Product Liability Immunity:
Understanding COVID-19 Immunity Under the PREP Act

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Roadmap for Discussion

- When does the PREP Act and Declaration for Countermeasures against COVID-19 provide products liability immunity?
- What are the limits of PREP Act immunity and how can companies protect themselves?
- How is PREP Act immunity likely to be applied for COVID-19 products?

The PREP Act and Declaration for Countermeasures Against COVID-19

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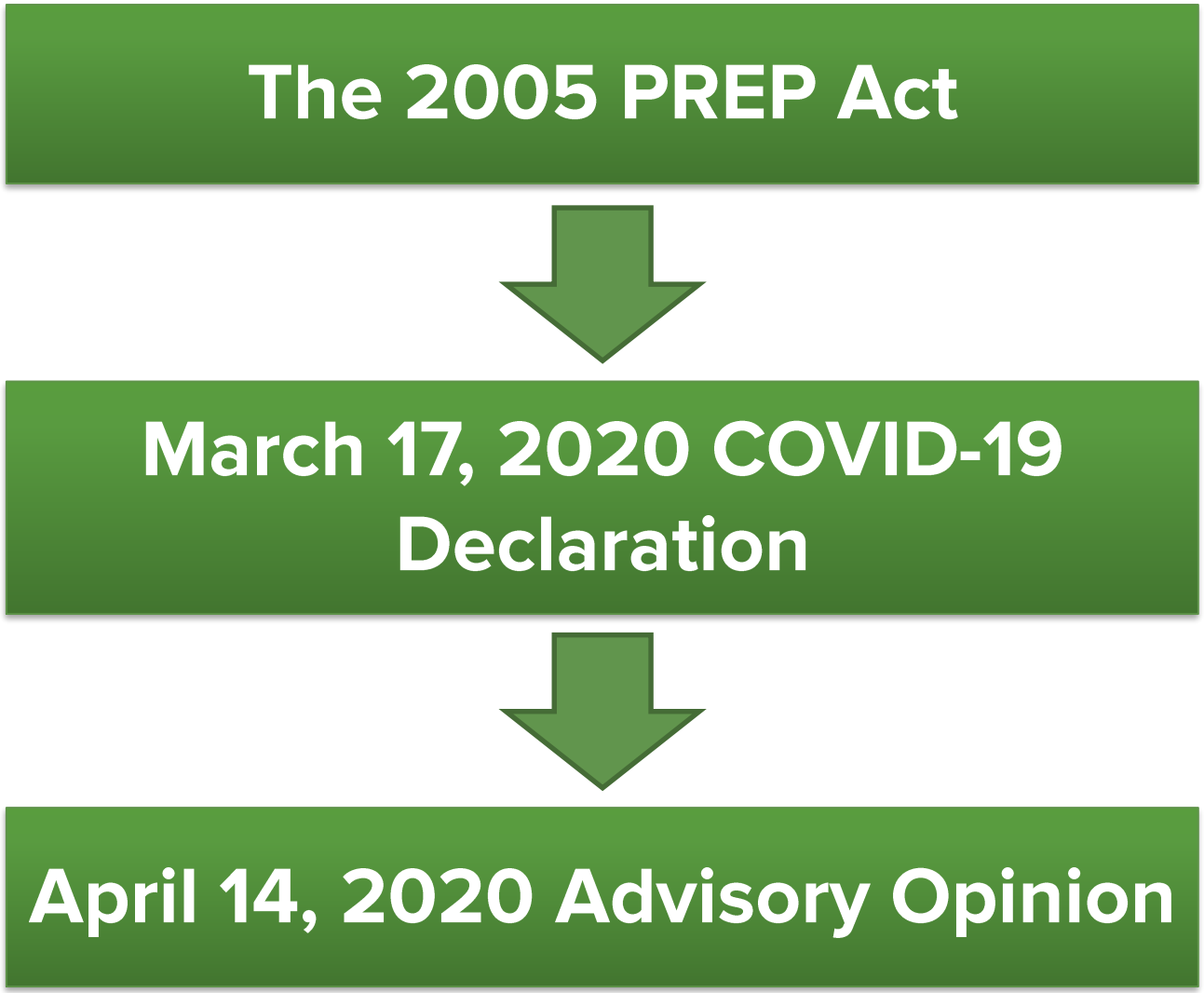
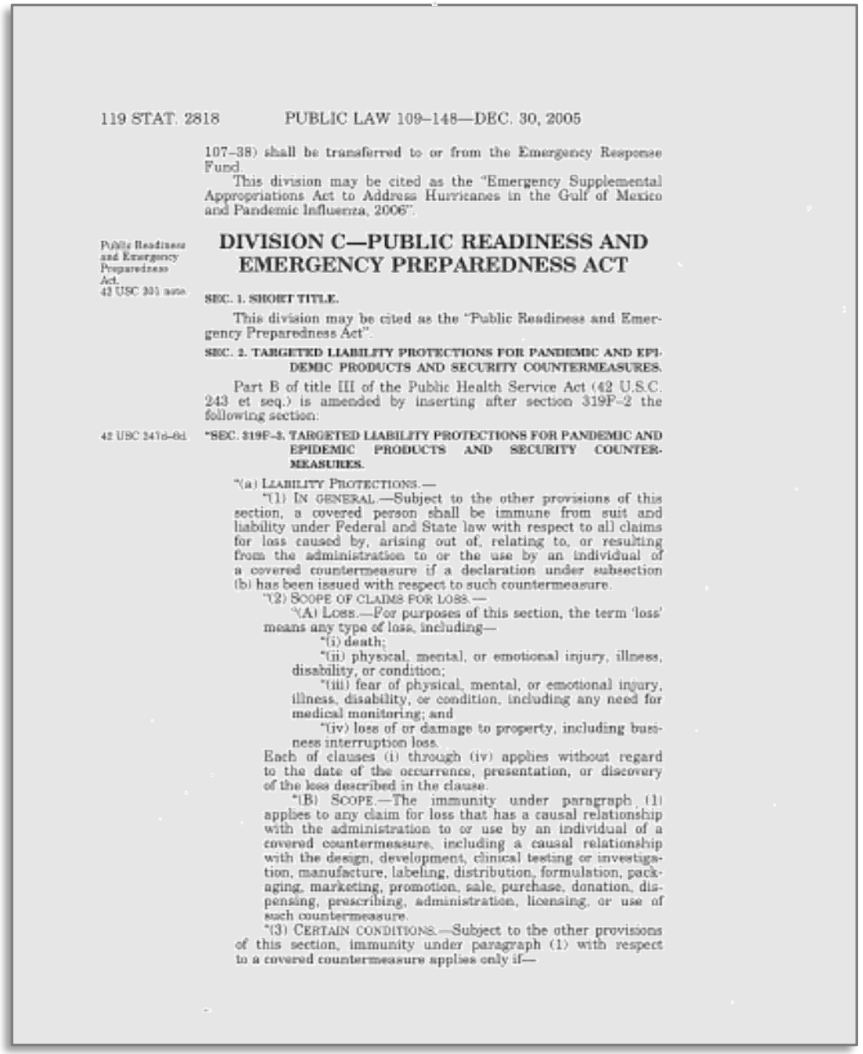
COVID-19 Products Immunity Key Documents



What is the PREP Act?



119 STAT. 2818 PUBLIC LAW 109–148—DEC. 30, 2005

107–38) shall be transferred to or from the Emergency Response Fund.

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Public Readiness and Emergency Preparedness Act.
42 USC 201 note.

DIVISION C—PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT

SEC. 1. SHORT TITLE.

This division may be cited as the "Public Readiness and Emergency Preparedness Act".

SEC. 2. TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319F–2 the following section:

42 USC 247d-6d.

"SEC. 319F–3. TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

"(a) LIABILITY PROTECTIONS.—

"(1) IN GENERAL.—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.

"(2) SCOPE OF CLAIMS FOR LOSS.—

"(A) LOSS.—For purposes of this section, the term 'loss' means any type of loss, including—

"(i) death;

"(ii) physical, mental, or emotional injury, illness, disability, or condition;

"(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

"(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

"(B) SCOPE.—The immunity under paragraph (1) 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, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

"(3) CERTAIN CONDITIONS.—Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

Public Readiness and Emergency Preparedness Act (2005) (42 U.S.C. § 247d-6d)

- Provides liability immunity against state and federal law claims to covered entities and individuals for covered countermeasures
  - Preempts state law
- Authorizes Secretary of HHS to issue a PREP Act Declaration identifying covered diseases that constitute a public health emergency
- Few courts have substantively commented on the Act's requirements

COVID-19 Declaration and Advisory Opinion

March 17, 2020: PREP Act COVID-19 Declaration

- Provides immunity to "Covered Persons" against all claims of loss "caused by, arising out of, relating to, or resulting from" the "manufacture, testing, development, distribution, administration, and use" of medical countermeasures against COVID-19 ("Covered Countermeasures")

April 14, 2020: Advisory Opinion from the General Counsel

- Omnibus advisory opinion
- Not a final agency action or final order; does not bind HHS or federal courts; does not have the force or effect of law
- Lists Covered Countermeasures covered by Emergency Use Authorizations

Necessary Components of Immunity Under the Declaration

Covered Countermeasures

- Includes an antiviral, drug, biologic, diagnostic, device, or vaccine
  - Device used in its administration; and
  - All components and constituents
- Used to treat, diagnose, cure, prevent, treat, or mitigate COVID-19 or limit its harm
- Must be a COVID-19 product:
  - Approved, licensed, or cleared by FDA;
  - Authorized under an EUA;
  - Described in an EUI; or
  - Used under an IND or an IDE

Covered Persons

- The United States; or
- Manufacturer, distributor, program planner, qualified person, or their agents or employees, of a Covered Countermeasure that:
  - Used, administered or distributed a Covered Countermeasure during the effective period of the Declaration (currently October 1, 2024 for COVID-19)

Recommended Activities

- For Covered Persons involving Covered Countermeasures related to:
  - Present or future federal contracts or agreements; or
  - Activities authorized by an Authority Having Jurisdiction following a Declaration
- Advisory Opinion broadly interprets these conditions to include:
  - Any arrangement with the federal government; or
  - Any activity that is part of an authorized emergency response at federal, regional, state, or local level

What are “Covered Countermeasures”?

- Drugs, biological products, or devices used to:
  - Diagnose, mitigate, prevent, treat or cure COVID-19 or limit its harm
  - Diagnose, mitigate, prevent, treat, or cure a serious or life threatening disease or condition caused by COVID-19
- A product or technology intended to enhance the use or effect of the above products
- Respiratory protective devices approved by NIOSH are included within the definition as codified by the CARES Act

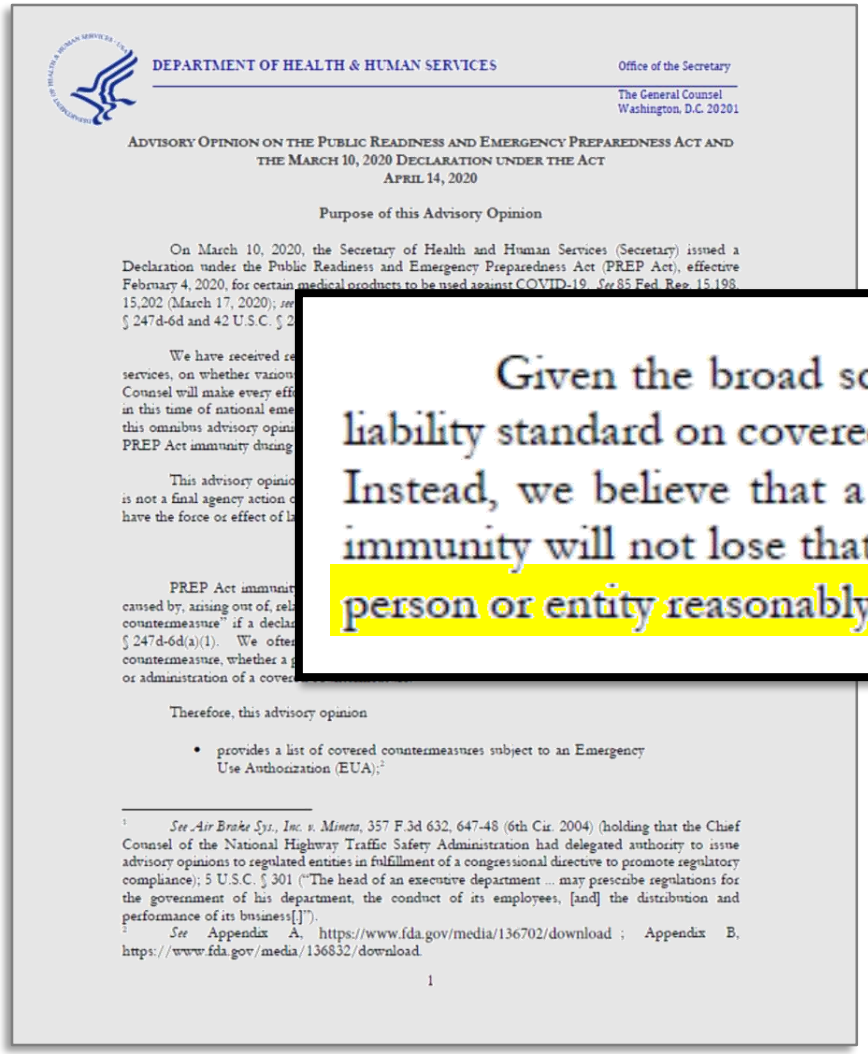
42 U.S.C. § 247d-6d(i)(1)(A); Advisory Opinion p. 3

Limitations on "Covered Countermeasures"

- To meet the definition, a COVID-19 product must be:
  - Approved, licensed, or cleared by FDA
  - Cleared for investigational use under an Investigational Drug Application or Investigational Device Exemption by FDA (or otherwise authorized)
  - Authorized for emergency use under an EUA, or
  - Described in Emergency Use Instructions issued by the CDC
- The number of products used "that are approved, licensed or cleared are too numerous to list," but the Declaration links to a list of products covered by EUAs

42 U.S.C. § 247d-6d(i)(7); March 10, 2020 Advisory Opinion at p.4; *FDA Combating COVID-19 with Medical Devices*, Appendix A, available at https://www.fda.gov/media/136702/download; *FDA combating COVID-19 with Therapeutics*, Appendix B, available at https://www.fda.gov/media/136832/download

“Reasonable Belief” Qualifies



DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE MARCH 10, 2020 DECLARATION UNDER THE ACT
APRIL 14, 2020

Purpose of this Advisory Opinion

On March 10, 2020, the Secretary of Health and Human Services (Secretary) issued a Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), effective February 4, 2020, for certain medical products to be used against COVID-19. *See* 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); *see* § 247d-6d and 42 U.S.C. § 2

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[1] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]").

[2] *See* Appendix A, https://www.fda.gov/media/136702/download ; Appendix B, https://www.fda.gov/media/136832/download.

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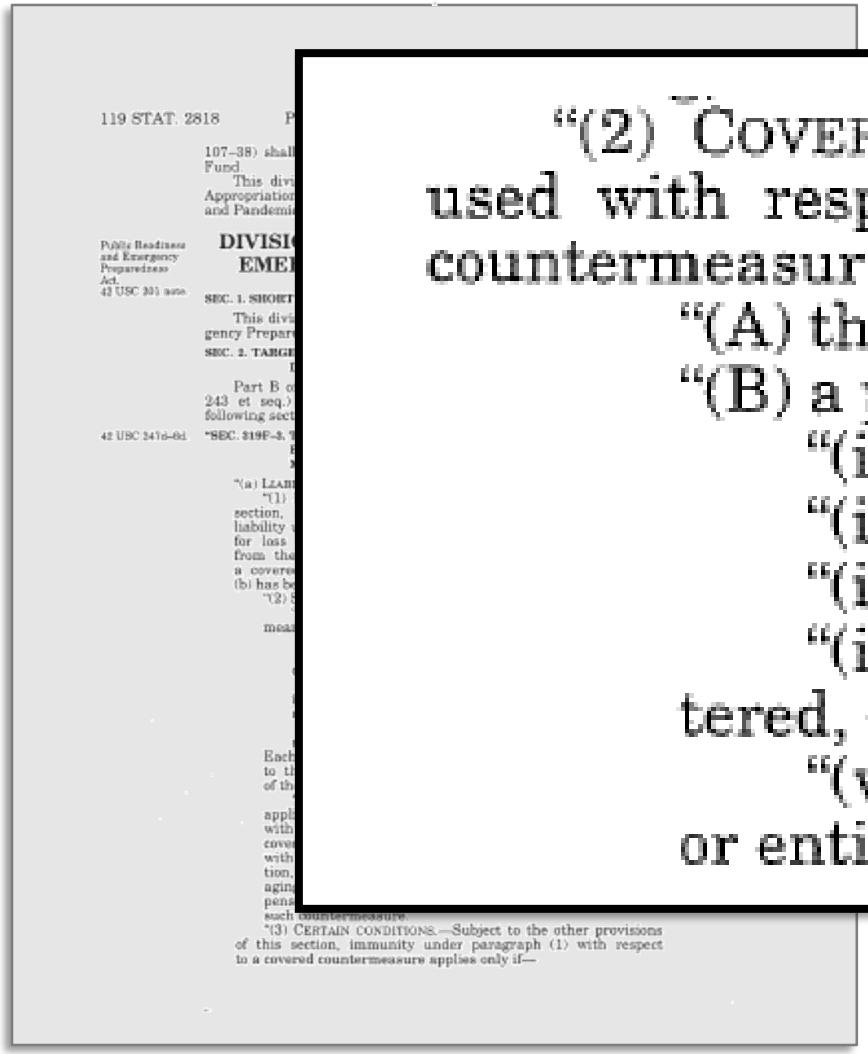
> Given the broad scope of PREP Act immunity, Congress did not intend to impose a strict-liability standard on covered persons for determining whether a product is a covered countermeasure. Instead, we believe that a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is *not* a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure.

April 14, 2020 Advisory Opinion, pp. 4-5

Who are “Covered Persons”?



“(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).

42 U.S.C. § 247d-6d(i)(2)

Who are “Program Planners”?

Broadly defined to include:

- State or local governments, including Indian tribes, or person employed by State or local government, or other person who administered or supervised security countermeasure, qualified pandemic, or epidemic product programs

- Private sector employees or community groups who “supplied technical or scientific advice” or “policy guidance” to those administering or using Covered Countermeasures

42 U.S.C. § 247d-6d(i)(6); Advisory Opinion, pp. 5-6

Who are "Qualified Persons"?

Defined as:

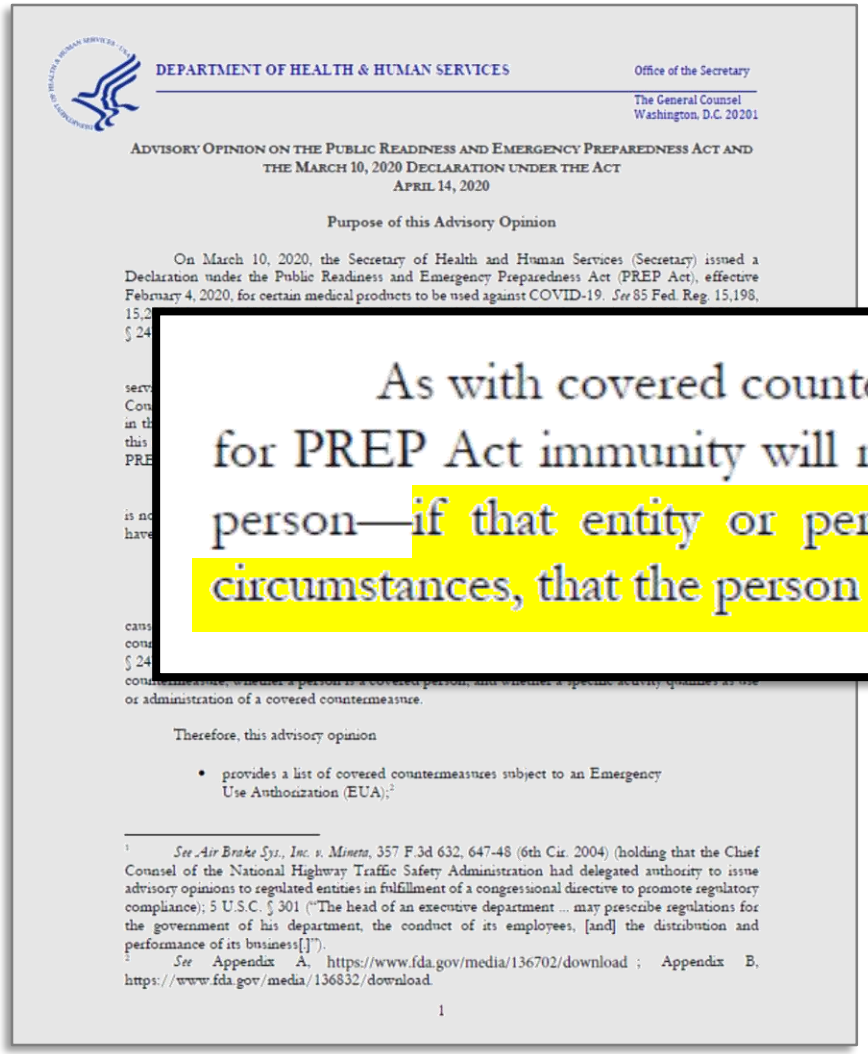
- A licensed health professional or other individual authorized under law of the relevant state to administer covered countermeasures
- A person within a category identified in a Secretary's Declaration
  - COVID-19 Declaration expanded to include "any person authorized in accordance with the…response of the Authority Having Jurisdiction".

Advisory Opinion clarifies:

- HHS is an "Authority Having Jurisdiction" to extend immunity
- More broadly includes any public agency or its delegate that has "legal responsibility and authority" for responding to COVID-19

42 U.S.C. § 247d-6d(i)(8); Declaration, Section V; Advisory Opinion, pp. 6-7

“Reasonable Belief” Qualifies



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[2] *See* Appendix A, https://www.fda.gov/media/136702/download ; Appendix B, https://www.fda.gov/media/136832/download.

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As with covered countermeasures, an entity or person that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the entity or person is *not* a covered person—if that entity or person reasonably could have believed, under the current, emergent circumstances, that the person was a covered person. *See, e.g.*, 42 U.S.C. § 247d-6d(a)(4)(B).

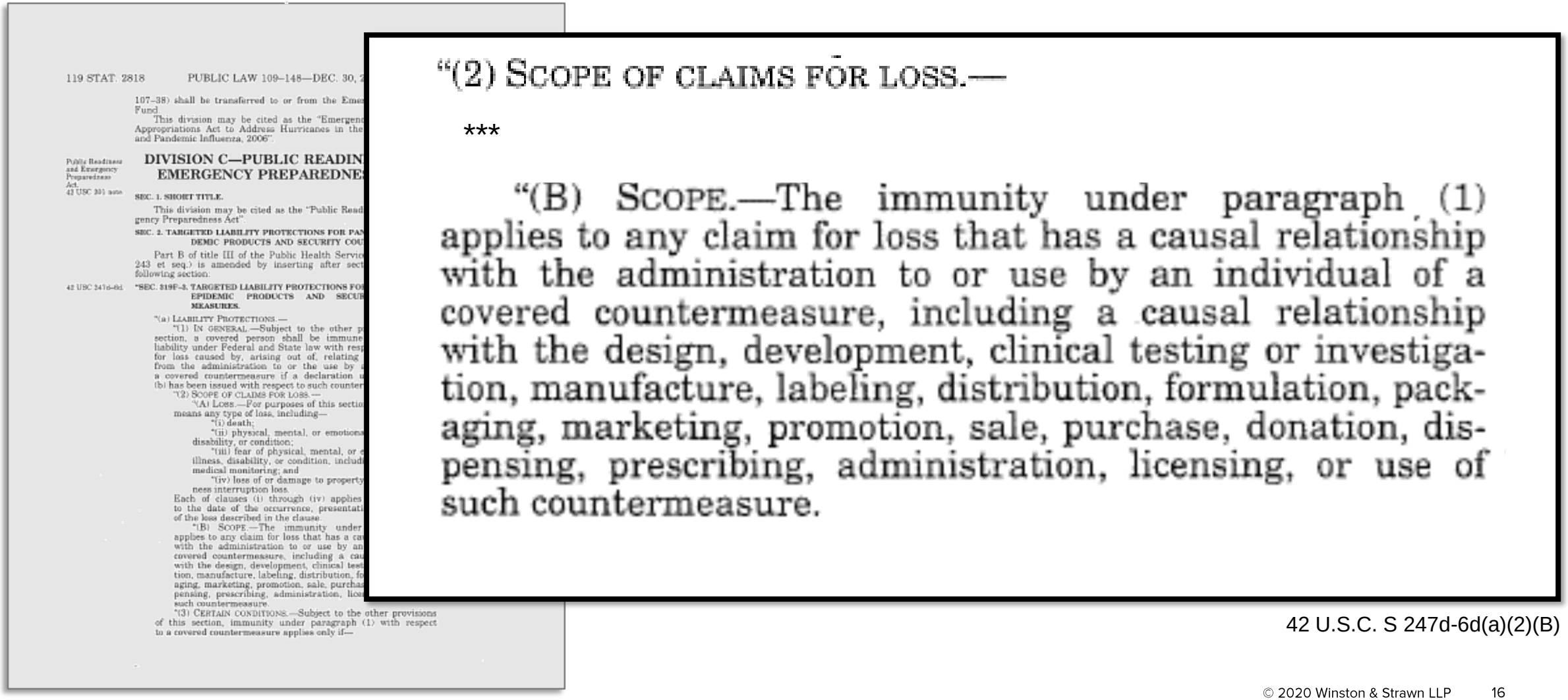
March 10, 2020 Advisory Opinion, p. 7

What are "Recommended Activities" Such that Immunity Applies?

- Immunity is afforded only to a Covered Person:
  - Engaging in activities related to an agreement or arrangement with the federal government, or
  - Acting according to an Authority Having Jurisdiction to respond to a declared emergency
- Advisory Opinion broadly interprets these conditions to include:
  - Any arrangement with the federal government—not limited to written contract
  - Any activity that is part of authorized emergency response at federal, regional, state or local level
    - Applies regardless of whether state or local authorities have declared State of Emergency

Declaration, Section VII; Advisory Opinion Advisory Opinion, p. 2

Scope of Claims for "Loss"



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"(B) SCOPE.—The immunity under paragraph (1) 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, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

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

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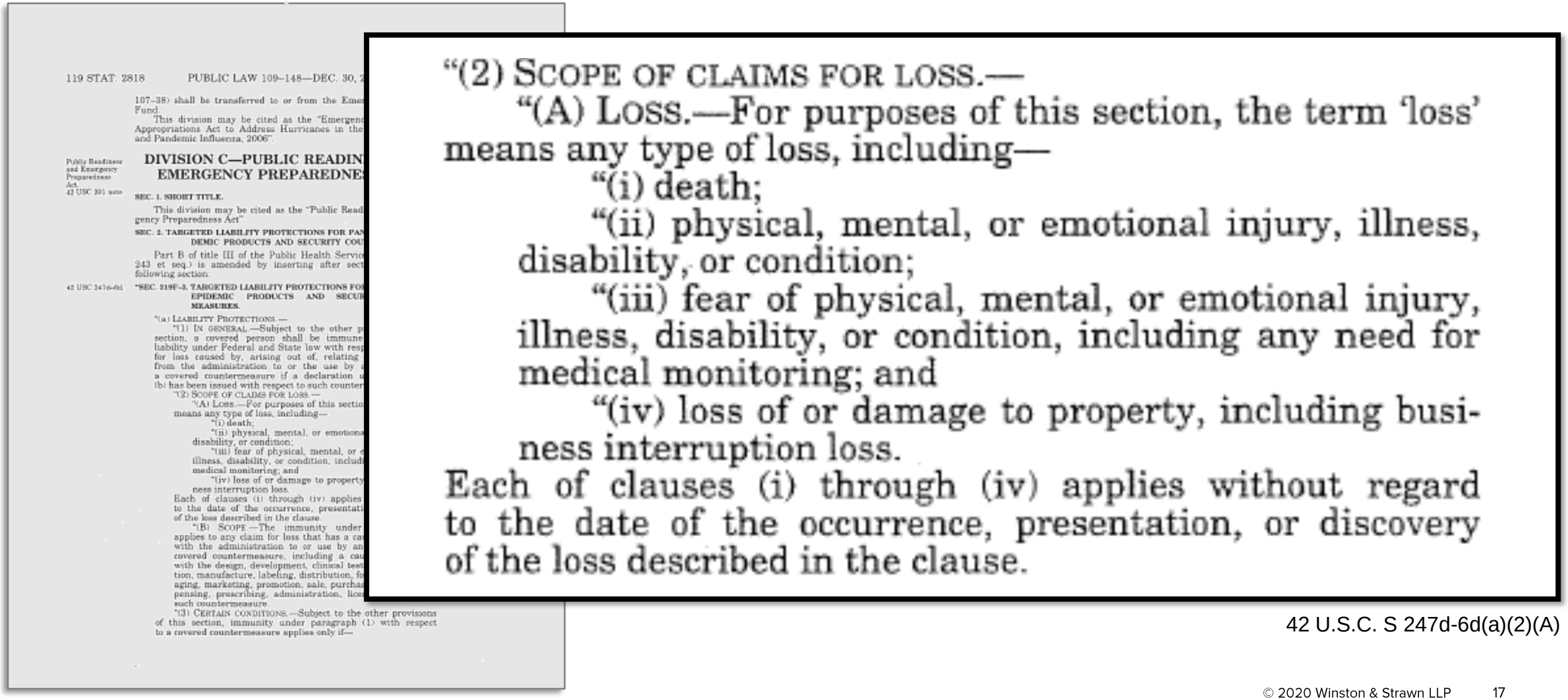

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"(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

"(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

42 U.S.C. S 247d-6d(a)(2)(A)

What Claims are Covered by Immunity?

- If all requirements of the PREP Act and Declaration are met, immunity covers:
  - Claims brought under state or federal law
  - Claims for loss sounding in tort or contract—but limited to claims for personal injury or damage to property
  - Claims related to compliance with local, state, or federal laws, regulations or other legal requirements
- Immunity applies "to a covered countermeasure regardless of whether [it] is obtained by donation, commercial sale, or any other means of distribution…"

March 10, 2020 Advisory Opinion Advisory Opinion, p. 2;

Limits of PREP Act Immunity

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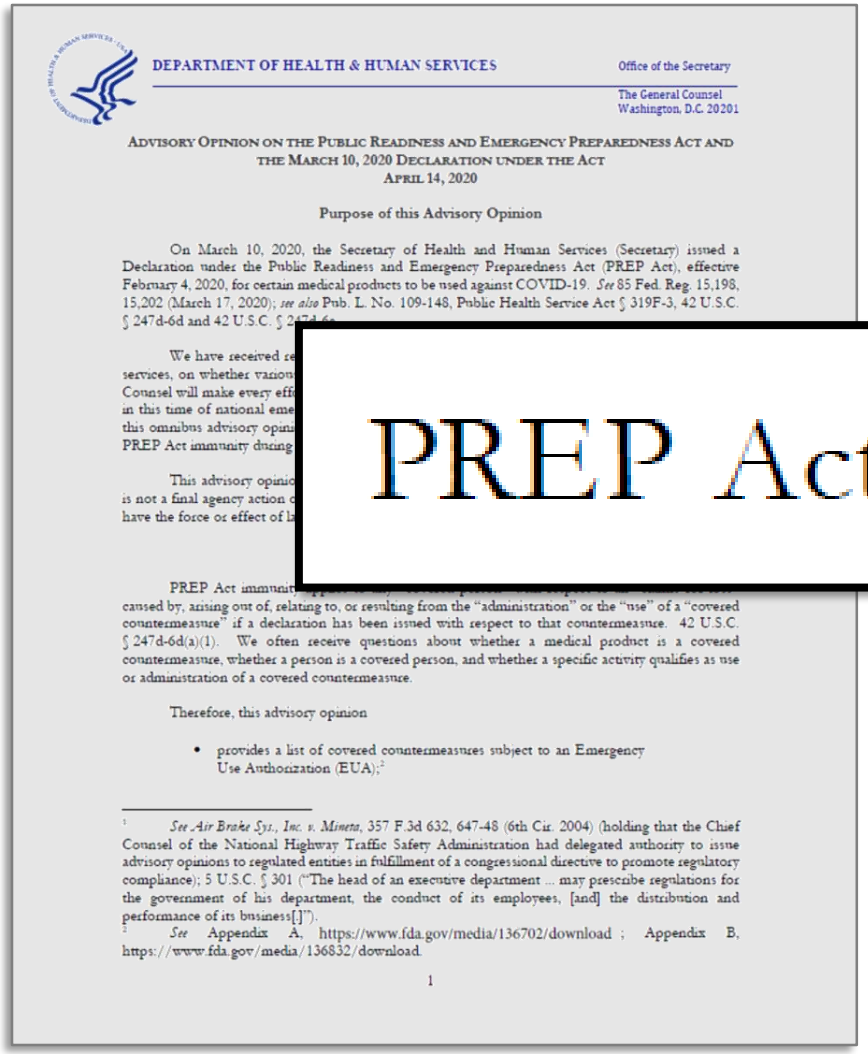
PREP Act Does Not Provide Total Immunity



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caused by, arising out of, relating to, or resulting from the "administration" or the "use" of a "covered countermeasure" if a declaration has been issued with respect to that countermeasure. 42 U.S.C. § 247d-6d(a)(1). We often receive questions about whether a medical product is a covered countermeasure, whether a person is a covered person, and whether a specific activity qualifies as use or administration of a covered countermeasure.

Therefore, this advisory opinion

- provides a list of covered countermeasures subject to an Emergency Use Authorization (EUA);[2]

[1] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]").

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PREP Act immunity is not absolute.

April 14, 2020 Advisory Opinion, pp. 2

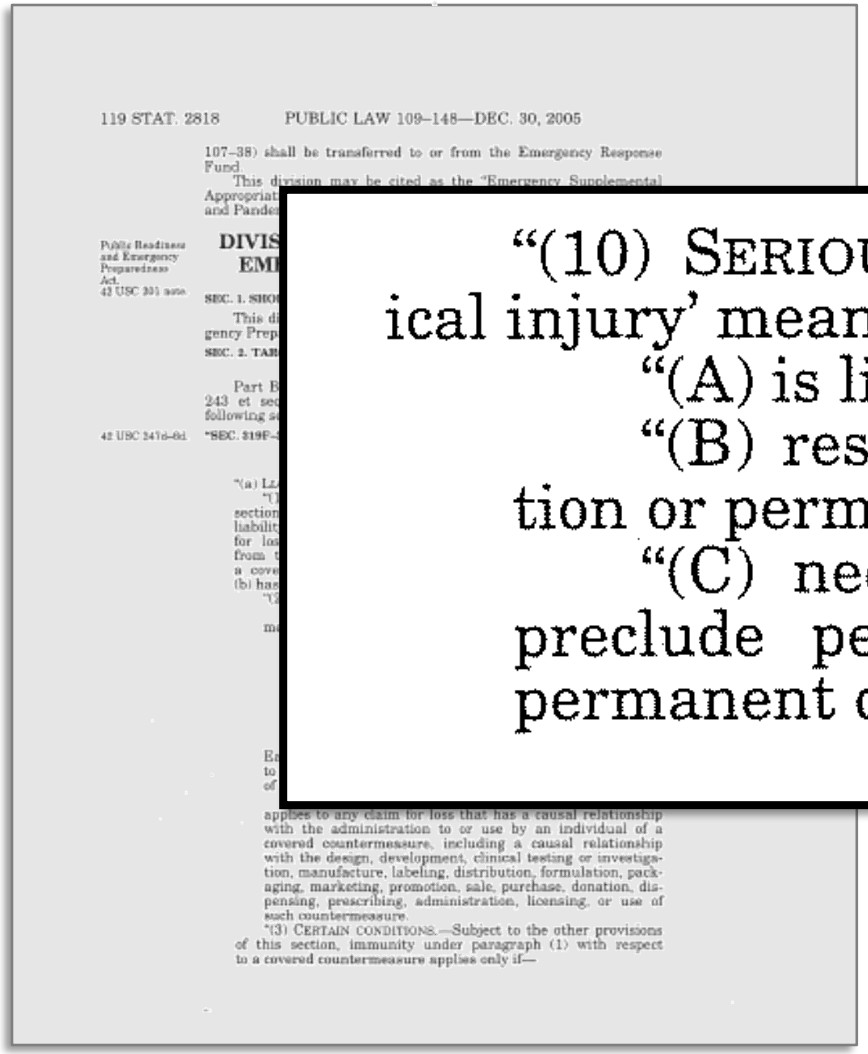
What are the Limits of PREP Act Immunity?

No immunity from/for:

- Claims under federal law for equitable relief
- Any governmental enforcement actions, whether civil, criminal or administrative
- Foreign claims where U.S. has no jurisdiction
- Death or serious injury caused by willful misconduct

Advisory Opinion, pp. 2; 42 U.S.C. § 247d-6d(f); U.S. Dept. of Health and Human Services, PREP Act Q&As, *available at* https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#q3; 42 U.S.C. § 247d-6d(d)

What is a “Serious Physical Injury”?



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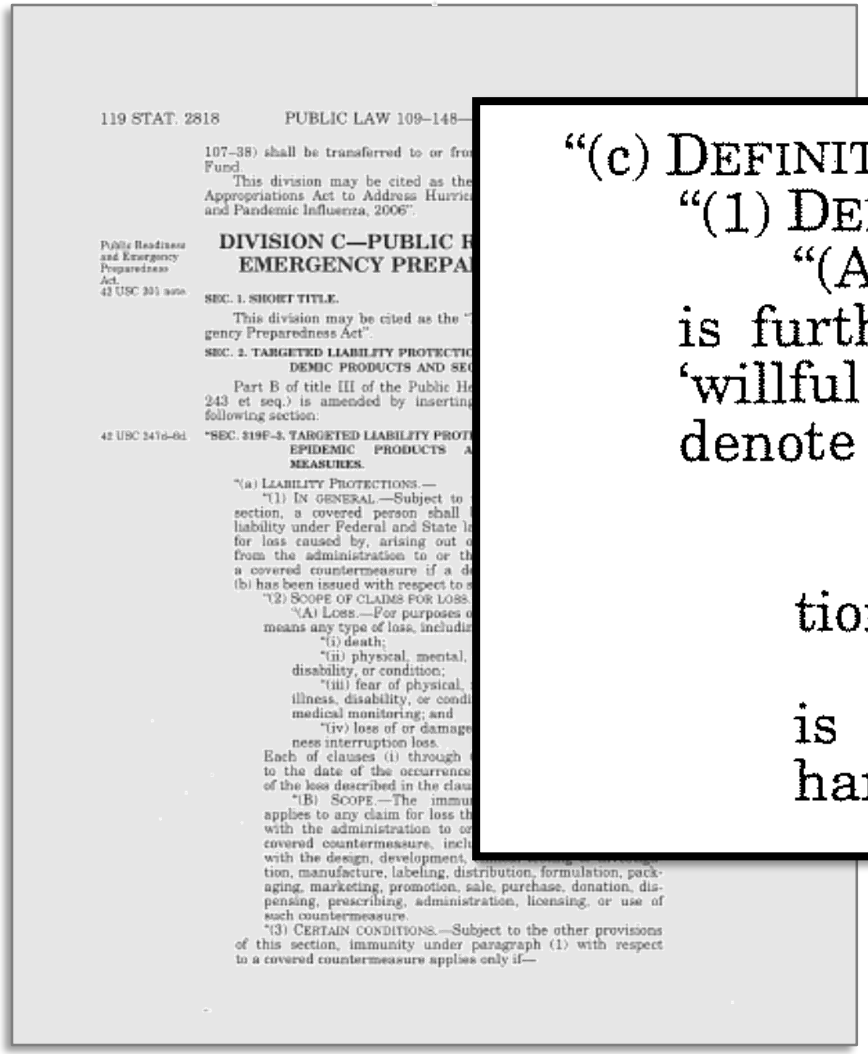
"(3) CERTAIN CONDITIONS.—Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

> “(10) SERIOUS PHYSICAL INJURY.—The term ‘serious physical injury’ means 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.”.

42 U.S.C. § 247d-6d(i)(10)

What is "Willful Misconduct"?



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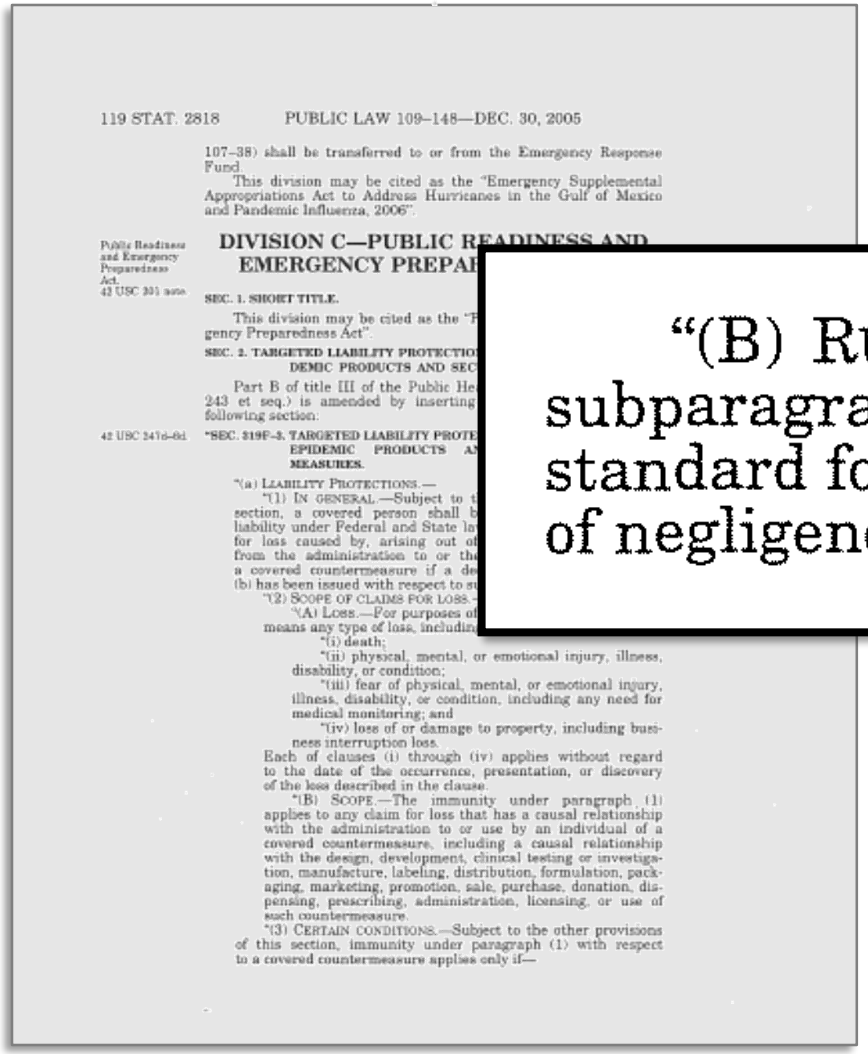
"(c) DEFINITION OF WILLFUL MISCONDUCT.—
"(1) DEFINITION.—
"(A) IN GENERAL.—Except as the meaning of such term is further restricted pursuant to paragraph (2), the term 'willful misconduct' shall, for purposes of subsection (d), denote an act or omission that is taken—
"(i) intentionally to achieve a 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.

42 U.S.C. § 247d-6d(c)(1)(A)

How is "Willful Misconduct" Construed?



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"(3) CERTAIN CONDITIONS.—Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

"(B) RULE OF CONSTRUCTION.—The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

42 U.S.C. § 247d-6d(c)(1)(B)

“Willful Misconduct” Safe Harbor Provisions

Program planners and qualified persons where:

- They act “consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure”; and
- Notice is provided to Secretary or health authority of serious physical injury or death within 7 days of discovery of such information.

42 U.S.C. § 247d-6d(c)(4)

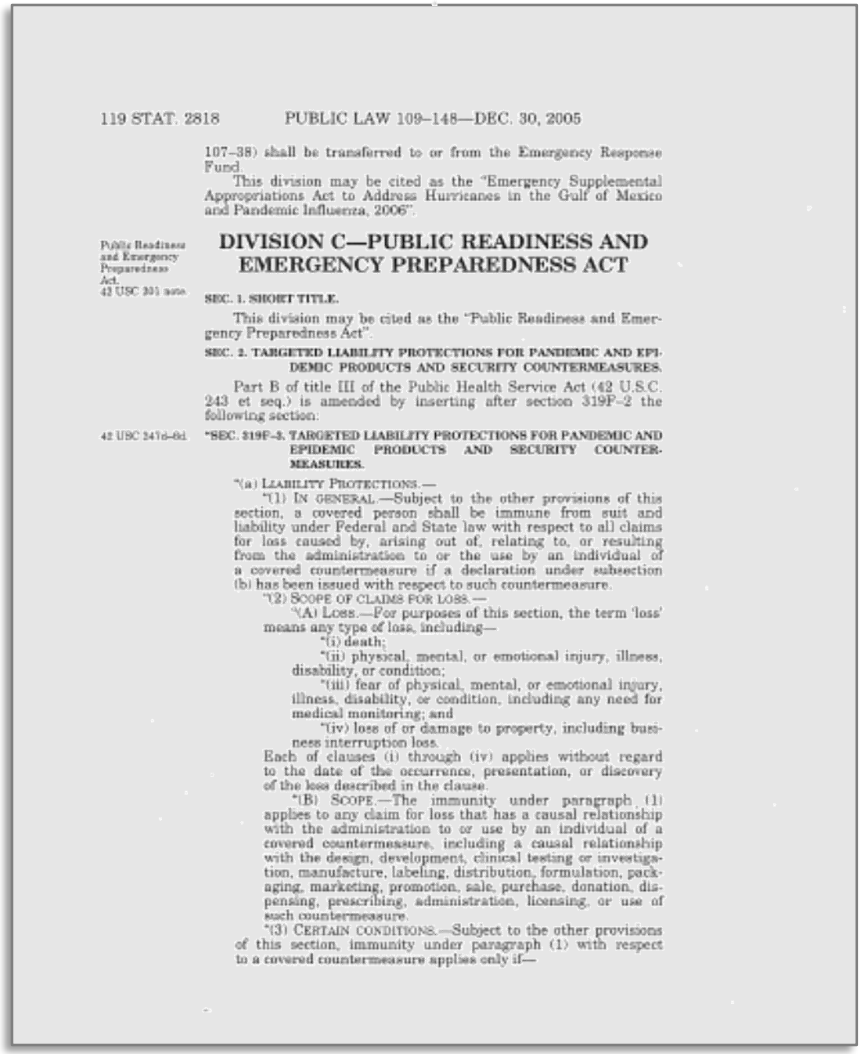
“Willful Misconduct” Safe Harbor Provisions

Manufacturer and distributors where:

- Act or omission alleged to constitute “willful misconduct” is governed by Food, Drug & Cosmetic Act; and
  - Enforcement action has not been initiated for such act or omission; or
  - Enforcement action was terminated or resolved without covered remedy (criminal conviction, injunction, civil payment, revocation of market approval, etc.)

42 U.S.C. § 247d-6d(c)(5)

How Has "Willful Misconduct" Been Applied?



119 STAT. 2818 PUBLIC LAW 109–148—DEC. 30, 2005

107–38) shall be transferred to or from the Emergency Response Fund.

This division may be cited as the "Emergency Supplemental Appropriations Act to Address Hurricanes in the Gulf of Mexico and Pandemic Influenza, 2006".

Public Readiness and Emergency Preparedness Act. 42 USC 201 note.

DIVISION C—PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT

SEC. 1. SHORT TITLE.

This division may be cited as the "Public Readiness and Emergency Preparedness Act".

SEC. 2. TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319F–2 the following section:

42 USC 247d-6d.

"SEC. 319F–3. TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.

"(a) LIABILITY PROTECTIONS.—

"(1) IN GENERAL.—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.

"(2) SCOPE OF CLAIMS FOR LOSS.—

"(A) LOSS.—For purposes of this section, the term 'loss' means any type of loss, including—

"(i) death;

"(ii) physical, mental, or emotional injury, illness, disability, or condition;

"(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

"(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

"(B) SCOPE.—The immunity under paragraph (1) 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, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

"(3) CERTAIN CONDITIONS.—Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

- To date, no courts have interpreted or applied PREP Act "willful misconduct" immunity exception
- Other standards may provide some limited guidance, but additional procedural and substantive protections under PREP Act for "covered persons"

Facts Supporting Fraud or Punitive Damages

- Manipulation or falsification of clinical data [1]
- Knowledge of faulty materials used in manufacturing [2]
- Fraudulent concealment of health or safety issues [3]
- False or misleading marketing [4]

[1] *E.g., Blackwood v. Atrium Med. Corp.*, No. 16-CV-379-LM, 2019 WL 3779698 (D.N.H. Aug. 12, 2019)

[2] *E.g., Cooper Tire & Rubber Co. v. Tuckier*, 826 So. 2d 679 (Miss. 2002)

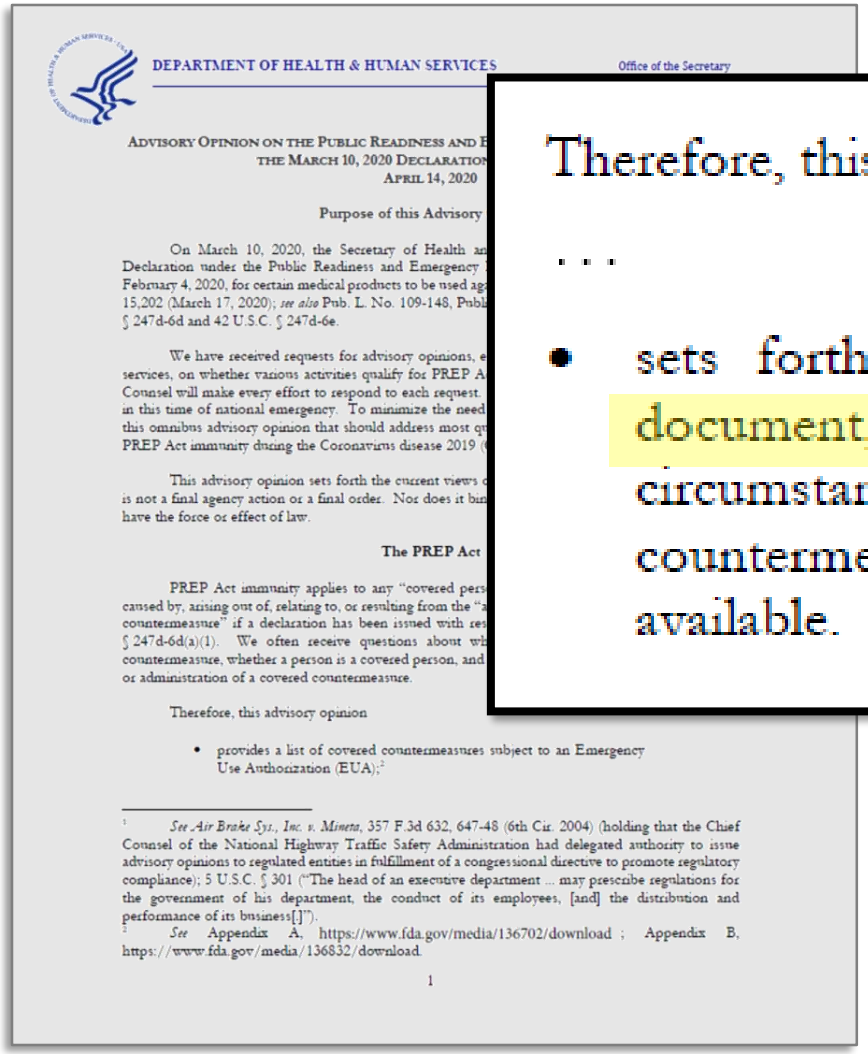
[3] *E.g., Kerrivan v. R.J. Reynolds Tobacco Co.*, 953 F.3d 1196 (11th Cir. 2020)

[4] *E.g., Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517 (D. Minn. 1989)

Proactive Measures to Consider

- Oversight protocols for data generating activities, such as clinical trials
- Quality control checks for new manufacturing processes or suppliers
- Confirm product labels fully reflect known risks
- Promptly update product labels with new safety information
- Ensure marketing statements are accurate and supported by validated data
- Exercise care regarding marketing claims of agency approval

Reasonableness is Key



DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of the Secretary

ADVISORY OPINION ON THE PUBLIC READINESS AND E
THE MARCH 10, 2020 DECLARATIO
APRIL 14, 2020

Purpose of this Advisory

On March 10, 2020, the Secretary of Health a
Declaration under the Public Readiness and Emergency
February 4, 2020, for certain medical products to be used ag
15,202 (March 17, 2020); *see also* Pub. L. No. 109-148, Publ
§ 247d-6d and 42 U.S.C. § 247d-6e.

We have received requests for advisory opinions, e
services, on whether various activities qualify for PREP A
Counsel will make every effort to respond to each request.
in this time of national emergency. To minimize the need
this omnibus advisory opinion that should address most q
PREP Act immunity during the Coronavirus disease 2019 (

This advisory opinion sets forth the current views
is not a final agency action or a final order. Nor does it bi
have the force or effect of law.

The PREP Act

PREP Act immunity applies to any "covered pers
caused by, arising out of, relating to, or resulting from the "
countermeasure" if a declaration has been issued with res
§ 247d-6d(a)(1). We often receive questions about wh
countermeasure, whether a person is a covered person, and
or administration of a covered countermeasure.

Therefore, this advisory opinion

- provides a list of covered countermeasures subject to an Emergency Use Authorization (EUA);[2]

[1] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]").

[2] *See* Appendix A, https://www.fda.gov/media/136702/download ; Appendix B, https://www.fda.gov/media/136832/download.

1

Therefore, this advisory opinion

. . .

- sets forth HHS's view that covered persons should take, and document, reasonable precautions under the current emergent circumstances to facilitate the safe use or administration of covered countermeasures and to make those documents publicly and easily available.

April 14, 2020 Advisory Opinion, pp. 1-2

Application of PREP Act Immunity

WINSTON & STRAWN LLP

Covered Public Health Threats

- Acute Radiation Syndrome (2008)
- Smallpox (2008)
- Anthrax (2008)
- Botulism (2008)
- Influenza Viruses (2008), including H1N1 Flu (2009)
- Ebola (2014)
- Nerve Agent Poisoning (2017)
- Zika (2017)
- COVID-19 (2020)

Public Readiness and Emergency Preparedness Act: Current Declarations, available at https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

PREP Act Litigation: Uncharted Territory

- Only one Court has considered the merits of the PREP Act immunity defense based on use of a covered countermeasure
  - In response to a 2009 outbreak of the H1N1 influenza virus, the HHS Secretary issued declarations recommending the administration of an influenza vaccination
  - New York appellate court affirmed dismissal of complaint alleging that inoculation of child without consent pursuant to Governor's disaster emergency authorization for vaccination program at schools constituted negligence and battery

> *"Considering the breadth of the preemption clause together with the sweeping language of the state's immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person … including one based upon a defendant's failure to obtain consent."*

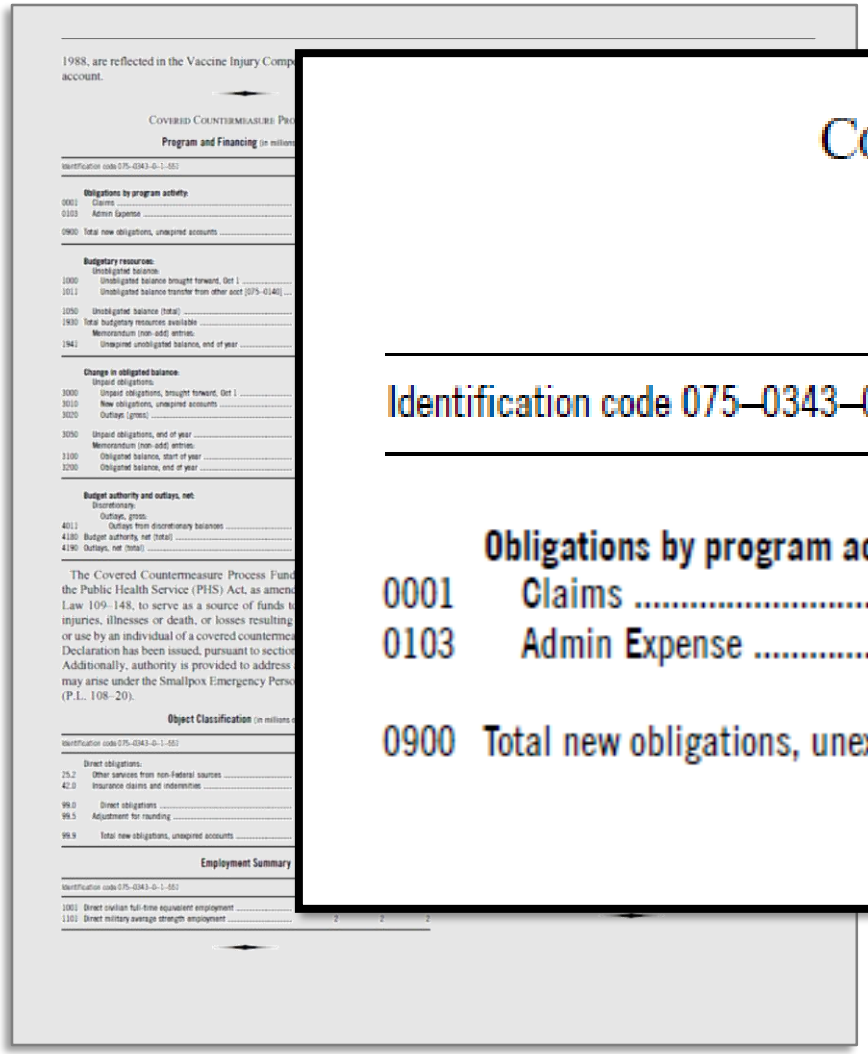
Parker v. St. Lawrence County Pub. Health Dept., 102 A.D.3d 140 (N.Y. App. Div. 2012)

Countermeasures Injury Compensation Program

- The PREP Act provides for the establishment of a Covered Countermeasure Process Fund to provide compensation to eligible individuals
- Only covers death or serious physical injury directly caused by a Covered Countermeasure
- Only covers expenses or provides benefits that other third-party payers do not have an obligation to pay
- Applicants must file benefits request within one year from the date they used the covered countermeasure alleged to have caused injury

42 U.S.C. 247d-6e; *Countermeasures Injury Compensation Program*, Health Resources & Services Administration, available at https://www.hrsa.gov/cicp/index.html

Covered Countermeasure Process Fund



COVERED COUNTERMEASURE PROCESS FUND

Program and Financing (in millions of dollars)

Identification code 075–0343–0–1–551	2016	2017	2018	2019	2020 est	2021 est
Obligations by program activity:						
0001 Claims	3	2	2		1	1
0103 Admin Expense	1			2	2	2
0900 Total new obligations, unexpired accounts	4	2	2	2	3	3

Budget of the United States, available at https://www.govinfo.gov/app/collection/budget/2020

PREP Act vs. Typical Product Liability Litigation

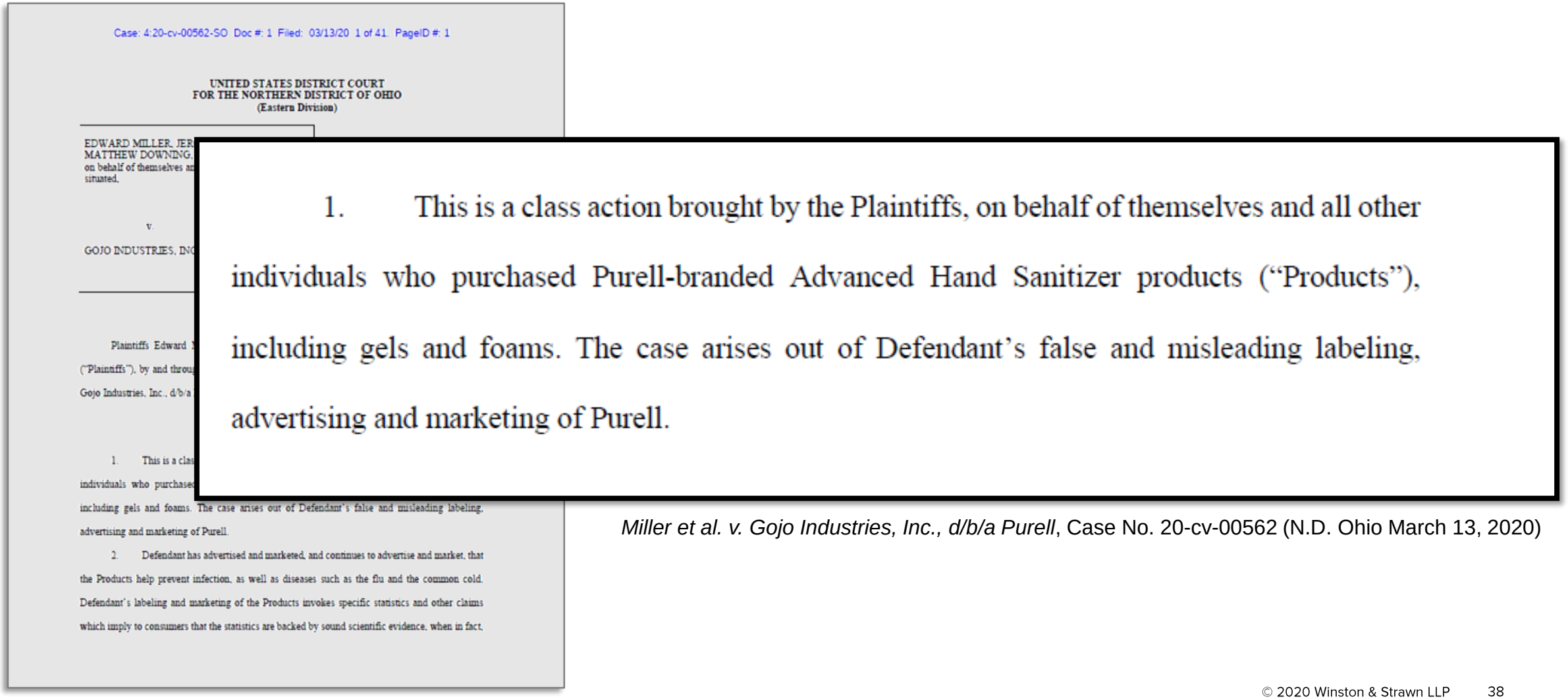
	PREP Act Litigation	Typical Products Litigation
Jurisdiction	Exclusive federal cause of action alleging PREP Act exception before 3-judge panel in D.D.C.	State or Federal Court; jury trial available
Governing Law	State where alleged misconduct occurred; federal law defines "willful misconduct" and "serious injury"	State law (typically where injury took place)
Pleading Requirements	With particularity; affidavits and certified medical records requirements	Notice pleading (FRCP 8) or State equivalent
Discovery	None before interlocutory appeal of MTD; limited to matters "directly related to material issues"	Relevant and proportional to claims and defenses (FRCP 26) or State equivalent
Damages	Reduced by amount of collateral source benefits; Proportional liability for noneconomic damages	Dependent on governing state law
Burden of Proof	Clear and convincing	Preponderance of the evidence

COVID-19 Product Categories

- In vitro diagnostic products
- High complexity molecular-based laboratory developed tests
- SARS-CoV-2 antibody tests
- Personal protective equipment and related devices
- Ventilators and other medical devices
- Therapeutics

FDA Emergency Use Authorization (EUA) information, and list of all current EUAs, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

False Advertising and Consumer Protection



Case: 4:20-cv-00562-SO Doc #: 1 Filed: 03/13/20 1 of 41. PageID #: 1

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
(Eastern Division)

EDWARD MILLER, JER
MATTHEW DOWNING,
on behalf of themselves an
situated,

v.

GOJO INDUSTRIES, INC

Plaintiffs Edward
("Plaintiffs"), by and throu
Gojo Industries, Inc., d/b/a

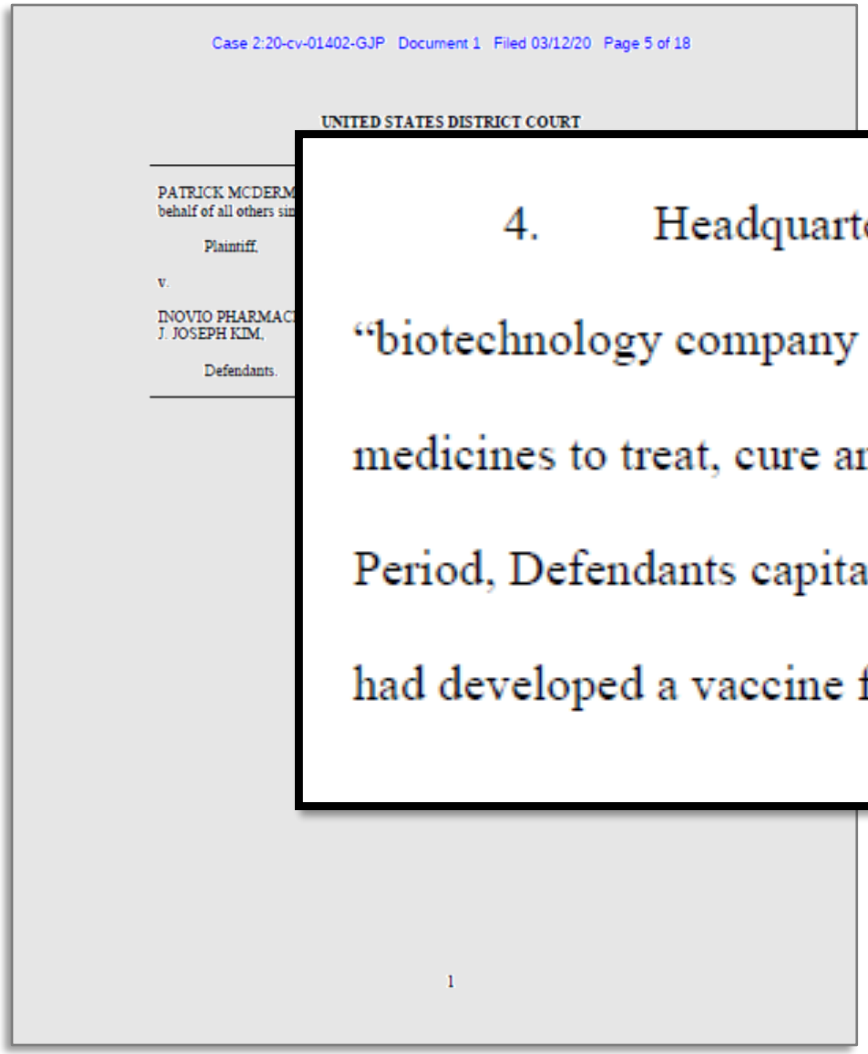
1. This is a clas
individuals who purchase
including gels and foams. The case arises out of Defendant's false and misleading labeling,
advertising and marketing of Purell.

2. Defendant has advertised and marketed, and continues to advertise and market, that the Products help prevent infection, as well as diseases such as the flu and the common cold. Defendant's labeling and marketing of the Products invokes specific statistics and other claims which imply to consumers that the statistics are backed by sound scientific evidence, when in fact,

1. This is a class action brought by the Plaintiffs, on behalf of themselves and all other individuals who purchased Purell-branded Advanced Hand Sanitizer products ("Products"), including gels and foams. The case arises out of Defendant's false and misleading labeling, advertising and marketing of Purell.

Miller et al. v. Gojo Industries, Inc., d/b/a Purell, Case No. 20-cv-00562 (N.D. Ohio March 13, 2020)

Product Statement-Based Securities Fraud


Case 2:20-cv-01402-GJP Document 1 Filed 03/12/20 Page 5 of 18

UNITED STATES DISTRICT COURT

PATRICK MCDERM
behalf of all others sim

Plaintiff,

v.

INOVIO PHARMAC
J. JOSEPH KIM,

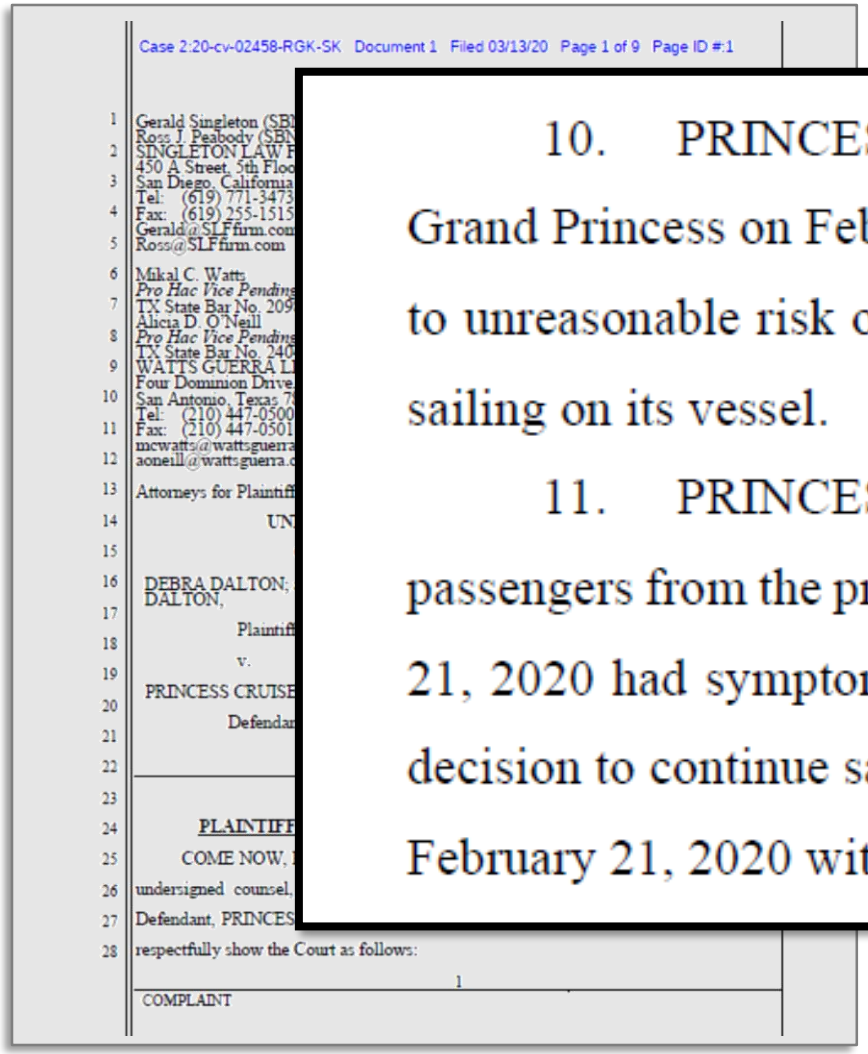
Defendants.

1

4. Headquartered in Plymouth Meeting, Pennsylvania, Inovio purports to be a "biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to treat, cure and/or protect people from . . . infectious diseases." During the Class Period, Defendants capitalized on widespread COVID-19 fears by falsely claiming that Invovio had developed a vaccine for COVID-19.

McDermid v. Inovio Pharmaceuticals, Inc. et al., Case No. 20-cv-01402 (E.D. Pa. March 12, 2020)

Negligent Exposure to Health Risks


Case 2:20-cv-02458-RGK-SK Document 1 Filed 03/13/20 Page 1 of 9 Page ID #:1

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Attorneys for Plaintiff

UN

DEBRA DALTON;
DALTON,

Plaintiff

v.

PRINCESS CRUISE

Defendar

PLAINTIFF

COME NOW,
undersigned counsel,
Defendant, PRINCES
respectfully show the Court as follows:

1

COMPLAINT

10. PRINCESS owed Plaintiffs, who were paying passengers who boarded the Grand Princess on February 21, 2020, the duty to ensure that they would not be exposed to unreasonable risk of harm that PRINCESS knew or should have known about while sailing on its vessel.

11. PRINCESS breached that duty. It had knowledge that at least one of its passengers from the prior voyage who disembarked the Grand Princess early on February 21, 2020 had symptoms of coronavirus. Despite that, PRINCESS made the conscious decision to continue sailing the next voyage of the Grand Princess, which began later on February 21, 2020 with another 3,534 passengers and crew on an infected ship.

Dalton et al. v. Princess Cruise Lines Ltd., Case No. 20-cv-02458 (C.D. Cal. March 13, 2020)

First Steps in PREP Act Litigation

Preemption

- Motion to dismiss where Complaint:
  - Alleges use of a Covered Countermeasure by a Covered Person
  - Fails to allege willful misconduct
- Likely cannot remove to Federal Court solely to determine preemption

Removal

- Applicability of PREP Act exception should be a Federal Question
- "Willful misconduct" and "serious injuries" are defined by Federal statute

Transfer

- 3-judge panel in the District Court of D.C. has exclusive jurisdiction over federal cause of action alleging PREP Act exception
- Federal Appeals Court for the District of Columbia has exclusive appellate jurisdiction

Q&A

WINSTON & STRAWN LLP

COVID-19 Client Resource Center

As a significant number of cities and states across the country start the process of relaxing stay-at-home orders and plan for reopening, our **COVID-19 Legal Task Force** is closely monitoring each state's specific guidance.

- To help you stay abreast of these developments, we have created a **state-by-state reopening tracker** with links to each state's government orders, plans, guidance, and press releases. We are updating this page regularly with new information as it becomes available.
- Updates to our current perspectives and guidance on specific COVID-19 legal issues are updated daily.

Visit www.Winston.com to access our COVID-19 Resource Center or to contact a member of the Task Force.

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