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# 42 U.S. Code § 247d–6d

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## Targeted liability protections for pandemic and epidemic products and security countermeasures

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### **(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—

- (A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;
- (B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and
- (C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who—

- (i) was in a population specified by the declaration; and
- (ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

#### **(4) Applicability of certain conditions**

With respect to immunity under paragraph (1) and subject to the other provisions of this section:

- (A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).
- (B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

#### **(5) Effect of distribution method**

The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

#### **(6) Rebuttable presumption**

For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b), of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

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