid-vaccine-injury-compensation/.

134. *Countermeasures Injury Compensation Program (CICP) Data*, HEALTH RESOURCES & SERVS. ADMIN. (Feb. 1, 2022), https://www.hrsa.gov/cicp/cicp-data. Of those deemed ineligible for medical review, thirty-eight missed the filing deadline, and fifty-five did not involve a covered product or the product was not specified. *Id.*

135. *Id.*

136. *Id.*

137. *Id.*

138. *See Table 2. CICP Claims Compensated (Fiscal Years 2010 – 2022) As of February 1, 2022*, HEALTH RESOURCES & SERVS. ADMIN. (Feb. 1, 2022), https://www.hrsa.gov/cicp/cicp-data#table-2 [hereinafter *Table 2*]; *Table 3. CICP Claims Eligible for Compensation, but No Eligible Reported Losses or Expenses (Fiscal Years 2010 – 2022) As of February 1, 2022*, HEALTH RESOURCES & SERVS. ADMIN. (Feb. 1, 2022), https://www.hrsa.gov/cicp/cicp-data#table-3.

from other COVID-19 countermeasures.[139] As of February 1, 2022, the CICP had not compensated any COVID-19 countermeasures claims and had denied four claims "because the standard of proof for causation was not met and/or a covered injury was not sustained."[140] One claim, a COVID-19 vaccine claim for an anaphylactic reaction, had been deemed eligible for compensation and was pending review of eligible expenses.[141]

Clearly, the COVID-19 pandemic and widespread use of countermeasures has led to an unprecedented number of filings with the CICP. This provides an opportune time to revisit the CICP and its many shortcomings. When considering potential reforms to the CICP, the VICP, another no-fault compensation program, provides a helpful comparison, which this Article turns to next.

B. Comparison to the Vaccine Injury Compensation Program

This Article covers more than vaccines, but claims relating to COVID-19 vaccines will likely constitute a large percentage of claims made for COVID-19 countermeasures, simply given the number of individuals who have received or will receive a COVID-19 vaccine. Indeed, based on data provided by the HRSA, approximately 57% of the COVID-19 countermeasure claims filed as of February 1, 2022, involved COVID-19 vaccines.[142] As of February 2022, all the COVID-19 vaccines authorized or approved for use in the United States were covered under the CICP rather than the VICP.[143]

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139. *Table 1. Alleged COVID-19 Countermeasure Claims Filed as of February 1, 2022*, HEALTH RESOURCES & SERVS. ADMIN. (Feb. 1, 2022), https://www.hrsa.gov/cicp/cicp-data#table-1 [hereinafter *Table 1*]. This second category includes 295 claims relating to failures to follow or enact certain procedures to reduce the risk of infection. *Id.*

140. *Countermeasures Injury Compensation Program (CICP) Data*, *supra* note 134.

141. *Id.*

142. This number was calculated by taking the total number of COVID-19 vaccine countermeasure claims filed as of February 1, 2022, (3,700) and dividing it by the total number of COVID-19 countermeasure claims filed as of February 1, 2022 (6,540). *Table 1*, *supra* note 139.

143. *Frequently Asked Questions*, HEALTH RESOURCES & SERVS. ADMIN. (Mar. 2022), https://www.hrsa.gov/vaccine-compensation/faq. The EUA "Fact Sheets" provided to patients and/or caregivers include information about the CICP. *See, e.g.*, PFIZER, VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, MRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND OLDER 8 (Jan. 31, 2022), https://www.fda.gov/media/153716/download [hereinafter PFIZER-BIONTECH, FACT SHEET FOR 12 YEARS OF AGE AND OLDER]; MODERNA, VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT SPIKEVAX (COVID-19 VACCINE, MRNA) AND THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER 6 (Jan. 31, 2022), https://www.fda.gov/media/144638/download [hereinafter MODERNA, FACT SHEET]; JANSSEN, FACT SHEET FOR RECIPIENTS AND CAREGIVERS: EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE

The VICP was created by the National Childhood Vaccine Injury Act of 1986 (Vaccine Act),[144] and provides liability protections for vaccine manufacturers and administrators as well as a no-fault alternative to the traditional tort system to compensate individuals found to be injured by certain vaccines.[145] Injury compensation through the VICP is available for many vaccines routinely administered in the United States that are listed in the Vaccine Injury Table.[146] For a new category of vaccines to be covered under the VICP, three things must occur: "(1) Congress must enact an excise tax on the vaccine, (2) the CDC must recommend it for routine administration to children or pregnant women, and (3) the Secretary must publish a notice of coverage in the Federal Register."[147]

The VICP applies to vaccine-related deaths or injuries that (1) have effects lasting for more than six months after administration of the vaccine, or (2) result in inpatient hospitalization and surgery.[148] The VICP has a slightly more generous statute of limitations than the CICP, ranging from two to four years, depending on the specific claim.[149] The statute of limitations is based on the date of death or the

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TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER 7–8 (Jan. 31, 2022), https://www.fda.gov/media/146305/download [hereinafter JANSSEN, FACT SHEET]; PFIZER-BIONTECH, VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 5 THROUGH 11 YEARS OF AGE 6–7 (Jan. 3, 2022), https://www.fda.gov/media/153717/download [hereinafter PFIZER-BIONTECH, FACT SHEET FOR AGES 5 THROUGH 11].

144. *See* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, §§ 301–23, 100 Stat. 3743, 3755–84 (Nov. 14, 1986) (codified at 42 U.S.C. §§ 300aa-1–34 (1986)); *see also* 42 U.S.C. §§ 300aa-10(a) (1989) (establishing the National Vaccine Injury Compensation Program).

145. *See Frequently Asked Questions*, *supra* note 143.

146. 42 U.S.C. § 300aa-14 (original Table); *Vaccine Injury Table*, HEALTH RESOURCES & SERVS. ADMIN. (Mar. 21, 2017), https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf (providing the Table applicable to petitions for compensation filed on or after March 21, 2017).

147. National Vaccine Injury Compensation Program: Rescission of Revisions to the Vaccine Injury Table, 86 Fed. Reg. 21,209, 21,211–12 (Apr. 22, 2021). As of March 2022, the CDC recommends COVID-19 vaccination for everyone five years of age and older, including people who are pregnant. *COVID-19 Vaccines While Pregnant or Breastfeeding*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 3, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html; *COVID-19 Vaccines for Children and Teens*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 7, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html. As of March 2022, however, COVID-19 vaccines remain covered countermeasures under the CICP and not the VICP. *Frequently Asked Questions*, *supra* note 143.

148. *See Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP)*, HEALTH RESOURCES & SERVS. ADMIN. (Apr. 2021), https://www.hrsa.gov/cicp/cicp-vicp [hereinafter *Comparison of CICP to VICP*].

149. *Who Can File a Petition*, HEALTH RESOURCES & SERVS. ADMIN. (Mar. 2022), https://www.hrsa.gov/vaccine-compensation/eligible/index.html.

date of "the first symptom or manifestation of onset or of the significant aggravation" of the injury, rather than the date on which the vaccine was administered.[150]

Unlike the CICP, the VICP may provide compensation for pain and suffering and attorneys' fees.[151] Claims are filed in the U.S. Court of Federal Claims and hearings are held before independent special masters.[152] Public decisions are issued after the proceedings, thereby providing the public with information about which injuries have or have not been found to be caused by a vaccine.[153] There is a right to appeal to the U.S. Court of Appeals for the Federal Circuit.[154] Furthermore, the Vaccine Injury Compensation Trust Fund receives consistent funding from a $0.75 excise tax on each dose of a covered vaccine, in contrast to discretionary appropriations like the CICP.[155]

From October 1, 1988, (the beginning of the VICP) through March 1, 2022, the VICP had received 24,824 petitions and 20,797 had been adjudicated.[156] Of the petitions adjudicated, 8,767 were deemed eligible for compensation and 12,030 were dismissed.[157] As of March 1, 2022, over $4.7 billion had been awarded from the Vaccine Injury Compensation Trust Fund, with over $4.3 billion awarded to petitioners and the rest awarded for attorneys' fees/costs.[158] To compare this with the awards from the CICP: approximately 42% of adjudicated petitions have been found eligible for compensation through the VICP[159] compared to approximately 9% of requests submitted to the CICP.[160] And the average payout under the VICP is approximately

150. 42 U.S.C. § 300aa-16; 42 C.F.R. § 110.42(a). With limited exceptions, all petitions must be filed within three years after the first symptom of the alleged vaccine injury or within two years of the death and four years after the first symptom of the alleged vaccine injury that resulted in death. 42 U.S.C. § 300aa-16(a).

151. *See* 42 U.S.C. § 300aa-15(a)(4), (e); *Comparison of CICP to VICP*, *supra* note 148.

152. 42 U.S.C. § 300aa-12(c)–(d).

153. *Id.* § 300aa-12(d).

154. *See id.* § 300aa-12(f); *Comparison of CICP to VICP*, *supra* note 148.

155. *About the National Vaccine Injury Compensation Program*, HEALTH RESOURCES & SERVS. ADMIN. (Mar. 2022), https://www.hrsa.gov/vaccine-compensation/about/index.html.

156. HEALTH RESOURCES & SERVS. ADMIN., NATIONAL VACCINE INJURY COMPENSATION PROGRAM DATA REPORT 1 (Mar. 1, 2022), [hereinafter NATIONAL VACCINE INJURY DATA] (data on file with author). "On average, it takes 2–3 years to adjudicate a petition after it is filed." *Id.* at 7.

157. *Id.* at 1.

158. *Id.* at 9.

159. This figure was calculated by taking the total number of claims found eligible for compensation as of March 1, 2022, (8,767) and dividing it by the number of claims adjudicated (20,797). *Id.* at 5, 7.

160. This figure was calculated by taking the number of requests found eligible for compensation as of February 1, 2022, (40) and dividing it by the total number of requests for which a decision had been made (i.e., not pending) (456) (363 eligible for medical review and denied; 93

$501,093 (not including attorney's fees)[161] compared to $209,520 under the CICP.[162]

Although not without its own limitations and critics,[163] the VICP provides a reasonable model from which to build when considering reforms to the CICP. Reforms are imperative to ensure that people injured by covered countermeasures are compensated adequately through a fair, transparent, efficient, and accessible process.

IV. IMPROVING THE COUNTERMEASURES INJURY COMPENSATION PROGRAM

Part III illustrated how the CICP fails to provide adequate recourse for individuals harmed by covered countermeasures. This Part unpacks the importance of a robust compensation program and proposes potential reforms to address the CICP's inadequacies.

A. Importance of a Robust Compensation Program

This Article does not take issue with the liability protections provided to manufacturers of covered countermeasures under the PREP Act. On the contrary, it recognizes the importance of the liability protections, which are critical to encouraging the research and development of countermeasures both prior to and during a public health emergency. These protections help ensure that countermeasures "are made available during [a] pandemic without hesitation."[164] As noted

ineligible for medical review). *See Countermeasures Injury Compensation Program (CICP) Data*, *supra* note 134.

161. This figure was calculated by taking the total "petitioners' award amount" ($4,357,511,715.61) and dividing it by the number of awards compensated (8,696) as of March 1, 2022. *See* NATIONAL VACCINE INJURY DATA, *supra* note 156, at 9.

162. This figure was calculated by taking the total compensation paid under the CICP ($6,076,087.47) and dividing it by the number of claims compensated (29) as of February 1, 2022. *See Countermeasures Injury Compensation Program (CICP) Data*, *supra* note 134.

163. *See, e.g.*, *National Vaccine Injury Compensation Fund*, CHILD. HEALTH DEF., https://childrenshealthdefense.org/national-vaccine-injury-compensation-program/ (last visited Jan. 16, 2022) ("Despite Congress's intentions, [the VICP] has produced . . . insufficient compensation for the vaccine-injured."); Dorit Rubenstein Reiss, *COVID-19 Vaccine Liability — What are the Legal Facts and Limits*, SKEPTICAL RAPTOR (Dec. 20, 2020), https://www.skepticalraptor.com/skepticalraptorblog.php/COVID-19-vaccine-liability-what-are-the-legal-facts-and-limits/#Liability_limits_on_routine_vaccines (noting some drawbacks of the VICP, such as certain caps on compensation for pain and suffering).

164. *Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act: Hearing Before the Subcomitt. on Health of the H. Comm. on Energy & Commerce*, 115th Cong. 160 (2018) (Letter from Charles D. "Chuck" Johnson, Jr., President, Int'l Safety Equip. Association, to Hon. Greg Walden, Chairman, House Comm. on Energy & Commerce et al. (May 31, 2018)); *see also* Fleisher et al., *supra* note 132 ("When a public health emergency happens, we don't want manufacturers to be afraid of liability and not pursue a countermeasure that could save many, many lives." (quoting Dr. Vito Caserta, former director of the CICP)).

by President George W. Bush during a speech about the nation's influenza preparedness efforts, litigation represents "one of the greatest obstacles to domestic vaccine production."[165] To encourage and increase domestic vaccine development, President Bush stated that "Congress must pass liability protection for the makers of life-saving vaccines," a goal he accomplished through the PREP Act.[166]

This Article also does not intend to suggest that available COVID-19 vaccines and therapeutics are unsafe or likely to cause harm to a significant number of individuals. On the contrary, this Article is premised on the belief—as supported by current data—that the countermeasures' benefits outweigh their risks and that the FDA, CDC, other regulatory authorities, and the countermeasures' manufacturers all have robust procedures in place to perform post-authorization safety monitoring.[167] Further, although the evidentiary bar for issuing EUAs is lower than that required for full approval/licensure, the FDA took a relatively conservative approach to therapeutic and vaccine EUAs during the COVID-19 pandemic compared to prior EUAs. In general, the Agency required positive data from at least one randomized clinical trial to support an EUA. The FDA required larger trials for vaccines than for therapeutics and required COVID-19 vaccine manufacturers to conduct post-authorization observational studies to evaluate the association between the vaccine and certain adverse events.[168]

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165. Press Release, Office of the Press Sec'y, President Outlines Pandemic Influenza Preparations and Response (Nov. 1, 2005), https://georgewbush-whitehouse.archives.gov/news/releases/2005/11/20051101-1.html (providing transcript of speech given by President George W. Bush at the William Natcher Center, National Institutes of Health, in Bethesda, Maryland).

166. *Id.*; *see also The Next Flu Pandemic: Evaluating U.S. Readiness: Hearing Before the H. Comm. on Gov't Reform*, 109th Cong. (2005) (stating that to encourage companies to engage in U.S.-based vaccine manufacturing, "[w]e need protections against the liabilities that [such companies] face." (quoting Dr. Anthony Fauci, Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Inst. of Health)).

167. *Cf.* Press Release, Ctrs. for Disease Control & Prevention, FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review (Apr. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough ("The surveillance systems that are in place to monitor the safety of COVID-19 vaccines authorized for emergency use are working, as demonstrated by both agencies' quick work to identify and investigate these rare, but serious adverse events.").

168. *See, e.g.*, Letter from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, Food & Drug Admin., to Michelle Olsen, ModernaTX, Inc. 16 (Mar. 29, 2022), https://www.fda.gov/media/144636/download (letter authorizing the emergency use of Moderna's COVID-19 vaccine); Letter from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, Food & Drug Admin., to Ruta Walawalkar, Janssen Biotech, Inc. 9 (Nov. 19, 2021), https://www.fda.gov/media/146303/download (letter authorizing the emergency use of the Janssen COVID-19 vaccine); Letter from Denise M. Hinton, Chief Scientist, Food & Drug Admin., to Elisa Harkins, Pfizer Inc. 8 (May 10, 2021), https://www.fda.gov/media/144412/download (letter authorizing the emergency use of the Pfizer-BioNTech COVID-19 vaccine).

According to the CDC, "COVID-19 vaccines are safe and effective," and they are receiving "the most intensive safety monitoring in US history."[169] Some vaccine recipients experience no side effects, while others experience common vaccine side effects such as swelling, redness, pain at the injection site, tiredness, and headaches.[170] A small number of recipients may experience serious, but very rare, adverse events such as anaphylaxis, thrombosis with thrombocytopenia, myocarditis, pericarditis, or Guillain-Barré syndrome.[171] The CDC notes, however, that long-term health problems following any vaccine are "extremely unusual."[172] In fact, vaccine side effects typically occur within six weeks of receiving a vaccine.[173] Prior to authorization, the COVID-19 vaccines were required to be studied for at least eight weeks after the final dose.[174]

Despite the overall safety of COVID-19 vaccines, side effects can occur, a small proportion of which may be serious or even fatal.[175] Causation, however, can be difficult to prove, and reports of adverse events do not necessarily mean that a vaccine *caused* the event.[176] In fact, the CDC accepts reports of any adverse event following a vaccination, regardless of whether there is evidence of a causal link between the vaccine and the adverse event.[177] Nevertheless, because harms can occur, strong liability protections must be provided in conjunction with a robust no-fault compensation program for such harms. All medical products come with some risk. And the broader a product's use, the greater the number of individuals who may experience an adverse event. Indeed, this is expected once a product is used outside clinical trials, which can lead to the discovery of new, previously unknown/unexpected adverse events.[178]

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169. *Safety of COVID-19 Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 28, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.

170. *Id.*

171. *Id.*

172. *Id.*

173. *Possible Side Effects After Getting a COVID-19 Vaccine*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 12, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.

174. *Id.*

175. *Selected Adverse Event Reports after COVID-19 Vaccination*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 18, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

176. *Id.*

177. *Id.*

178. For example, the Fact Sheets for vaccine recipients and caregivers all state that the side effects listed in the Fact Sheet "may not be all the possible side effects" of the vaccine and that "serious and *unexpected* side effects may occur" (emphasis added). *See, e.g.*, PFIZER-BIONTECH, FACT SHEET FOR 12 YEARS OF AGE AND OLDER, *supra* note 143, at 5. MODERNA, FACT SHEET,

Just as liability protections are important to foster the research and development of countermeasures, a robust and effective compensation program proves similarly important to encourage the public to actually use these countermeasures when needed, especially among the most hesitant.

The public was asked to trust the vaccine development and distribution process,[179] and building public trust and confidence represents a critical component of increasing vaccine acceptance and instilling confidence in the countermeasure authorization process more generally. In exchange for such trust, the public needs assurance that in the rare event something does go wrong, they will not be left without recourse.[180] Surveys over the course of the pandemic show that the intent to get a COVID-19 vaccine increased steadily after hitting a low

supra note 143, at 4; JANSSEN, FACT SHEET, *supra* note 143, at 5; PFIZER-BIONTECH, FACT SHEET FOR AGES 5 THROUGH 11, *supra* note 143, at 4. A key purpose of postmarketing surveillance systems and requirements is to identify new or unexpected adverse events. *See Postmarketing Surveillance Programs*, U.S. FOOD & DRUG ADMIN. (Apr. 2, 2020), https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs ("Because all possible side effects of a drug can't be anticipated based on preapproval studies involving only several hundred to several thousand patients, FDA maintains a system of postmarketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug approval process."); *see also* Jamie Ducharme, *People are Reporting Unexpected Side Effects After COVID-19 Vaccination—But That's Actually Normal*, TIME (Apr. 22, 2021, 5:39 PM), https://time.com/5957222/covid-vaccine-side-effects/ ("There are bound to be more side effects observed and reported by the general population than are uncovered during a clinical trial . . . . Even side effects that were uncommon during clinical trials may affect a relatively large number of people once vaccines are widely distributed . . . ." (paraphrasing Dr. Stanley Perlman, Professor, Univ. of Iowa Carver Coll. of Med. and member of the FDA's vaccine advisory committee)).

179. *See, e.g.*, Ashley Kirzinger et al., *KFF COVID-19 Vaccine Monitor: July 2021*, KAISER FAMILY FOUND. (Aug. 4, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-july-2021/; Marissa Tansino, '*Trust the Process': Health Department Prepared to Store Vaccine, Says Widespread Use Needed to Stop COVID-19 Spread*, KARE11 (Dec. 3, 2020, 10:16 PM), https://www.kare11.com/article/news/local/covid-19-vaccine-health-department-prepared-to-store/83-c716d528-0bc8-4b62-9020-1d81e39c60bd (asking the public to trust the process, stating "[a]lthough vaccines were developed quickly over the course of this year, corners were not cut" (quoting Dr. Mandy Cohen, Sec'y, N.C. Dep't of Health & Hum. Servs.)); Joseph Spector, *Dr. Fauci Urges Governors to Accept FDA Approval of COVID Vaccine: 'It is a Sound Process'*, DEMOCRAT & CHRON. (Nov. 24, 2020, 5:00 AM), https://www.democratandchronicle.com/story/news/2020/11/24/fauci-covid-vaccine-safe-states-new-york-cuomo/6403986002/ (quoting Dr. Anthony Fauci, Dir., Nat'l Inst. of Allergy & Infectious Diseases, who asked states to "trust the process" of the development and review of COVID-19 vaccines).

180. Kendra Lippy, for example, was hospitalized for twenty-two days in the intensive care unit after she developed severe blood clots thought to be caused by the Johnson & Johnson/Janssen vaccine. Shinn, *supra* note 109. She is now hundreds of thousands of dollars in debt and wants to see the CICP, "a complex and opaque federal compensation system . . . improved." *Id.* (noting the backlog of cases in the VICP). *Cf.* Jennifer Schlesinger & Karina Hernandez, *Compensation for Victims of COVID Vaccine Injuries is Limited*, CNBC (Mar. 25, 2021, 8:00 AM), https://www.cnbc.com/2021/03/25/compensation-for-victims-of-covid-vaccine-injuries-is-limited.html (discussing amendments to the VICP, Rep. Lloyd Doggett (D-Tex.) stated that "[i]t will encourage confidence to know that in the extraordinarily unlikely event, maybe 1 in a mil-

point in 2020. Yet, as of February 2022, the percentage of adults saying they would "definitely not" get the vaccine (16%) had held relatively steady since December 2020.[181] Importantly, studies found that unvaccinated adults often expressed a lack of confidence in the safety of available vaccines.[182]

An effective, fair, and transparent compensation program can reduce hesitancy caused by a lack of trust,[183] concerns about safety,[184] and skepticism of liability protections.[185] A "robust and reassuring" compensation program "serves a dual role by protecting and guaranteeing compensation for those harmed by vaccines and by reassuring

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lion chance, that you suffer adverse consequences, that there is a fund there to protect you so that you are not saddled with big medical bills and other loss").

181. *KFF COVID-19 Vaccine Monitor*, KAISER FAMILY FOUND., https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor-dashboard/ (last visited Mar. 4, 2022). The percentage of Americans who said they would get a COVID-19 vaccine fluctuated throughout the pandemic. *Id.* According to data collected by the Pew Research Center in September 2020, 51% of U.S. adults said they "definitely" or "probably" would get a vaccine. Cary Funk & Alex Tyson, *Growing Share of Americans Say They Plan to Get a COVID-19 Vaccine – or Already Have*, PEW RESEARCH CENTER (Mar. 5, 2021), https://www.pewresearch.org/science/2021/03/05/growing-share-of-americans-say-they-plan-to-get-a-covid-19-vaccine-or-already-have/ . By February 2021, 19% had received at least one dose of the vaccine, and an additional 49% said they "probably" or "definitely" would get a vaccine. *Id.* In September 2020, 49% had said they "probably" or "definitely" would *not* get a vaccine, but by February 2021, this had decreased to 30%. *Id.*

182. Kirzinger et al., *supra* note 179.

183. Analyses by the Pew Research Center found that trust in the vaccine research and development process is tied strongly to attitudes and behaviors about vaccines. Funk & Tyson, *supra* note 181. Intent to receive a vaccine was seventy-five points higher among those with a high trust in the process. *Id.*

184. *Id.*

185. Shannon Kruner, clinical psychologist and executive director of Freedom of Religion–United Solutions, believes that much hesitancy "stems from 'the risk of injury and lack of liability that comes with vaccination.'" Hollie McKay, *What's Driving Coronavirus Hesitancy in US?*, FOX NEWS (Dec. 3, 2020, 4:42 PM), https://www.foxnews.com/health/coronavirus-hesitancy-what-is-driving-it. She also cites the accelerated development of the vaccines and "being forced to consume a product 'where injury is possible and where there is no liability.'" *Id.* Vaccine opponents frequently cite liability protections as a reason to not trust vaccines. *See e.g.*, Barbara Loe Fisher, *Vaccination: What's Trust Got to Do With It?*, NAT'L VACCINE INFO. CTR. (Sept. 13, 2020, 8:23:57 AM), https://www.nvic.org/nvic-vaccine-news/september-2020/vaccination-whats-trust-got-to-do-with-it.aspx ("Now the people are being told that there is one – and only one – simple solution to resolving the [COVID-19] crisis and getting back to normal: that is . . . for every person living in every country to get injected with one of the liability-free COVID-19 vaccines being fast tracked to market."); *Vaccine Safety Group Calls Liability Protection With No Compensation for the Vaccine Injured 'Heartless'*, INFECTION CONTROL TODAY (Jan. 17, 2003), https://www.infectioncontroltoday.com/view/vaccine-safety-group-calls-liability-protection-no-compensation-vaccine-injured ("If you combine mandated vaccines with no liability and no accountability for anyone involved, it is a prescription for injustice and abuse of the public trust." (quoting Barbara Loe Fisher, co-founder and president of the National Vaccine Information Center, a well-known anti-vaccine group)).

the broader public that these situations are exceptionally rare."[186] Angela Marie Wulbrecht, who experienced severe side effects after receiving the COVID-19 vaccine, said she still supports the vaccination campaign, "[b]ut it would help those who are hesitant if they took care of those of us who got injured."[187] As stated astutely by Professor Katherine Van Tassel, "if you're going to take one for the team, the team has to have your back. . . . That's a moral imperative."[188] The CICP cannot achieve this as currently structured.

B. Amending the Countermeasures Injury Compensation Program

A frequently proposed reform would require coverage of COVID-19 vaccines under the VICP rather than CICP.[189] This approach, however, proves problematic for a few reasons.

First, doing so would remove liability protections for certain categories of "covered persons" who are protected under the COVID-19 PREP Act Declaration but not the Vaccine Act, which only provides liability protections to vaccine manufacturers and administrators. For example, this would eliminate liability protections for covered persons such as program planners, retail pharmacies, private nursing homes, or other entities such as employers or schools involved in vaccine administration.[190]

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186. *The Path Forward on COVID-19 Immunizations: Hearing Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 117th Cong. 10 (2021) (written testimony of Ashish K. Jha, Professor of Health Servs., Policy, & Practice, Dean of the Sch. of Pub. Health, Brown Univ.) [hereinafter Written Testimony of Professor Jha].

187. Arthur Allen, *Federal Vaccine Court Hasn't Helped Those Whose Lives Were Altered by COVID-19 Shots*, L.A. TIMES (Aug. 17, 2021, 2:00 AM), https://www.latimes.com/science/story/2021-08-17/severe-covid-vaccine-injuries-help-federal-vaccine-court. Wulbrecht filed a claim in February 2021 with the CICP. *Id.* She received a note acknowledging her claim but as of August 2021, had not heard anything further. *Id.* She had to leave her job and has experienced "severe fatigue, brain fog, imbalance and other symptoms" since receiving the vaccine. *Id.* Even though she has health insurance, she has still paid at least $35,000 in out-of-pocket medical expenses. *Id.*

188. *Id.*; *see also Avian Flu Addressing the Global Threat: Hearing Before the H. Comm. on Int'l Relations*, 109th Cong. 52 (2005) ("[W]e cannot give millions of vaccinations knowing that there is going to be side effects, and leave these people high and dry if they are damaged." (quoting Sen. Dan Burton)); Jacquie Lee & Ian Lopez, *COVID-19 Vaccine Recipients Face Injury Payment 'Black Hole'*, BLOOMBERG L. (Mar. 23, 2021, 5:16 AM), https://news.bloomberglaw.com/health-law-and-business/covid-19-vaccine-recipients-face-injury-payment-black-hole ("If we're going to ask the soldiers to enter the battlefield of public health—which we need . . . to create the herd immunity that is so necessary for our collective well-being—we need to make sure when those soldiers are downed on the battlefield, they are cared for." (quoting Professor Nora Freeman Engstrom)).

189. Written Testimony of Professor Jha, *supra* note 186, at 10; Meyers, *supra* note 132, at 5; Katherine Van Tassel et al., *Covid-19 Vaccine Injuries — Preventing Inequities in Compensation*, 384 N. ENG. J. MED. e34(1), e34(2)–(3) (2021); Reiss, *supra* note 133.

190. 42 U.S.C. § 247d-6d(i)(6) (defining "program planner"); ADVISORY OPINION NO. 20-04, *supra* note 29, at 2–3 (discussing the definition of "program planner").

Second, the Vaccine Act provides less robust liability protections than the PREP Act. For example, the Vaccine Act generally only covers claims for injuries caused by receipt of a "properly prepared" vaccine that is "accompanied by proper directions and warnings."[191] Among others, claims relating to circumstances surrounding vaccine administration but unrelated to the vaccine itself, such as failure to obtain informed consent, or claims relating to failure to vaccinate due to short supply and purposeful allocation, would generally not receive protection.[192] The PREP Act provides broader coverage, going beyond claims related to the actual administration of the vaccine.[193]

Third, the VICP itself has faults and needs reforms. Amendments to the VICP have been proposed, such as (1) increasing staffing and funding, including an increase in the number of special masters that hear claims to reduce a backlog of cases and to ensure more timely decisions; and (2) increasing the caps on compensation to be adjusted for inflation.[194]

Lastly, simply transferring COVID-19 vaccines to the VICP would leave claims relating to other countermeasures subject to the inadequate CICP. While this Article focuses on vaccines, requests have been and will continue to be made for therapeutics, devices, and diagnostics.[195] All covered countermeasures should be subject to the same liability protections and compensation system. Thus, merely transferring COVID-19 vaccines to the VICP would be an inadequate and incomplete solution.

The following sections outline some of the key areas that should be addressed to make the CICP more effective, fair, and transparent.

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191. 42 U.S.C. § 300aa-22(b)(1).

192. Cheri Falvey et al., *PREP Act Protections for COVID-19 Vaccine Liability*, PHARMEXEC.COM (Jan. 10, 2021), https://www.pharmexec.com/view/prep-act-protections-for-covid-19-vaccine-liability.

193. As discussed in Part I.A., the PREP Act applies to:

> [*A*]*ny claim for loss* that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the *design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing*, or use of such countermeasure.

42 U.S.C. § 247d-6d(a)(2)(B) (emphasis added).

194. On June 1, 2021, Representatives Lloyd Doggett (D-Tex.) and Fred Upton (R-Mich.) introduced the Vaccine Injury Compensation Modernization Act of 2021. Among other things, the Act would increase the number of special masters to reduce the current case backlog, increase compensation based on inflation, and increase the statute of limitations to five years. *See* Vaccine Injury Compensation Modernization Act of 2021, H.R. 3655, 117th Cong. (1st Sess. 2021); *see also* Written Testimony of Professor Jha, *supra* note 186, at 10–11 (making recommendations); Shinn, *supra* note 109 (noting the backlog of cases in the VICP).

195. *See supra* note 139 and accompanying text.

These suggestions are not exhaustive, but rather a starting point to highlight major concerns. As the world emerges from an unprecedented global pandemic, reforms to the CICP are necessary to ensure that those injured by COVID-19 countermeasures receive the attention and compensation they deserve.

1. Funding

The CICP is likely unprepared to handle a pandemic of COVID-19's magnitude. During the H1N1 pandemic, for example, approximately 81–123 million Americans over the age of six months received the H1N1 vaccine.[196] In contrast, as of March 2, 2022, over 253 million Americans five years of age and older had received at least one dose of a COVID-19 vaccine.[197] Unlike the H1N1 vaccine data, which included the pediatric population over the age of six months, the COVID-19 numbers do not include the full pediatric population, as no COVID-19 vaccine is yet authorized or approved for use in children under five.[198] Furthermore, these numbers do not even consider claims that could be made for other COVID-19 countermeasures, such as therapeutics, devices, and diagnostics. As of March 4, 2022, over 821 million COVID-19 lab tests had been reported to the CDC.[199] And as of March 5, 2022, there have been over 79 million cases of COVID-19 in the United States reported to the CDC,[200] and some of these patients have certainly received a therapeutic countermeasure.

The number of claims that will be eligible for compensation from the CICP cannot be predicted, but thousands are already under re-

196. The total number of individuals who received the H1N1 vaccine is somewhat unclear, with different sources reporting different numbers. *Compare Final Estimates for 2009–10 Seasonable Influenza and Influenza A (H1N1) 2009 Monovalent Vaccination Coverage – United States, August 2009 through May, 2010*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 13, 2011), https://www.cdc.gov/flu/fluvaxview/coverage_0910estimates.htm (reporting 80.8 million persons over the age of six months received the H1N1 vaccine), *with* Tom Hals, *Americans Seek Compensation for Failed COVID-19 Treatments from U.S. Fund*, REUTERS (Mar. 11, 2021, 5:04 AM), https://www.reuters.com/article/us-health-coronavirus-usa-compensation/americans-seek-compensation-for-failed-covid-19-treatments-from-u-s-fund-idUSKBN2B31DH (stating that 123 million people received the H1N1 vaccine).

197. *COVID-19 Vaccinations in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 3, 2022), https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

198. *COVID-19 Vaccines for Children and Teens*, *supra* note 147.

199. *United States COVID-19 Cases, Deaths, and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 5, 2022), https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days (under "view," select "tests performed").

200. *Id.* (under "view," select "cases").

view and at least some will likely be eligible for compensation. The system and the Countermeasures Fund itself may be quickly overburdened, unable to review such a volume of requests in a timely manner and unable to compensate eligible claims adequately. The CICP's funding mechanism must therefore be improved. Even though Congress appropriated funds to various COVID-19 efforts and authorized the transfer of funds to the Countermeasures Fund,[201] it remains unclear whether any of the appropriated funds have been or will be transferred or how much money is in the Countermeasures Fund at this time.

The CICP needs a consistent and guaranteed source of funding prior to and/or upon the declaration of a public health emergency.[202] There are a few different ways to achieve this objective, alone or in combination:

- Mandatory Appropriations: Amendments to the PREP Act could require that appropriations be made to the Countermeasures Fund with every PREP Act declaration. The amount of the appropriation could depend, in part, on the total funds in the Countermeasures Fund at that time, the potential breadth and length of the applicable public health emergency, and the scope of the applicable PREP Act declaration (e.g., the number of countermeasures, persons, and activities covered). If the scope of a PREP Act declaration expands, such as through amendments to add other covered countermeasures, additional appropriations would need to be considered. Mandatory appropriations will ensure the Countermeasures Fund receives funding with every PREP Act declaration, unlike the current situation with COVID-19, in which funds have been appropriated that merely "may be" transferred to the Countermeasures Fund.[203]
- Excise Tax: Like the Vaccine Injury Compensation Trust Fund,[204] the Countermeasures Fund could be funded by an excise tax on each dose or unit of a covered countermeasure. But unlike the excise tax imposed on vaccines, which requires Con-

201. *See supra* notes 127–28 and accompanying text.

202. An ongoing, consistent source of funding is important because "[i]f a pandemic strikes and Congress were in a budget crisis, or merely underestimated the amount of funding the [CICP] would require," injured individuals "would be left 'high and dry' without recourse." Copper, *supra* note 14, at 92.

203. *See* Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281, 560–61 (2020); Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 146, 149 (2020).

204. *About the National Vaccine Injury Compensation Program*, *supra* note 155.

gress to pass legislation for each vaccine before it can be covered under the VICP (which can be a lengthy process), the excise tax should apply automatically once the product is deemed a covered countermeasure.[205] Because countermeasures are frequently (and at times exclusively) purchased by the government, it would be necessary to ensure that government contracts cannot carve out this excise tax.[206]

- User Fees: Various "user fee" acts provide the FDA with the authority to collect fees from companies that produce certain products.[207] With respect to drugs and vaccines, the Prescription Drug User Fee Act was passed by Congress in 1992 and authorizes the FDA to collect fees from entities that submit a human drug application to the FDA.[208] A human drug application is defined as "an application for—(A) approval of a new drug submitted under section 355(b) of [Title 21 of the U.S. Code, the FDCA], or (B) licensure of a biological product under subsection (a) of section 262 of [Title 42 of the U.S. Code, the PHSA]."[209] This definition does not include applications for an EUA, which are submitted pursuant to section 564 of the FDCA.[210] Thus, the user fee provisions of the FDCA could be amended to authorize the FDA to collect fees from EUA applicants.[211] A few reasons make this funding approach less ideal than others. It would likely require amendments to various pro-

205. *See* 26 U.S.C. § 4131 (1997); *id.* § 4132 (listing "taxable vaccines"). Proposals have been made to amend the relevant provisions of the Internal Revenue Code so that the excise tax is automatically imposed on vaccines that are added to the Vaccine Injury Table. *See, e.g.*, Vaccine Access Improvement Act of 2021, H.R. 3656, 117th Cong. (2021); Vaccine Access Improvement Act of 2019, H.R. 1973, 116th Cong. (2019).

206. Given that the federal government purchases other vaccines for which it would pay an excise tax under the VICP, such as childhood vaccines and the seasonal flu vaccine, it should not be an issue to impose an excise tax on countermeasure vaccines and other products purchased by the government. *See* Meyers, *supra* note 132, at 10. If for any reason an excise tax would not be feasible, then an analogous mechanism could be used. For example, for each purchase of a particular countermeasure, a specific percentage of the purchase price could be required to be allocated to the Countermeasures Fund.

207. *See, e.g.*, 21 U.S.C. § 379h (2017) (authorizing user fees for certain drugs and biologics (including vaccines)); *id.* § 379j (authorizing user fees for certain medical devices); *id.* § 379j-42 (authorizing user fees for certain human generic drugs).

208. *Id.* § 379h.

209. *Id.* § 379g(1).

210. *Id.* § 360bbb-3.

211. Because companies that receive EUAs are expected to continue to pursue full approval/licensure, which would subject them to the typical user fees for human drug applications, the user fees assessed on such companies at the time they file an application for full approval could take into consideration the amount already paid by such companies when they filed an EUA application.

visions of the FDCA[212] and may face opposition by companies that may be subject to these user fees. It may also discourage smaller biopharmaceutical companies from exploring potentially beneficial countermeasures prior to or during a public health emergency.[213] Further, user fees could have the unintended consequence of causing companies to increase the prices of their EUA products, which some companies made available on a not-for-profit basis during the pandemic.[214]

2. Accessibility and Equitability

The compensation program must also be fair, transparent, and accessible to all individuals who believe they were injured by a covered countermeasure. Claimants may benefit from the assistance of an attorney when navigating the complicated system and filing a request. Attorneys' fees, therefore, should be eligible for reimbursement, regardless of whether other compensation is awarded, for requests made in good faith and with a reasonable basis for the claim(s) brought.[215] Without reimbursement for attorneys' fees, individuals—particularly lower-income individuals—(1) may try to navigate the system without the benefit of an attorney, thus reducing their likelihood of success; (2) may not seek compensation at all; or (3) will face additional financial hardship by paying out-of-pocket for an attorney. Medical bills from a countermeasure-related injury already have a greater impact on low-income individuals, and the process to obtain compensation

212. For example, the Secretary can grant a waiver or reduction of user fees if the "waiver or reduction is necessary to protect the public health." 21 U.S.C. § 379h(d)(1)(A). An EUA applicant could typically make this argument. Further guidance and clarity would be needed as to how this provision would apply to EUA applicants if the law was amended to require user fees for EUA applicants.

213. This risk is mitigated by the fact that (1) an applicant can seek a waiver or reduction of the fees if the fees "would present a significant barrier to innovation because of limited resources available to such person or other circumstances" and (2) the Secretary must consider the assets of the applicant when determining whether to grant a waiver or reduction of fees. 21 U.S.C. § 379h(d)(1)(B), (2).

214. *See* Press Release, Johnson & Johnson, Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use – First Single-Shot Vaccine in Fight Against Global Pandemic (Feb. 27, 2021), https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-usefirst-single-shot-vaccine-in-fight-against-global-pandemic (stating that Johnson & Johnson's COVID-19 vaccine would be "available on not-for-profit basis for emergency pandemic use").

215. Under the VICP, even when a claim is otherwise not eligible for compensation, compensation may be awarded to cover reasonable attorneys' fees and other costs incurred in the proceedings "if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa-15(e)(1).

should not impose additional burdens or unnecessary barriers to those most in need of compensation.

Considering the emphasis on ensuring equitable distribution of COVID-19 vaccines and concerns about the disparate impact of the pandemic on low-income populations and people of color, a compensation program that is not equally accessible to all represents a tremendous oversight and exacerbates these disparities.[216] Furthermore, a compensation program structured in a way that makes it less accessible to certain populations could increase vaccine hesitancy among those populations, as it could suggest they are less worthy of receiving compensation for their injuries. Given the disparate impact of the COVID-19 pandemic on low-income populations and people of color, society must "provide strong safety nets and supports," including adequate injury compensation, to ensure that people feel comfortable using COVID-19 countermeasures.[217] People should not hesitate to use covered countermeasures when needed because they fear they will be left without recourse for injuries that could occur after using a countermeasure.[218]

In addition to payment of attorneys' fees, pain and suffering should be eligible for compensation. Furthermore, because inappropriately low recovery caps are "bound to be least generous to the most devastatingly disabled," the caps on compensation must be reassessed and adjusted periodically for inflation.[219]

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216. *See, e.g.*, Carlos Irwin A. Oronce et al., *Association Between State-Level Income Inequality and COVID-19 Cases and Mortality in the USA*, 35 J. OF GEN. INTERNAL MED. 2791, 2791 (2020) (finding that states with the highest level of income inequality had a larger number of COVID-19-related deaths compared to states with lower income inequality); Caroline Kelly et al., *Low-Income COVID-19 Patients Die Needlessly Because They Are Stuck in the Wrong Hospitals—While the Right Hospitals Too Often Shut Them Out*, HEALTH AFF. (Apr. 2, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210401.95800/full/ ("[L]ow-income COVID-19 patients continue to face barriers in accessing life-saving care . . . . Under our current health care system, the COVID-19 patients most likely to be treated at underresourced hospitals are often Medicaid recipients or uninsured, and many are people of color.").

217. *See* Van Tassel et al., *supra* note 189, at e34(2).

218. Prior experience suggests that concerns about compensation can impact one's willingness to use a countermeasure. For example, a survey of healthcare workers asked to volunteer for a smallpox vaccination found that 49% of workers who declined the vaccine believed their chances of being compensated were low or very low, compared to 23% of those who agreed to be vaccinated. Pascale M. Wortley et al., *Predictors of Smallpox Vaccination Among Healthcare Workers and Other First Responders*, 32 AM. J. PREVENTIVE MED. 538, 539 (2007).

219. Robert L. Rabin, *Some Thoughts on the Efficacy of a Mass Toxics Administration Compensation Scheme*, 52 MD. L. REV. 951, 976 (1993).

3. Statute of Limitations

The CICP requires a request to be submitted within one year of the date of the administration or use of the covered countermeasure alleged to have caused the injury.[220] Unlike the VICP, it does not provide for filing in relation to the date of death or date of the onset of the injury or symptoms. Even though long-term health problems are "extremely unusual" following any vaccination,[221] a one-year statute of limitations from the date of the use or administration of the covered countermeasure is far too short. Furthermore, therapeutic countermeasures may have long-term side effects that have yet to be discovered.[222] It takes time to determine whether an injury might be related to a covered countermeasure and thus eligible for compensation, and it also takes time to gather the information needed to file a claim with the CICP. At a minimum, the statute of limitations should be lengthened to mirror the limitations period of the VICP.

4. Transparency

The CICP's lack of transparency is problematic and needs to be addressed. First, requesters should have the opportunity to be more involved in the process after they file their requests. Like the VICP, there should be an opportunity for a hearing before an independent adjudicator (e.g., a special master) during which both parties can present evidence. Decisions should not be made behind closed doors. Currently, decisions can be at the sole discretion of the Secretary because the Secretary "*may*," but is not required to, obtain the opinions of qualified medical experts in making determinations concerning covered injuries.[223]

Importantly, decisions must be made public. Publishing the decisions will help inform potential requesters of the types of injuries that may be eligible for compensation and the types of information and evidence needed to be deemed eligible for compensation. Not only

220. 42 C.F.R. § 110.42(a).

221. *Safety of COVID-19 Vaccines*, *supra* note 169.

222. For example, an analysis of all 222 novel therapeutics approved by the FDA between January 1, 2001, and December 31, 2010, and monitored through February 28, 2017, found that the median time from approval to first "postmarket safety event" was 4.2 years, and the proportion of the drugs affected by a postmarket safety event at 10 years was 30.8%. *See* Nicholas S. Downing et al., *Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010*, 317 J. AM. MED. ASS'N 1854, 1854 (2017). This analysis looked at three types of postmarket safety events: (1) withdrawals due to safety concerns; (2) FDA issuance of boxed warnings to the product label after initial approval; and (3) FDA issuance of safety communications. *Id.* at 1856.

223. 42 C.F.R. § 110.20(a).

will this make the process more transparent, but it may also make the process more efficient and fair by preventing inconsistent or unsupported decisions[224] and discouraging individuals from filing unsupported claims.

Greater transparency can also help combat skepticism. It will allow individuals to better understand the potential risks of a countermeasure and provide confidence that recourse may be available if they are injured. Without greater transparency, "[t]he CICP 'is the perfect target'" for vaccine opponents and others who believe that unsafe countermeasures are being "foisted upon a vulnerable public."[225] As noted by Professor Peter Meyers, "an open and more forthcoming perspective" could help counteract the hesitancy some Americans feel about COVID-19 vaccines and other countermeasures.[226]

Since the beginning of the pandemic, the HRSA has made some progress toward greater transparency. Previously, very little information except the total number of claims filed, denied, and compensated was available to the public. The HRSA now provides additional details by listing the alleged injury and the category of the alleged countermeasure for filed claims.[227] Furthermore, for compensated claims, the HRSA now provides the compensation amount per claim.[228] To increase transparency further, the HRSA should list the total amount of money currently available in the Countermeasures Fund. An additional data point that may be helpful to put the injuries in context would be to include the total number of each type of countermeasure used in the United States as of the date of the report (e.g., "Of [x]

224. For example, making the decisions public could help counteract a concern about compensation programs noted by Professor Robert L. Rabin: that those making decisions "might exhibit undue conservatism in the face of a staggering volume of claims," which would result in inadequate compensation being provided to victims. Rabin, *supra* note 219, at 975–76.

225. Meyers, *supra* note 132, at 2 (quoting Wendy E. Parmet, *Pandemics, Popularism and the Role of Law in the H1N1 Vaccine Campaign*, 4 ST. LOUIS U. J. HEALTH L. POL'Y 113, 146 (2010)). Liability protections for vaccine manufacturers have been cited as one of the legal structures that leads to vaccine hesitancy and skepticism. *See* Eugene McCarthy, *The Regulatory Production of Vaccine Hesitancy*, 86 BROOK. L. REV. 81, 83 (2020).

226. Rebecca Lindstrom & Lindsey Basye, *A First Look at Injury Claims Associated with COVID-19 Treatments. On the List, Attempted Murder*, 11ALIVE (Apr. 22, 2021, 4:51 PM), https://www.11alive.com/article/news/investigations/the-reveal/covid-vaccine-injury-claims-investigated/85-8ca25ede-ac31-4192-ade3-e05711844b0b; *see also* Hals, *supra* note 196 ("It's important to have openness to gain the trust of the American public and to counter the vaccine hesitancy." (quoting Meyers)).

227. The HRSA does not list the specific manufacturer. Requesters must identify the alleged countermeasure generally, but they are not required to list the specific manufacturer or trade name on their claim. *See Countermeasures Injury Compensation Program (CICP) Data*, *supra* note 134.

228. *Table 2*, *supra* note 138.

doses of the COVID-19 vaccine administered in the United States, [y] claims have been filed seeking compensation for injury or death").

Absent these and other changes, the CICP will remain an inadequate solution for those potentially injured by covered countermeasures. The unprecedented magnitude of the COVID-19 pandemic makes it imperative to revisit and reform the CICP to ensure it is a fair, accessible, and transparent process.

Conclusion

The COVID-19 pandemic ushered in an era during which the expeditious research and development of safe and effective countermeasures were more important than ever before. The liability protections provided by the PREP Act helped make this happen. This Article builds from the premise that the PREP Act's liability protections are important and should be retained. That said, liability protections must go hand-in-hand with a robust no-fault compensation program. One need not come at the expense of the other, and a no-fault compensation program must not be a mere afterthought. This Article unpacked the inadequate and enigmatic no-fault CICP currently available to individuals injured by COVID-19 countermeasures and proposed possible reforms. Given the scale of the COVID-19 pandemic and the hundreds of millions of individuals who have used and will use COVID-19 countermeasures, the time is now to reform a relatively unknown and inadequate compensation program to ensure it is adequate, fair, and accessible to all.