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Commentary: COVID-19 countermeasures receive broad immunity

By Kathleen M. Loucks

The Department of Health and Human Services (HHS) passed a declaration under the Public Readiness and Emergency Preparedness (PREP) Act effective as of Feb. 4, 2020, through Oct. 1, 2024. Manufacturers are protected from legal liability for an additional 12 months from the above expiration date.[1]

Under the PREP declaration, negligence cases involving future COVID-19 vaccines, treatments and certain medical devices will be barred from state and federal courts with narrow exceptions. As such, the only remedy for injured parties will be the Countermeasures Injury Compensation Program (CICP).[2]

By way of background, the PREP Act was originally enacted by President George W. Bush in response to concerns regarding the Avian bird flu pandemic in the early 2000s.[3] Later, in 2009, HHS invoked the PREP Act to declare liability immunity for H1N1 (swine flu) vaccine manufacturers and health care providers who administered the vaccine.[4] Later, other countermeasures against other pathogens like Ebola, Zika, anthrax and smallpox were added.[5]

What does immunity from liability mean?

Immunity means that the courts must dismiss claims brought by any entity or individual covered by the PREP Act. This includes claims for any loss that is related to the design, development, testing, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure recommended in the declaration.[6]

This includes claims for physical, mental, or emotional injury, illness, disability or fear of any such injury, illness, disability or condition, any need for medical monitoring, or property damage or loss including business interruption losses.[7]

Is there any exception to the immunity?

Yes. Immunity is not available for death or serious physical injury caused by willful misconduct. Willful misconduct is misconduct that is greater than any form of recklessness or negligence. It is defined as an act or failure to act that is taken: (1) intentionally to achieve a wrongful purpose; (2) knowingly without legal or factual justification; and (3) 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.[8]

What are covered countermeasures?

Generally under the PREP Act, covered countermeasures are: a vaccination, medication, device or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic or security threat.[9] Coverage, however, is limited to three categories of countermeasures: (1) "qualified pandemic or epidemic products," (2) "security countermeasures," or (3) drugs, biological products, or devices authorized for investigational or emergency use."[10] Each category is defined in other federal acts.[11]

The Families First Coronavirus Response Act specifically amended the PREP Act's definition of covered countermeasures to include "personal respiratory protective devices."[12]

Who are covered persons?

Covered persons include the United States, as well as persons or entities that are manufacturers, distributors or program planners of countermeasures, health care providers or agents of any of the above-mentioned categories.[13]

In sum, absent willful misconduct the PREP Act Declaration will shield any health care provider treating a COVID-19 patient. It will also cover anyone who administers a vaccine as well as companies engaged in manufacturing biologics or products used to treat the virus. As a result, persons injured by COVID-19 treatment or a vaccination will not have their day in court but will be limited to filing a claim in the CICP, an obscure program run by the Department of Health and Human Services which has limited damages and no right to appeal.

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Footnotes

1. Declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against Covid-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020); 42 U.S.C. 247d-6d.
2. 42 U.S.C 247d-6e.
3. Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L. 19-148, 119 Stat. 2818 (2005).
4. Pandemic Influenza Vaccines-Amendment, 74 Fed. Reg. 30,294 (June 25, 2009).
5. Ebola Virus Disease Vaccines – Amendment, 84 Fed. Reg. 764 (notice Jan. 31, 2019) (extending liability immunity through Dec. 31, 2023); Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines, 83 Fed. Reg. 38,701 (notice Aug. 7, 2018) (extending Aug. 1, 2016 declaration until Dec. 31, 2022); Anthrax Medical Countermeasures – Amendment, 80 Fed. Reg. 76,514 (notice Dec. 9, 2015) (extending Oct. 1, 2008 declaration until Dec. 31, 2022); Smallpox Medical Countermeasures – Amendment, 80 Fed. Reg. 76,546 (notice Dec. 9, 2015) (extending Oct. 10, 2008 declaration until Dec. 31, 2022); Pandemic Influenza Medical Countermeasures – Amendment, 80 Fed. Reg. 76,506 (notice Dec. 9, 2015) (extending Oct. 17, 2008 declaration until Dec. 31, 2022).
6. 85 Fed. Reg. 15198-01 § III.
7. 42 U.S.C. § 247d-6d(a)(2)(A).
8. 42 U.S.C. § 247d-6d(c)(1)(A).
9. 42 U.S.C. 247d-6b(c)(1)(B), 42 U.S.C. 247d-6d(i)(1) and (7).
10. 85 Fed. Reg. 15198-01 § VI.
11. For the definition of "qualified pandemic or epidemic product," see 42 U.S.C. § 247d-6d(i)(7); for "security countermeasure," see 42 U.S.C. § 247d-6b(c)(1)(B); and for regulations pertaining to authorization for medical products for use in emergencies, see 21 U.S.C. § 360bbb-3.
12. H.R.6201 – Families First Coronavirus Response Act, Pub. L. 116-127, 134 Stat. 178 (2020).
13. 42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B).