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On December 31, 2019, health authorities in Wuhan, China, confirmed that countless individuals were being treated for pneumonia-like symptoms from an unknown source.¹ Shortly thereafter, that source was identified as SARS-CoV-2, a novel coronavirus disease known as COVID-19.² COVID-19 has since plagued the entire globe, hundreds of millions of people have been infected, and millions of others have lost their lives.³ While this respiratory illness might be microscopic to the human eye, the effects of COVID-19 have changed the day-to-day lives of all.⁴

On January 21, 2020, the first case of COVID-19 in the United States was confirmed in the state of Washington.⁵ As of December 14, 2021, one case multiplied into a total of over 50,000,000 cases of COVID-19 and over 797,000 deaths.⁶ The United States acted swiftly to protect the interest of the health and safety of its citizens from COVID-19. Mask mandates and social distancing were rapidly implemented to slow down the spread of COVID-19.⁷ Life since the onset of COVID-19 has changed substantially, from the declaration of a global health emergency⁸ and mandatory lockdowns,⁹ to record-breaking unemployment rates¹⁰ and social interactions hosted via online platforms;¹¹ the list is extensive and the impact unsurpassed.

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¹ *First Travel-related Case of 2019 Novel Coronavirus Detected in United States*, CDC (Jan. 21, 2020), <https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html>.

² Brenda L. Tesini, *Coronavirus and Acute Respiratory Syndromes (COVID-19, MERS, and SARS)*, MERCK MANUAL PROFESSIONAL VERSION, <https://www.merckmanuals.com/professional/infectious-diseases/respiratory-viruses/coronaviruses-and-acute-respiratory-syndromes-covid-19-mers-and-sars> (last updated Sept. 2021).

³ Eric Schumaker, *Timeline: How coronavirus got started*, ABC NEWS (Sept. 22, 2020), <https://abcnews.go.com/Health/timeline-coronavirus-started/story?id=69435165>.

⁴ Fortune Staff & Rachel Lobdell, *One year later: 15 ways life has changed since the onset of the COVID pandemic*, FORTUNE (Mar. 9, 2021), <https://fortune.com/2021/03/09/covid-pandemic-how-life-has-changed-coronavirus-one-year-later-march-2020/>.

⁵ CDC, *supra* note 1.

⁶ *Coronavirus in the U.S.: Latest Map and Case Count*, THE NEW YORK TIMES, <https://www.nytimes.com/interactive/2021/us/covid-cases.html> (last updated Dec. 14, 2021).

⁷ Rebekah E. Gee, et al., *Mask Mandates: A Public Health Framework For Enforcement*, HEALTH AFFAIRS BLOG (Oct. 5, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20201002.655610/full/>.

⁸ Schumaker, *supra* note 3.

⁹ FT Visual & Data Journalism Team, *Lockdowns compared: tracking governments' coronavirus response*, FINANCIAL TIMES (Aug. 11, 2021), <https://ig.ft.com/coronavirus-lockdowns/>.

¹⁰ Rakesh Kochhar, *Unemployment rose higher in three months of COVID-19 than it did in two years of the Great Recession*, PEW RESEARCH CENTER (June 11, 2020), <https://www.pewresearch.org/fact-tank/2020/06/11/unemployment-rose-higher-in-three-months-of-COVID-19-than-it-did-in-two-years-of-the-great-recession/>; see *How to Protect Yourself & Others*, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html> (last updated Aug. 12, 2021).

¹¹ Minh Hao Nguyen, et al., *Changes in Digital Communications During the COVID-19 Global Pandemic: Implications for Digital Inequality and Future Research*, SAGE JOURNALS (Sept. 9, 2020), <https://journals.sagepub.com/doi/full/10.1177/2056305120948255>.

From the onset of this highly contagious respiratory disease, equitable access to safe and effective vaccines was critical to quelling the beast of COVID-19.¹² With all hands on deck, dedicated scientific and health professionals effectively collaborated and worked tirelessly to expedite the development of COVID-19 vaccines for consumer use.¹³ However, this achievement was not without a price. Due to the circumstances, the government wanted manufacturers to develop vaccines at a rapid rate.¹⁴ As a result, manufacturers and health care providers expected protection from multimillion-dollar lawsuits.¹⁵ Simply put, vaccines do not always go as planned. Whether administering the vaccine or through adverse side effects, history has proven that sometimes the vaccine itself can be more deadly than the disease it seeks to cure.¹⁶ In exchange for immunity from lawsuits “[i]n the wake of rising COVID-19 infections, many private companies [continued] work[ing] to develop antiviral drugs that will be effective against the novel virus.”¹⁷

I. The PREP Act and COVID-19 Vaccines

On March 17, 2020, Alex Azar, acting as Secretary of Health and Human Services (“HHS”), declared a public health emergency pursuant to the Public Readiness and Emergency Preparedness Act (“PREP Act”).¹⁸ The breadth and scope of the PREP Act is wide, and in sum explains that COVID-19 tests, drugs, and vaccines are warranted liability protections from tort claims.¹⁹ As stated by Rogge Dunn, a labor and employment attorney, “It is very rare for a blanket immunity law to be passed,” this immunity, in turn, will last until 2024.²⁰ Merely nine months after the PREP Act was invoked, on December 11, 2020, the U.S. Food and Drug Administration (“FDA”) issued the first emergency use authorization for a vaccine, *Pfizer BioNTech COVID-19*; this vaccine was to be distributed in the United States for deterrence of COVID-19 and the building

¹² *COVID-19 vaccines*, WORLD HEALTH ORGANIZATION, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/COVID-19-vaccines> (last visited June 20, 2021).

¹³ *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine*, FDA (Dec. 11, 2020), <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>.

¹⁴ See Susan Decker & Valerie Bauman, *Drugmakers Shielded from COVID Vaccine Liability But Funds for Injury Claims in Doubt*, INSURANCE JOURNAL (Aug. 14, 2020), <https://www.insurancejournal.com/news/national/2020/08/14/579150.htm>.

¹⁵ *Id.*

¹⁶ See Brooke Kim & Jessica C. Wilson, *COVID-19: Tort immunity for vaccines and antivirals – lessons from the swine flu of 1976*, DLA PIPER, (Apr. 8, 2020), <https://www.dlapiper.com/en/us/insights/publications/2020/04/covid-19--tort-immunity-for-vaccines-and-antivirals/> (explaining that the federal government’s rapid decision to produce the swine flu vaccine resulted in more injuries to the public than it did in intending to help the public).

¹⁷ Kenya S. Woodruff, *COVID-19 and PREP Act Immunity*, THE NATIONAL LAW REVIEW (Aug. 5, 2020), <https://www.natlawreview.com/article/covid-19-and-prep-act-immunity>.

¹⁸ *Expanding the COVID-19 Vaccination Workforce*, DEPARTMENT OF HEALTH & HUMAN SERVICES - USA, <https://www.phe.gov/emergency/events/COVID19/Documents/covid19-vaccination-wrkfrc-factsheet-508.pdf> (last visited Sept. 18, 2021).

¹⁹ *Id.*

²⁰ MacKenzie Sigalos, *You can’t sue Pfizer or Moderna if you have severe Covid vaccine side effects. The government likely won’t compensate you for damages either*, CNBC, <https://www.cnbc.com/2020/12/16/covid-vaccine-side-effects-compensation-lawsuit.html> (last updated Dec. 23, 2020).

of herd immunity.²¹ However, great tension arose amongst society when COVID-19 vaccines were only available to healthcare personnel, long-term care facility residents, those who were sixty-five and older, and those who suffered from underlying health conditions.²² Although this was at first the case, today in the United States, COVID-19 vaccines are available to those over the age of five who wish to get vaccinated.²³ COVID-19 vaccines can be found in local doctors' offices, retail pharmacies, hospitals, clinics, and even car drive-throughs.²⁴ As of December 9, 2021, there were 200,717,387 fully vaccinated Americans, equivalent to 60.5% of the country's population.²⁵ Additionally, as of December 10, 2021, the FDA has authorized three COVID-19 vaccines; Pfizer-BioNTech, Moderna, and Johnson & Johnson's Janssen.²⁶

Although a sigh of relief was felt by the nation, the question still posed by many individuals involves the potential side effects and the right to bring a claim if something goes wrong. This comment (1) unravels and argues the appropriateness of the stringent limitations the PREP Act's immunity provisions have had in preempting injured individuals to recover compensation for harm experienced from the vaccine; (2) discusses the current remedies that injured individuals have; and (3) proposes solutions for how the federal government can provide support to those individuals who have suffered such injuries.

II. Scope of The PREP Act: Limitations On COVID-19 Liability

The legislative history and evolution of the PREP Act can be traced back to 1798, where the first Public Health Service Act gave permission to marine hospitals to care for American merchant seamen.²⁷ Since then, the PREP Act has evolved significantly, and subsequent legislation has paved the path to protect and advance "better *national* health."²⁸ Under the PREP Act, 42 U.S.C. § 247D, the HHS is authorized to respond to public health emergencies as well as

²¹ FDA, *FDA Approves First COVID-19 Vaccine: Approval Signifies Key Achievement for Public Health*, FDA NEWS RELEASE (Aug. 23, 2021), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

²² Corey Stieg, *When Dr. Fauci and other experts say you can expect to get vaccinated for COVID-19*, CNBC MAKE IT (Dec. 14, 2020), <https://www.cnbc.com/2020/12/14/who-gets-the-covid-vaccine-first-timeline-and-priority-explained.html>.

²³ *COVID-19 Vaccines for Children and Teens - Most Children and All Teens Can Get COVID-19 Vaccines*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Frecommendations%2Fadolescents.html (last updated Nov. 4, 2021).

²⁴ *Id.*

²⁵ Katie Adams, *States ranked by percentage of population fully vaccinated: June 17*, BECKER'S HOSPITAL REVIEW (June 17, 2021), <https://www.beckershospitalreview.com/public-health/states-ranked-by-percentage-of-population-vaccinated-march-15.html>.

²⁶ *Different COVID-19 Vaccines*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html> (last updated Dec. 14, 2021); Alyssa Billingsley, PharmD, *FDA COVID-19 Vaccine Approval: Live Updates on Pfizer, Moderna, and J&J Vaccines*, GOODRX HEALTH, <https://www.goodrx.com/conditions/covid-19/fda-covid-19-vaccine-approval-updates> (last updated Dec. 10, 2021) (currently Pfizer-BioNTech has obtained full FDA approval while Moderna and Johnson & Johnson's Janssen are still under Emergency Use Authorization).

²⁷ Ramunas Kondratas, Ph.D., *Images from the History of the Public Health Service, Disease Control and Prevention*, U.S. NATIONAL LIBRARY OF MEDICINE, https://www.nlm.nih.gov/exhibition/phs_history/seamen.html (last updated Jan. 5, 2012).

²⁸ Franklin D. Roosevelt, *Statement of the President on Signing the Public Health Service Act.*, THE AMERICAN PRESIDENCY PROJECT (July 1, 1944), <https://www.presidency.ucsb.edu/node/210871>.

any matters related to its federal public health and medical responses.²⁹ The HHS’s role is pivotal in the procedures of the PREP Act because this position holds the authority to use broad discretion, and such decisions are not subject to judicial review.³⁰

In December of 2005, the assigned secretary at the time used the authority granted within his role to add Sections 319F-3 and 319F-4 as amendments to the PREP Act.³¹ These sections respectively addressed the liability immunity and the creation of a means of compensation for those injured by individuals and entities classified as “covered persons.”³²

The PREP Act provides that “covered persons” include:

- (A) the United States; or
- (B) a person or entity that is—
 - (i) a manufacturer of such countermeasure.
 - (ii) a distributor of such countermeasure.
 - (iii) a program planner of such countermeasure.
 - (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or
 - (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).³³

Thus, when the HHS invokes the PREP Act, such declaration will hold “covered persons” as immune “from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.”³⁴ Furthermore, such countermeasures include qualified pandemic or epidemic products, a security countermeasure, a drug, or a respiratory protective device approved by the National Institute for Occupational Safety and Health that the HHS deems as a priority throughout the course of a public health emergency.³⁵

The PREP Act authorizes the Secretary of Health and Human Services to issue a Declaration that provides immunity to claims against liability to certain individuals and entities.³⁶ However, claims subject to willful misconduct will not warrant such protection, and the Secretary

²⁹ *HHS Legal Authorities Related to Disasters and Emergencies*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES <https://www.phe.gov/Preparedness/planning/authority/Pages/default.aspx> (last updated June 16, 2021).

³⁰ See 42 U.S.C. § 247d-6d(b)(7).

³¹ *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, FEDERAL REGISTER THE DAILY JOURNAL OF THE UNITED STATES GOVERNMENT (Mar. 17, 2020), <https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>.

³² § 247d-6d(a)(1).

³³ § 247d-6d(i)(2).

³⁴ *Lopez v. Life Care Ctrs. of Am., Inc.*, No. CV 20-0958 JCH/LF, 2021 U.S. Dist. LEXIS 56102, at *10 (D.N.M. Mar. 24, 2021).

³⁵ § 247d-6d. (A “covered person” under the parameters of the PREP Act constitutes: “(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b)”).

³⁶ David W. Ogden, et al., *COVID-19: Immunity Under the PREP Act: When Does It Apply to Private Sector Efforts to Help Combat COVID-19?*, WILMER HALE (Mar. 30, 2020), <https://www.wilmerhale.com/en/insights/client-alerts/20200330-immunity-under-the-prep-act-when-does-it-apply-to-private-sector-efforts-to-help-combat-covid19>.

has the discretion to amend as circumstances permit.³⁷ Willful misconduct in the purview of the PREP Act is defined by Congress as an act with the intention of bringing about a wrongful purpose or a disregard for a known risk that is greatly outweighed by any intended benefit.³⁸ Specifically, in order for a plaintiff to successfully litigate a claim against liability, there must be *clear and convincing evidence* to support its contention; as such, this burden of proof makes it virtually *impossible* for these individuals to recover remedies or damages.³⁹ In addition, the individual must demonstrate that the “covered persons[’]” “willful misconduct” was the proximate cause of the injury or death, a substantially high burden to prove.⁴⁰

III. COVID-19 Brings Amendments to The PREP Act: An Expansion of Immunity

The discretion of the HHS to make amendments to the PREP Act at any time broadens the immunity for “covered persons,” but narrows and greatly restricts the ability for injured individuals to successfully litigate their claim in a court of law.⁴¹ On January 28, 2021, HHS Secretary Azar used the broad discretion granted within his role to authorize the fifth amendment to the PREP Act.⁴² This amendment, out of the nine that have been enacted as of July 2021 due to the COVID-19 pandemic, broadened the category of individuals authorized to administer the COVID-19 vaccines.⁴³ The HHS’s goal for this amendment was to ensure that vaccine supply was more widely available and that the demands of the nation were being met, and to alleviate the enormous influx of patients in state health departments.⁴⁴ To place this amendment into perspective, it allowed for any physician, registered nurse, or practical nurse whose *license expired* within the past five years to administer COVID-19 vaccinations.⁴⁵ The mere prerequisite was that any of the above-mentioned professionals must undergo an on-site observation period by a practicing health care professional.⁴⁶ Further, this amendment preempted conflicting state law; if a state’s law conflicts with a provision granted within the scope of the PREP Act, the amendment will prevail

³⁷ *Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule*, FEDERAL REGISTER THE DAILY JOURNAL OF THE UNITED STATES GOVERNMENT, (Oct. 15, 2010), <https://www.federalregister.gov/documents/2010/10/15/2010-25110/countermeasures-injury-compensation-program-cicp-administrative-implementation-interim-final-rule>.

³⁸ See § 247d-6d(c)(1)(A).

³⁹ Kyle W. Robisch, *Litigating COVID-19 Claims in Florida- A Lawyer’s Guide*, BRADLEY (July 6, 2021), <https://www.bradley.com/insights/publications/2021/07/litigating-covid19-claims-in-florida-a-lawyers-guide>.

⁴⁰ See Cornell Law School, *Clear and Convincing Evidence*, LEGAL INFORMATION INSTITUTE https://www.law.cornell.edu/wex/clear_and_convincing_evidence; see also Kinsey-Sallis & Owens, *infra* note 54.

⁴¹ § 247d-6d(b)(4).

⁴² *Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, FEDERAL REGISTER THE DAILY JOURNAL OF THE UNITED STATES GOVERNMENT (Feb. 2, 2021),

<https://www.federalregister.gov/documents/2021/02/02/2021-02174/fifth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical>.

⁴³ Public Readiness and Emergency Preparedness Act, *COVID-19 PREP Act Declarations*, PHE, <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx> (last visited Nov. 6, 2021).

⁴⁴ *HHS Amends PREP Act Declaration to Increase Workforce, HHS Authorized to Administer COVID-19 Vaccines*, HHS (Jan. 28, 2021), <https://www.hhs.gov/about/news/2021/01/28/hhs-amends-prep-act-declaration-increase-workforce-authorized-administer-covid-19-vaccines.html>.

⁴⁵ *U.S. States and Territories Expediting Licensure for Inactive, Retired Licensees in Response to COVID-19*, FSMB (July 9, 2021), <https://www.fsmb.org/siteassets/advocacy/pdf/states-expediting-licensure-for-inactive-retired-licensees-in-response-to-covid19.pdf> (emphasis added).

⁴⁶ HHS, *supra* note 44.

over the state law.⁴⁷ The language of the PREP Act “indicates not that any and all state claims related to COVID-19 are preempted, but only those that conflict with or differ from the PREP Act are preempted.”⁴⁸ As a result, the PREP Act preempts and supersedes any state law passed that would otherwise prohibit such healthcare professionals from ordering and administering authorized COVID-19 countermeasures.⁴⁹

As recently as March 12, 2021, the HHS amended the PREP Act once again to include the Seventh Amendment.⁵⁰ “Covered persons” included trained individuals who prescribe, dispense, and administer COVID-19 countermeasures, even if it is not within their scope of license or responsibilities.⁵¹ The acting Secretary deemed this important due to the urgent need to expand the number of individuals who could administer the COVID-19 vaccines to respond effectively to the pandemic.⁵² Nonetheless, the amendments expanded the scope of immunity while injured individuals’ ability to litigate their claims narrowed.⁵³

IV. Bringing A Claim Against “Covered Persons” – In A Nutshell

The broad immunity issued by the HHS makes an injured individual’s claim difficult to survive beyond the statutory immunity of 42 U.S.C. § 247-6d.⁵⁴ In addition, many states have adopted legislation to deter certain COVID-19-related lawsuits and weed out meritless claims.⁵⁵ For an individual to start a COVID-19 claim in a court of law, the plaintiff must first file a complaint and plead with *particularity*, a standard which in most instances is reserved for cases that involve fraud or mistake.⁵⁶ If the complaint does not meet the *particularity* requirement, it will be dismissed.⁵⁷ Furthermore, if the court determines that the complaint meets the requirement of *particularity* and has the appropriate affidavit attached, the court will then determine if “the defendant made a good faith effort to substantially comply with authoritative or controlling

⁴⁷ § 247d-6d(b)(8).

⁴⁸ *Khalek v. S. Denver Rehab.*, No. 1:20-cv-02240-RBJ, 2021 U.S. Dist. LEXIS 113165, at *13 (D. Colo. June 11, 2021).

⁴⁹ Department of Health and Human Services; Health Resources and Services Administration; Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration, 86 Fed. Reg. 14462 (Mar. 16, 2021) (Applicable to “Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered.”).

⁵⁰ Jesse Coleman & Andrew del Junco, *Seventh Amendment to Prep Act Declaration Further Increases the Pool of Authorized COVID-19 Vaccinators*, JD SUPRA (Mar. 30, 2021), <https://www.jdsupra.com/legalnews/seventh-amendment-to-prep-act-2855828/>.

⁵¹ *Id.*

⁵² 86 Fed. Reg. 14462, *supra* note 49.

⁵³ *Khalek*, No. 1:20-cv-02240-RBJ.

⁵⁴ LaKisha M. Kinsey-Sallis & Brett P. Owens, *Florida’s New Law Shields Various Businesses, Institutions, and Healthcare Providers Against COVID-19 Liability*, FISHER PHILLIPS (Mar. 31, 2021), <https://www.fisherphillips.com/news-insights/floridas-new-law-shields-various-businesses.html>.

⁵⁵ *Florida Adopts New Covid-19 Civil Liability Limitations*, DUANE MORRIS (Apr. 5, 2021), https://www.duanemorris.com/alerts/florida_adopts_new_covid19_civil_liability_limitations_0421.html.

⁵⁶ Kinsey-Sallis & Owens, *supra* note 54 (emphasis added).

⁵⁷ 42 U.S.C.S. § 247d-6d.

government-issued health standards or guidance at the time the cause of action accrued.”⁵⁸ Generally, where a defendant has complied with the good faith effort standard, that defendant shall be immune from civil liability, and the claim will be dismissed; however, if the defendant has not done so, the plaintiff may proceed with their claim.⁵⁹ Following the complaint, the defendant will present affirmative defenses arguing that the manufacturer or health care professional has no liability for a COVID-19-related claim.⁶⁰ Furthermore, the plaintiff bears the burden of proof by clear and convincing evidence – which, if the plaintiff satisfies such a heavy burden, the defendant will have to, by a greater weight of evidence, show that there was no liability to the injured individual.⁶¹ The statute of limitations for bringing a civil COVID-19-related claim is within one year of the cause of action.⁶²

V. The Reality

The goal of affording immunity to pharmaceutical manufacturers and health care professionals is to incentivize the development and administration of COVID-19 vaccinations and countermeasures.⁶³ Yet, the PREP Act immunity does not provide much, if any, protection to individuals injured from COVID-19 vaccinations because there is no party to hold accountable in a court of law.⁶⁴ Injured individuals cannot sue the FDA either, because the authorization of the COVID-19 vaccines during a public health emergency preempts individuals from bringing a claim.⁶⁵ Additionally, injured individuals cannot hold their employers liable for vaccine adverse events, even if that employer has mandated the requirement of the vaccine as a condition of employment.⁶⁶ As a result of litigation impediments placed on a plaintiff and the substantially high burden, bringing a claim into the scope of PREP Act litigation is nearly impossible.⁶⁷ Although this is presented as a remedy for injured plaintiffs, it is unmistakably an additional layer or shield for “covered persons.”⁶⁸

⁵⁸ April Boyer & Rio J. Gonzalez, *COVID-19: Shielding Businesses And Health Care Providers Acting In Good Faith, Florida Passes Protections For Civil Liability Relating To Covid-19*, K&L GATES (Mar. 30, 2021), <https://www.klgates.com/Shielding-Businesses-and-Health-Care-Providers-Acting-in-Good-Faith-Florida-Passes-Protections-for-Civil-Liability-Relating-to-COVID-19-3-30-2021>.

⁵⁹ *Id.*

⁶⁰ See 42 U.S.C. § 247d-6d.

⁶¹ 42 U.S.C. §§ 247d-6d(b)(6) & (c)(3)-(4).

⁶² Jodie Fleischer, et al., *Critics Question Vaccine Injury Compensation Program Readiness as Covid-19 Claims Come In*, NBC MIAMI (Feb. 25, 2021), <https://www.nbcmiami.com/investigations/critics-question-vaccine-injury-compensation-program-readiness-as-covid-19-claims-come-in/2392118/>.

⁶³ Samuel A. Garner, *Immunity from Liability under the U.S. Prep Act for Medical Countermeasures during the SARS-COV-2/ COVID-19 Pandemic*, BRYAN CAVE LEIGHTON PAISNER (May 22, 2020), <https://www.bclplaw.com/en-US/insights/immunity-from-liability-under-the-us-prep-act-for-medical-countermeasures-during-the-sars-cov-2COVID-19-pandemic.html>.

⁶⁴ Glenn Kessler, *The false claim that the fully-approved Pfizer vaccine lacks liability protection*, THE WASHINGTON POST (Aug. 30, 2021), <https://www.washingtonpost.com/politics/2021/08/30/false-claim-that-fully-approved-pfizer-vaccine-lacks-liability-protection/>.

⁶⁵ Sigalos, *supra* note 20.

⁶⁶ *Id.*

⁶⁷ Robisch, *supra* note 39.

⁶⁸ Sigalos, *supra* note 20.

a. The Last Resort

42 U.S.C. § 247 delegates the authority to the HHS to oversee the compensation program of the Administrator of the Health Resources and Services Administration.⁶⁹ In efforts to remedy those injured by a vaccine, in 2009, Congress created the Countermeasures Injury Compensation Program (“CICP”) and National Vaccine Injury Compensation Program (“VICP”).⁷⁰ “The Act provides a civil remedy to compensate individuals through the Countermeasures Injury Compensation Fund for injuries resulting from the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures.”⁷¹ Importantly, this sole and nearly impossible avenue is much narrower than the PREP Act itself; its compensation is contingent on whether the individual has suffered death or serious injury resulting in hospitalization by a COVID-19 vaccine, in order to recover for reasonable medical expenses, loss of employment income, and in the case of death, survivor benefits.⁷² If the injured individual brings a claim under the CICP and accepts compensation, they waive any tort claim from the injury sustained in either federal or state court.⁷³ As of October 1, 2021, there has been a total 3,158 COVID-19-related claims filed with the federal program, 1,357 of which are due to an injury associated with the COVID-19 vaccination.⁷⁴

Despite the efforts of Congress to provide such funds to injured individuals, the CICP rarely compensates individuals for their filed claims, approximately 90% of claims are rejected.⁷⁵ In other words, since 2009, the CICP program has only compensated twenty-nine claims related to the H1N1 and the smallpox vaccines, one of which included a shoulder injury.⁷⁶ Those twenty-nine claims came from a total of 449 initial claims filed.⁷⁷ The CICP places extreme limitations on the recovery and procedural aspect of its process; it does not allow injured individuals the right to appeal the decision of the CICP, and there is no recovery allowed for legal fees or pain and suffering.⁷⁸ The absence of statutorily provided attorney’s fees directly disincentivizes qualified attorneys from representing injured individuals in these claims.⁷⁹

⁶⁹ *Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule*, 75 FED. REG. 63, 655 (Oct. 15, 2010).

⁷⁰ KEVIN J. HICKEY, CONG. RSCH. SERV. LSB 10443, *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures* (2021).

⁷¹ *Gunter v. CCRC OPCO-Freedom Square, LLC*, No. 8:20-cv-1546-T-36TGW, 2020 U.S. Dist. LEXIS 201622, at *8 (M.D. Fla. Oct. 29, 2020).

⁷² Jennifer Schlesinger & Karina Hernandez, *Compensation for victims of Covid vaccine injuries is limited*, CNBC (Mar. 25, 2021), <https://www.cnbc.com/2021/03/25/compensation-for-victims-of-covid-vaccine-injuries-is-limited.html>.

⁷³ *PREP Act Q&As*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx> (last visited Nov. 16, 2021).

⁷⁴ *Countermeasure Injury Compensation Program (CICP) Data*, HRSA, <https://www.hrsa.gov/cicp/cicp-data#table-1> (last updated Oct. 1, 2021).

⁷⁵ Schlesinger & Hernandez, *supra* note 72.

⁷⁶ *Id.*

⁷⁷ Leah Easterby, *Can I Sue If I’m Harmed by the Coronavirus Vaccine?*, NOLO, <https://www.nolo.com/legal-encyclopedia/can-i-sue-if-im-harmed-by-the-coronavirus-vaccine.html> (last visited Oct. 23, 2021).

⁷⁸ *Id.*

⁷⁹ See Kathleen M. Loucks, *What Happens If I Am Injured By Covid-19 Related Care Or A Vaccine?*, LOMMEN ABDO (Apr. 15, 2020), <https://www.lommen.com/what-happens-if-i-am-injured-by-covid-19-related-care-or-a-vaccine/>.

i. “Black Hole Claims”

Not only are the rights of an injured individual limited in the chances of recovery and resources available, the CICIP does not provide a specific court or judge.⁸⁰ Claims made through the CICIP are often referred to as “black hole claims,” because generally, those who deal with the injured plaintiff’s claim are “nameless” administrators.⁸¹ Despite the extensive restrictions, such compensations are necessary resources for society; it has been predicted that nearly 6,000 individuals across the United States may suffer an adverse reaction to the COVID-19 vaccine.⁸² Therefore, a well-functioning system is necessary to address the remedies provided to those injured individuals.

ii. Procedural Steps Under the CICIP

With the above in tow, for an individual to receive compensation under the CICIP, the plaintiff must exhaust any and all available remedies in order to qualify for the CICIP federal fund program provided to those injured from a COVID-19 countermeasure.⁸³ First, the plaintiff’s statute of limitation for filing a claim with the CICIP is one year from the date of the suffered injury or death related to the COVID-19 vaccination or countermeasure.⁸⁴ Additionally, the claimant’s injury must result in either hospitalization, disability, or death.⁸⁵ More importantly, an individual seeking compensation under the CICIP must be aware that determinations are made by the Secretary, and the Secretary is the ultimate decisionmaker regarding qualifications for eligibility of funding.⁸⁶ If the CICIP determines that the case does not qualify for benefits, the injured party may request a reconsideration of their case and must send the notice in writing within sixty days of the determination of ineligibility.⁸⁷

**iii. Injuries Associated With COVID-19 Vaccines:
(1) Adverse Reactions and (2) Shoulder Injuries**

The most common injury that has been reported to the CICIP is a shoulder injury known as SIRVA.⁸⁸ The cause of SIRVA arises from the techniques used in administering a vaccine, such

⁸⁰ *COVID-19 VACCINE INJURY COMPENSATION PROGRAMS*, MCTLAW, <https://www.mctlaw.com/vaccine-injury/vaccinations/coronavirus-covid-19/> (an assigned judge can ease the process of claims entering the courts by providing legal support to claims brought by injured individuals and the judges ability to process remedies).

⁸¹ *Id.*

⁸² Schlesinger & Hernandez, *supra* note 72.

⁸³ 42 U.S.C. § 247d-6e(d)(1).

⁸⁴ Health Resources & Services Administration (HRSA), *How to File and Deadline for Filing*, <https://www.hrsa.gov/get-health-care/conditions/counter-measures-comp/howtofile.html> (last visited Nov. 17, 2021).

⁸⁵ *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures*, CRS LEGAL SIDEBAR, LSB10443, 2 (2020); *Compensation Programs for Potential COVID-19 Vaccine Injuries*, CRS LEGAL SIDEBAR, LSB10584, 2 (2021).

⁸⁶ Health Resources & Services Administration, *Frequently Asked Questions, Geared Towards Survivors*, HRSA, <https://www.hrsa.gov/cicp/faq/geared-toward-survivors.html> (last visited Nov. 17, 2021).

⁸⁷ *Id.*

⁸⁸ *Shoulder Injury Related to Vaccine Administration (SIRVA)*, SANDS ANDERSON VACCINE INJURY LEGAL TEAM, <https://www.vaccineinjurylegalteam.com/blogs-information/vaccine-injury-information/sirva/> (explaining that

as a COVID-19 vaccination.⁸⁹ Notwithstanding the advanced scientific research and medical treatment available today, adverse reactions and injuries to vaccines still affect individuals on a daily basis.⁹⁰ The express rolling out of the COVID-19 vaccines was necessary due to the circumstances, but there is some risk involved in rapidly providing vaccines to the public.⁹¹ Common drug-related adverse reactions are prevalent in older individuals with underlying conditions.⁹² According to the CDC, anaphylaxis is an extremely rare side effect, with around two to five people per million experiencing this effect.⁹³ Moreover, these side effects are mainly reported by women, which hold 79% of vaccine cases.⁹⁴ Even with all the technology in place, it is *still* critical that vaccines go through essential clinical trials.⁹⁵ To illustrate – the mumps vaccine took *four years* and was licensed in 1967; comparatively, Pfizer’s COVID-19 vaccine was developed and cleared for emergency use in merely *eight months*.⁹⁶ The rushed rollout was a fact that fueled great public mistrust of the COVID-19 vaccinations in the United States.⁹⁷

a. Weighing The Interests of All

i. Amending the Standard

It is inevitable that plaintiffs will continue to suffer physical injuries from COVID-19 vaccines.⁹⁸ One proposal suggests Congress lessen the restraint and modify certain rules.⁹⁹ Some critics of the COVID-19 liability shield argue that it violates individuals’ Equal Protection by limiting their ability to seek compensation through the tort system.¹⁰⁰ As such, Congress should terminate the blanket immunity and narrowly define the scope of “covered persons” for purposes of the PREP Act.¹⁰¹ Moreover, in revising the scope of the PREP Act, Congress would incentivize manufacturers and health care professionals to ensure they are administering COVID-19

SIRVA is an injury triggered by a vaccine which was not administered properly or administered with an incorrect needle, causing intense muscle irritation and pain in the shoulder resulting in difficulty to move the arm) (last visited Nov. 17, 2021).

⁸⁹ *Prevent shoulder injuries during COVID-19 vaccinations*, ISMP (Dec. 17, 2020), <https://www.ismp.org/resources/prevent-shoulder-injuries-during-covid-19-vaccinations>.

⁹⁰ Kim & Wilson, *supra* note 16.

⁹¹ FDA, *supra* note 13.

⁹² See Amanda Hanora & Paul Gallagher, *Predicting risk of adverse drug reactions in older adults*, 7 THERAPEUTIC ADVANCES IN DRUG SAFETY 11, 11-22 (2016).

⁹³ Minseo Jeong, *Global Covid-19 vaccine summary: side effects*, MEDICAL NEWS TODAY (June 29, 2021), <https://www.medicalnewstoday.com/articles/global-covid-19-vaccine-summary-side-effects#Potential-side-effects-per-vaccine>; Julianne Gee, et al., *First Month of COVID-19 Vaccine Safety Monitoring- United States*, CDC (Jan. 13, 2021), <https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm>.

⁹⁴ *Id.*

⁹⁵ *Vaccine Testing and Approval Process*, CDC, <https://www.cdc.gov/vaccines/basics/test-approve.html>.

⁹⁶ Sigalos, *supra* note 20.

⁹⁷ Kelly Elterman, MD, *COVID-19 Vaccine Distrust: Why It’s High, and How to Respond to It*, GOOD RX (Feb. 9, 2021), <https://www.goodrx.com/blog/distrust-of-the-covid-19-vaccine/>.

⁹⁸ Jillian Smukler, *Woman suffers ‘life-altering injuries’ after COVID vaccine, teams up with Utah senator to demand answers*, ABC4, <https://www.abc4.com/news/local-news/woman-suffers-life-altering-injuries-after-covid-vaccine-teams-up-with-utah-senator-to-demand-answers/> (last updated July 13, 2021).

⁹⁹ *Id.*

¹⁰⁰ *State and Federal Authority to Mandate COVID-19 Vaccination*, CRS REPORT, R46745, 2-3 (2021).

¹⁰¹ *Legal Issues in COVID-19 Vaccine Development and Deployment*, CRS REPORT, R46399, 32-34 (2020).

countermeasures in a safe and effective manner.¹⁰² These recommendations would make the process safer more efficient for an individual to have their claim litigated.

ii. Educating Patients

Many individuals do not read the terms of consent forms prior to receiving COVID-19 vaccines, specifically in the context of the PREP Act.¹⁰³ Found on the Florida Health COVID-19 Vaccine Screening and Consent Form is a release and hold harmless clause that states the following:

I hereby release and hold harmless the State of Florida, the Florida Department of Health (DOH), the Florida Division of Emergency Management (FDEM) and their staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine.¹⁰⁴

It is crucial that health care personnel play a key and essential role in educating the public on not only the benefits, but also the potential undesirable effects of the COVID-19 vaccines. Those receiving the COVID-19 vaccine should be informed of the potential risks involved in the procedure and their rights if something goes wrong, either with the administration of receiving the vaccine or its adverse effects.¹⁰⁵

b. Adding COVID-19 Vaccines to Other Available Funds

The Vaccine Injury Compensation Program does not currently cover COVID-19 vaccines.¹⁰⁶ However, the VICP is a rather compelling alternative to the CICIP program; the program has compensated injured individuals to the tune of over four billion dollars, and payouts have been received by thousands of people who have suffered vaccine adverse reactions.¹⁰⁷ Unlike the CICIP, the VICP has resources available for injured individuals.¹⁰⁸ For example, the VICP

¹⁰² *Legal Issues in COVID-19 Vaccine Development and Deployment*, CRS REPORT, R46399, 32-34 (2020).

¹⁰³ Ezekiel J. Emanuel, MD, PhD, & Connor W. Boyle, BA, *Assessment of Length and Readability of Informed Consent Documents for COVID-19 Vaccine Trials*, JAMA NETWORK (Apr. 28, 2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2779247> (illustrating the importance of informed consent and the complexity of reading COVID-19 vaccine informed consent documents)

¹⁰⁴ Florida Health, *COVID-19 Vaccine Screening and Consent Form*, FLORIDA DEPARTMENT OF HEALTH, <http://brevard.floridahealth.gov/files/documents/events/2020/12/documents/covid19-vaccine-screening-and-consent-form-moderna.pdf> (The Florida Health COVID-19 Vaccine and Screening and Consent Form is signed by all patients receiving a COVID-19 vaccines in the state of Florida, and the “release and hold harmless” clause provides for release of all liabilities and claims arising from administration of the vaccine to several parties of the state of Florida).

¹⁰⁵ Kristen Nunez, *What You Need to Know About Informed Consent*, HEALTHLINE (Oct. 11, 2019), <https://www.healthline.com/health/informed-consent#necessary-information>.

¹⁰⁶ HRSA, *National Vaccine Injury Compensation Program*, HEALTH RES. & SERV. ADMIN., <https://www.hrsa.gov/vaccine-compensation/index.html> (last visited Dec. 16, 2021).

¹⁰⁷ MCTLaw, *supra* note 80.

¹⁰⁸ HRSA, *supra* note 106.

includes a court, a judge, and provides individuals the right to present evidence of their injury.¹⁰⁹ The program also provides plaintiffs the ability to appeal their decision(s), all the way to the Supreme Court if deemed necessary.¹¹⁰ Therefore, the fund should apply to COVID-19 vaccine claims, allowing injured individuals' cases to be heard and appropriate resources allocated.

IV. Recommendations

With the above issues in mind, courts should allow injured individuals to litigate their claims without stringent restraints. It is clear that the FDA plays a critical role in the implementation of COVID-19 prevention tactics.¹¹¹ First, the FDA should independently confirm the safety and accuracy of COVID-19 vaccines and the qualified persons who administer them. Congress should narrow and eliminate the “blanket immunity” and all its surrounding barriers and obstacles that make it virtually impossible to bring a claim in a court of law. Moreover, Congress should provide effective means of recovery apart from the CICIP, such as the VICP that is currently available to those injured by other vaccines.¹¹² The VICP not only provides better resources to injured individuals but allows for accessible remedies.¹¹³

Although the federal government has provided significant protection to manufacturers, distributors, and health care professionals administering the vaccine, it is essential that those who suffer such injuries receive the same priority.¹¹⁴ Initiatives start with educating patients, narrowing the types of amendments made, eliminating the blanket immunity, and providing substantial and reasonable alternative funds for those who have been injured through such measures. For these reasons, the courts should not preempt such claims with the PREP Act and should allow for a less severe burden. Additionally, it would be more appropriate in COVID-19 vaccine injury cases for the manufacturer or distributor to have a narrower scope of immunity with respect to the PREP Act.

Through these unprecedented times, it is important to act in unison and protect the interest of all to prevail through the COVID-19 pandemic, as such, those who have suffered harm from a COVID-19 vaccine should not have to face great obstacles and hurdles to receive compensation, rather there should be options at the disposal of our citizens and our nation.

¹⁰⁹ MCTLaw, *supra* note 80.

¹¹⁰ *Id.*

¹¹¹ *COVID-19 Vaccines*, FDA, <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines> (last visited Nov. 17, 2021).

¹¹² Health Resources & Services Administration (HRSA), *supra* note 84.

¹¹³ Health Resources & Services Administration, *Comparison of Countermeasures Injury Compensation Program (CICIP) to the National Vaccine Injury Compensation Program (VICP)*, HRSA, <https://www.hrsa.gov/cicp/cicp-vicp> (last updated Apr. 1, 2021).

¹¹⁴ Jenna Greene, *A 'black hole' for COVID vaccine injury claims*, REUTERS (June 29, 2021), <https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/>.