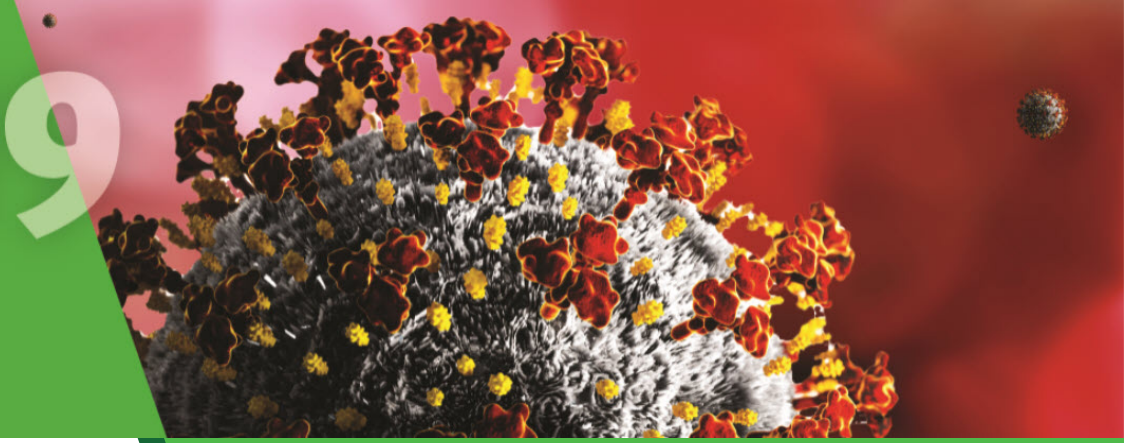
COVID-19

SPECIAL EDITION
PANDEMIC RESPONSE



Jordan Lipp
Attorney, Managing Member
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An Overview of PREP Act Liability Immunity for Products Meant to Counter COVID-19 Under the PREP Act

March 31, 2020

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 PREP Act

- The PREP Act provides liability immunity to a large group of entities and individuals for the manufacture, distribution, prescription, and use of drugs, biological products, or devices meant to combat a pandemic.

- *See* 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; *see also* www.phe.gov/Preparedness/legal/prepact/

Wikipedia Page on PREP Act

even in states that have enacted such bans.

See also [edit]

- Vaccines for the New Millennium Act

External links [edit]

- GallatinNewsExaminer.com - 'Hastert, Frist said to rig bill for drug firms: Frist denies protection was added in secret', Bill Theobald, Gannett News Service (February 9, 2006)
- Pitt.edu - 'Vaccine liability law changes proposed by Democrats', Chris Buell, *Jurist Legal News & Research*, University of Pittsburgh School of Law (February 15, 2006)
- Senate.gov - 'Harkin Calls on Frist and Hastert to Repeal "Dead of Night" Vaccine Liability Provision and Enact Real Protections (February 15, 2006)
- SLWeekly.com - 'Side Effects: Leavitt's new power to limit suits against pharmaceutical companies has some critics feeling a bit ill', Louis Godfrey, *Salt Lake City Weekly* (February 9, 2006)
- SMMirror.com - 'Allowing the Drug Companies to Poison Our Children' (editorial), Lewis Seiler and Dan Hamburg, *Santa Monica Mirror* (March 30, 2006)
- UMN.edu - 'Pandemic funding, liability shield clear Congress' (December 28, 2005)

V · T · E **Artificial induction of immunity / Immunization: Vaccines, Vaccination, Infection, Inoculation (J07)** [show]

Categories: Vaccination law | United States federal health legislation | 2005 in law | Disaster preparedness in the United States | Vaccination in the United States

This page was last edited on 15 January 2020, at 20:46 (UTC).

https://en.wikipedia.org/wiki/Public_Readiness_and_Emergency_Preparedness_Act

DEFINING A "COVERED PERSON"

(2) Covered person. The term "covered person", when used with respect to the administration or use of a covered countermeasure, means—

(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).

(3) Distributor. The term "distributor" means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

(4) Manufacturer. The term "manufacturer" includes—

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

42 U.S.C. § 247d-6d(i)(2)-(4).

DEFINING A "COVERED COUNTERMEASURE" PART ONE

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(1) Covered countermeasure. The term "covered countermeasure" means—

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 319F-2(c)(1)(B) [42 USCS § 247d-6b(c)(1)(B)]);

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act [42 USCS § 262(i)]), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3, 360bbb-3a, or 360bbb-3b]; or

(D) a personal respiratory protective device that is—

(i) approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or successor regulations);

(ii) subject to the emergency use authorization issued by the Secretary on March 2, 2020, or subsequent emergency use authorizations, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (authorizing emergency use of personal respiratory protective devices during the COVID-19 outbreak); and

(iii) used during the period beginning on January 27, 2020, and ending on October 1, 2024, in response to the public health emergency declared on January 31, 2020, pursuant to section 319 [42 USCS § 247d] as a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV).

42 U.S.C. § 247d-6d(i)(1).

EUA for COVID-19 Test Kits

Information available at:
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidothermeddev

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DETERMINATION OF A PUBLIC HEALTH EMERGENCY AND DECLARATION THAT CIRCUMSTANCES EXIST JUSTIFYING AUTHORIZATIONS PURSUANT TO SECTION 564(b) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C. § 360bbb-3

As of this date, I hereby determine pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV).

On the basis of this determination, I hereby declare that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Date FEB 04 2020

-- / S / --
Alex M. Azar II

EUA for Personal Respiratory Protective Devices

Information available at:
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidothermeddev

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DECLARATION THAT CIRCUMSTANCES EXIST JUSTIFYING AUTHORIZATIONS PURSUANT TO SECTION 564 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C. § 360bbb-3

On February 4, 2020, I determined, pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act, that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2009-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

On the basis of this determination, I hereby declare that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

--/s/--

MAR 0 2 2020
Date

Alex M. Azar II

EUA for Ventilators

Information available at:
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidothermeddev

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DECLARATION THAT CIRCUMSTANCES EXIST JUSTIFYING AUTHORIZATIONS PURSUANT TO SECTION 564 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C. § 360bbb-3

On February 4, 2020, I determined pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2009-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

On the basis of this determination, I hereby declare that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

MAR 2 4 2020

Date

Alex M. Azar II

DEFINING A "COVERED COUNTERMEASURE" PART ONE

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(1) Covered countermeasure. The term "covered countermeasure" means—

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 319F-2(c)(1)(B) [42 USCS § 247d-6b(c)(1)(B)]);

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act [42 USCS § 262(i)]), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3, 360bbb-3a, or 360bbb-3b]; or

(D) a personal respiratory protective device that is—

(i) approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or successor regulations);

(ii) subject to the emergency use authorization issued by the Secretary on March 2, 2020, or subsequent emergency use authorizations, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (authorizing emergency use of personal respiratory protective devices during the COVID-19 outbreak); and

(iii) used during the period beginning on January 27, 2020, and ending on October 1, 2024, in response to the public health emergency declared on January 31, 2020, pursuant to section 319 [42 USCS § 247d] as a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV).

42 U.S.C. § 247d-6d(i)(1).

DEFINING A "COVERED COUNTERMEASURE" PART TWO

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(7) Qualified pandemic or epidemic product. The term "qualified pandemic or epidemic product" means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act [42 USCS § 262(i)]), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is—

(A)

(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)

(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 USCS §§ 351 et seq.] or licensed under section 351 of this Act [42 USCS § 262];

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(i) or 360j(g)]; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3, 360bbb-3a, or 360bbb-3b].

42 U.S.C. § 247d-6d(i)(7).

Immunity

- "Subject to the other provisions of this section, a covered person shall be 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 if a declaration under subsection (b) has been issued with respect to such countermeasure."

- 42 U.S.C. § 247d-6d(a)(1).

- Declaration of Public Health Emergency for COVID-19
- 85 FR 15198

Ohio, Court of Federal Claims No: 20–0225V
71. Shannon Pyors, Dresher, Pennsylvania, Court of Federal Claims No: 20–0231V
72. Lisa Macon, Englewood, New Jersey, Court of Federal Claims No: 20–0232V

[FR Doc. 2020–05525 Filed 3–16–20; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of declaration.

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID–19.

DATES: The Declaration was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of "Covered Countermeasures" and "qualified pandemic and epidemic products" in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

COVID–19 is an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus or a virus mutating therefrom. This virus is similar to other betacoronaviruses, such as Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Although the complete clinical picture regarding SARS-CoV-2 or a virus mutating therefrom is not fully understood, the virus has been known to cause severe respiratory illness and death in a subset of those people infected with such virus(es).

In December 2019, the novel coronavirus was detected in Wuhan City, Hubei Province, China. Today, over 101 countries, including the United States have reported multiple cases. Acknowledging that cases had been reported in five WHO regions in one month, on January 30, 2020, WHO declared the COVID–19 outbreak to be a Public Health Emergency of International Concern (PHEIC) following a second meeting of the Emergency Committee convened under the International Health Regulations (IHR).

To date, United States traveler-associated cases have been identified in a number of States and community-based transmission is suspected. On January 31, 2020, Secretary Azar declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the nation's health care community response to the COVID–19 outbreak.[1] The outbreak remains a significant public health challenge that requires a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread of COVID–19.[2]

Description of This Declaration by Section

Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under Section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. Accordingly in Section I of the Declaration, the Secretary determines that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID–19, constitutes a public health emergency for purposes of this Declaration under the PREP Act.

Section II. Factors Considered by the Secretary

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure. In Section II of the Declaration, the Secretary states that he has considered these factors.

Section III. Activities Covered by This Declaration Under the PREP Act's Liability Immunity

The Secretary must delineate the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures

[1] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[2] CDC COVID–19 Summary; *https://www.cdc.gov/coronavirus/2019-ncov/summary.html*, accessed 27Feb2020.

Previous Declarations of Public Health Emergencies

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- COVID-19 - Medical Countermeasures (effective February 4, 2020)
- Ebola Disease Vaccines - Amendment (effective December 1, 2018)
- Ebola Disease Therapeutics - Amendment (effective December 1, 2018)
- Nerve Agents and Certain Insecticides (Organophosphorus and/or Carbamate) Countermeasures (effective April 11, 2017)
- Zika Virus Vaccines (effective August 1, 2016)
- Pandemic Influenza Medical Countermeasures (amended effective January 1, 2016)
- Anthrax Medical Countermeasures (amended effective January 1, 2016)
- Acute Radiation Syndrome Medical Countermeasures (amended effective January 1, 2016)
- Botulinum Toxin Medical Countermeasures (amended effective January 1, 2016)
- Smallpox Medical Countermeasures (amended effective January 1, 2016)

https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

Claims Precluded Per the Secretary

Claims precluded by the PREP Act per the Federal Register:

[1] "liability claims alleging negligence by a manufacturer in creating a vaccine;"

[2] "liability claims alleging … negligence by a health care provider in prescribing the wrong dose;" or

[3] "liability claim[s] … such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control."

Claims not precluded by the PREP Act per the Federal Register:

[1] "liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities [], such as a slip and fall with no direct connection to the countermeasure's administration or use."

85 FR 15198 at 15200.

Willful Misconduct:

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- High standard
- Shown by clear and convincing evidence
- Sole jurisdiction is federal court in D.C.
- Plead with particularity
- Only for serious injury or death
- Verified complaint
- Expert affidavit
- No regular discovery permitted while motion to dismiss is pending
- Any damages reduced by collateral source benefits

Case Law on PREP Act

- *Parker v. St. Lawrence Cty. Pub. Health Dep't*, 2012 NY Slip Op 7934, 102 A.D.3d 140, 954 N.Y.S.2d 259 (App. Div. 3rd Dept.);

- *Kehler v. Hood*, No. 4:11CV1416 FRB, 2012 U.S. Dist. LEXIS 74502, 2012 WL 1945952 (E.D. Mo. May 30, 2012); and

- *Casabianca v. Mount Sinai Med. Ctr., Inc.*, 2014 NY Slip Op 33583(U) (N.Y. Sup. Ct., N.Y. Cty. Dec. 2, 2014).

QUESTIONS?

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