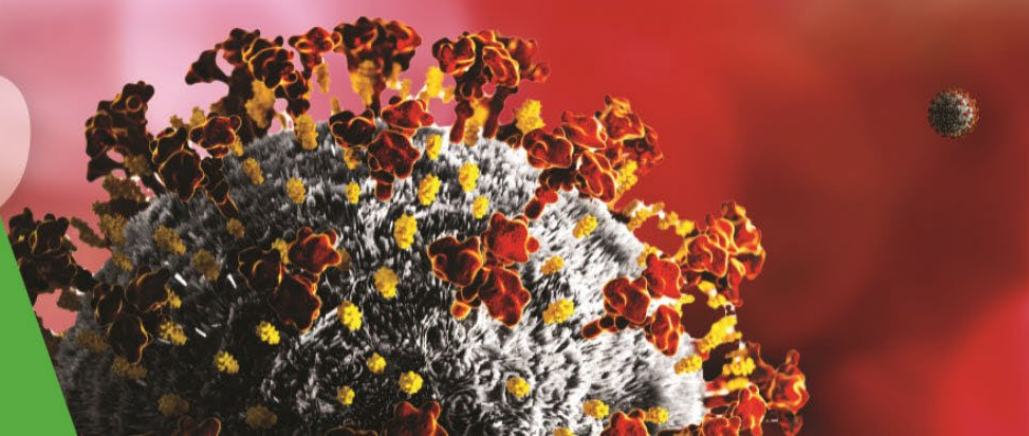


COVID-19

**SPECIAL EDITION
PANDEMIC RESPONSE**



Jordan Lipp
Attorney, Managing Member
Childs McCune, LLC



MEDMARC[®]

Treated Fairly

A ProAssurance Company

**Two Years and
Counting:
The PREP Act
and
COVID-19**

April 20, 2022

Public Readiness and Emergency Preparedness Act (“PREP Act”)

Enacted December 30, 2005

42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e

Overview of the PREP Act

- ▶ The PREP Act provides liability immunity to “covered persons” (i.e., manufacturers, distributors, prescribers, etc.) for “covered countermeasures” (i.e., drugs, devices, biologics) meant to combat a pandemic.
 - ▶ 42 U.S.C. § 247d-6d
- ▶ The PREP Act also creates a Countermeasure Injury Compensation Program (“CICP”).
 - ▶ 42 U.S.C. § 247d-6e

Countermeasure Injury Compensation Program



My Health Connection - jordanlip | x My Health Connection - eCheck- x +

https://mychart.uhealth.org/MyChart/echeckin?csn=WP-24RzqR-2Fn7gAev9ZOHPH-2BSBDQ-3D-3D-24V3115HC...

uhealth Jordan Health Record Tools Appointments Messaging Billing Settings Jordan Lipp Log Out

eCheck-In

Please review and

UCHealth HIP
Signed on 4/2

COVID-19 Va
Not Signed Yet

COVID-19 Vaccine Consent

designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IIS visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these

Countermeasure Injury Compensation Program



- ▶ COVID-19 Countermeasure Claims Filed (as of April 1, 2022):
 - ▶ 7,669 Total
 - ▶ 4,691 Involving COVID-19 Vaccines
 - ▶ 2,978 Involving Other COVID-19 Countermeasures

- ▶ Non-COVID-19 Countermeasure Claims Filed (as of April 1, 2022):
 - ▶ 449 claims (or 551 claims depending on which iteration of the HRSA website you read).

- ▶ See <https://www.hrsa.gov/cicp/cicp-data> (last checked 4/18/22).

Countermeasure Injury Compensation Program

COVID-19 Countermeasure Claim Status (as of April 1, 2022):

- ▶ 7,669 Total
- ▶ 1 Has Been Determined Eligible, Pending Review of Eligible Expenses
- ▶ 13 Have Been Denied
- ▶ 7,655 Claims Pending

Non-COVID-19 Claims Status (as of April 1, 2022):

- ▶ 551 or 449 Total
- ▶ 30 Have Been Compensated (totaling over \$6,000,000).
- ▶ 461 Have Been Denied
- ▶ Unclear Number of Claims Pending

(Yes, I know the numbers do not actually add up.)

Third Medmarc Webinar on the PREP Act



▶ March 31, 2020

- “I hope this presentation is good news. ... The PREP Act should be reassuring to manufacturers, component part manufacturers, and distributors.”

▶ March 18, 2021

- “Hopefully the PREP Act is doing exactly what it was supposed to do, let us focus on making good products without having to worry about lawsuits.”

▶ April 20, 2022

- Drumroll please ...

Hypothesis:

- ▶ The PREP Act Will Prevent Product Liability Lawsuits
- ▶ Interim results are in (and look very favorable).

Product Liability PREP Act Decisions:



- ▶ *Kehler v. Hood*, No. 4:11CV1416 FRB, 2012 WL 1945952 (E.D. Mo. May 30, 2012) (H1N1 vaccination).

- ▶ *Avicoli v. BJ's Wholesale Club, Inc.*, No. CV 21-1119, 2021 WL 1293397 (E.D. Pa. Apr. 7, 2021) (hand sanitizer).

Ongoing or Recently Resolved PREP Act Product Liability Lawsuits:



- *Avicolli v. BJ's Wholesale Club, Inc.*, No. 2:21-cv-01119-MAK (E.D. Pa.) (hand sanitizer case - settled).
- *Druhan v. Modernatx, Inc.*, No. 1:22CV10437 (D. Mass.) (pro se COVID-19 vaccine case).
- *Perez v. Oxford University*, No. 21-CV-4844 (AJN) (SLC) (S.D.N.Y.) (pro se COVID-19 vaccine case).
- *Piescik v. CVS Pharmacy, Inc.*, No. 9:21-cv-81298-DMM (S.D. Fla.) (hand sanitizer class action case – dismissed on other grounds).





Medical Malpractice and Pharmacy Cases and Decisions



Examples of Decisions:

- *Mills v. Hartford Health Care Corp.*, No. HHDCV206134761S, 2021 WL 4895676 (Conn. Super. Ct. Sept. 27, 2021) (PREP Act bars claim of medical malpractice in failing to diagnose heart attack prior to decedent's negative COVID-19 test results, but not after decedent's negative COVID-19 test).
- *Parker v. St. Lawrence Cty. Pub. Health Dep't*, 102 A.D.3d 140, 141(N.Y. Ap. Div. 2012) (PREP Act bars negligence and battery claims for providing influenza vaccine without consent).
- *Tonkinson v. Walmart, Inc.*, No. 21-2588-SAC-GEB, 2022 WL 425868 (D. Kan. Feb. 11, 2022) (providing COVID-19 vaccination without parental consent belongs in state court owing to lack of diversity jurisdiction).

Examples of Ongoing or Recent Cases:

- *Cowen v. Walgreen Co.*, Docket 4:22-CV-00157 (N.D. Okla.) (alleges plaintiff sought flu vaccine but given COVID-19 vaccine).
- *Marshall v. Georgia CVS Pharmacy, LLC*, No. 21-cv-02561-AT (N.D.Ga.) (alleges false positive test results caused emotional harm – case remanded to state court).
- *Roeder v. Giant Food Stores, LLC*, No. 22CV01146 (E.D. Pa.) (fall in pharmacy bathroom after receiving COVID-19 vaccine – voluntary dismissal filed by plaintiffs).

The Nursing Home Removal Decisions



Nursing Home Appellate Decisions on Removal

- ▶ *Maglioli v. All. HC Holdings LLC*, 16 F.4th 393, 413 (3d Cir. 2021).
- ▶ *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580 (5th Cir. 2022).
- ▶ *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679 (9th Cir. 2022).

- ▶ Above decisions all hold that removal of nursing home lawsuits improper, whether under doctrines of:
 - ▶ (i) complete preemption;
 - ▶ (ii) substantial federal question (*Grable*); or
 - ▶ (iii) federal officer removal.

- ▶ Diversity jurisdiction is still a viable basis for removal. *Carroll v. Comprehensive Healthcare Management Servs., LLC*, No. CV 21-1298, 2022 WL 129953 (W.D. Pa. Jan. 12, 2022).

Use of Countermeasures v. Failure to Use Countermeasures



- ▶ *Walsh v. SSC Westchester Operating Co. LLC* , No. 20 CV 4505, 2022 WL 846901 (N.D. Ill. Mar. 22, 2022) (collecting cases).
 - ▶ In the nursing home cases, PREP Act “is designed to protect those who employ countermeasures, not those who decline to employ them.”

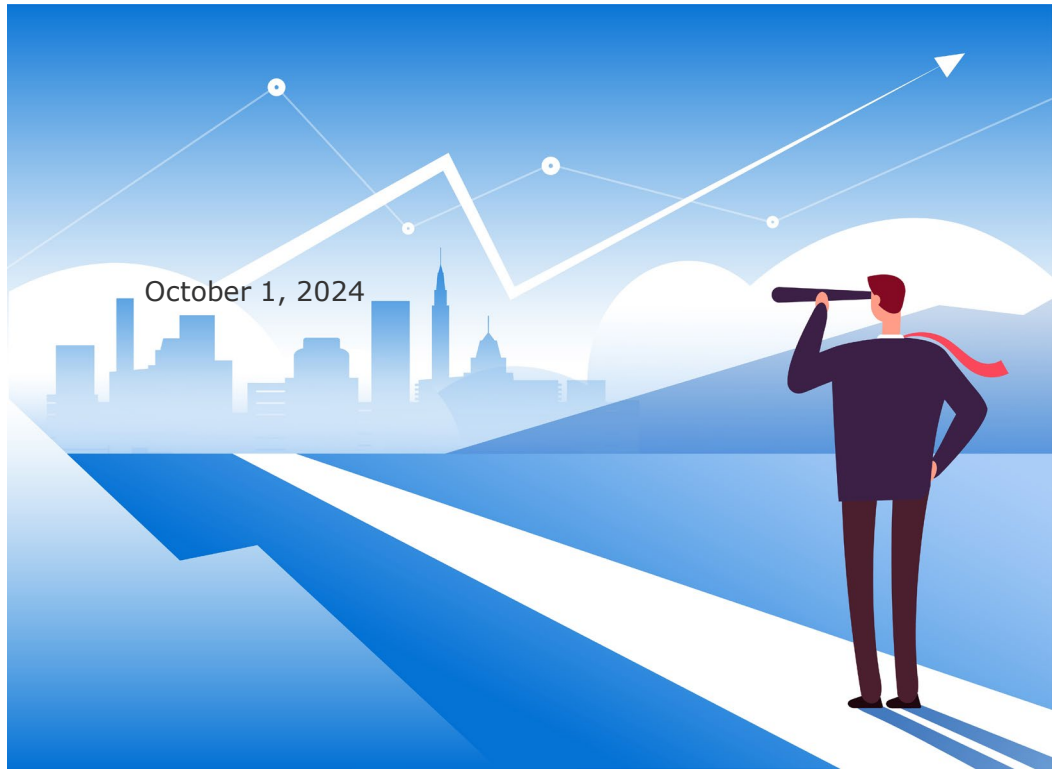
- ▶ *Maney v. Brown*, No. 6:20-CV-00570-SB, 2022 WL 377900 (D. Or. Feb. 8, 2022).
 - ▶ The PREP Act does not immunize Oregon officials from their decision not to include prisoners in the first round of the vaccination efforts, as the decision did not follow CDC guidance.

- ▶ *Fourth Amendment to PREP Act COVID-19 Declaration*, 85 FR 79190-01 (Dec. 3, 2020, published Dec. 9, 2020).
 - ▶ “Where there are limited Covered Countermeasures, *not* administering a Covered Countermeasure to one individual in order to administer it to another individual ... can fall within the PREP Act and this Declaration’s liability protections.”
 - ▶ “Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can” fall under the PREP Act.

Tentative Conclusions from Case Law on the PREP Act:

- ▶ The PREP Act has all but eliminated product liability lawsuits;
- ▶ PREP Act in and of itself not a basis for removal to federal court; and
- ▶ Courts generally find that the failure to use a countermeasure is likely not protected by PREP Act.

Gazing Into the Future ...





QUESTIONS?

Contact Information:

Jordan Lipp, Esq.

Childs McCune, LLC

jlipp@childsmccune.com

720-630-2952



Medmarc.com

Copyright © 2022 - Medmarc

All statements and opinions in this presentation are for informational and educational purposes only. None of the information presented should be considered as offering legal advice or legal opinion. We are not liable for any errors, inaccuracies or omissions. In the event any of the information presented conflicts with the terms and conditions of any policy of insurance offered by Medmarc Insurance Group, the terms and conditions of the actual policy will apply.