

1 **DIVISION E—PUBLIC READI-**
2 **NESS AND EMERGENCY PRE-**
3 **PAREDNESS ACT**

4 **SEC. 1. SHORT TITLE.**

5 This division may be cited as the “Public Readiness
6 and Emergency Preparedness Act”.

7 **SEC. 2. TARGETED LIABILITY PROTECTIONS FOR PAN-**
8 **DEMIC AND EPIDEMIC PRODUCTS AND SECU-**
9 **RITY COUNTERMEASURES.**

10 Part B of title III of the Public Health Service Act
11 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
12 tion 319F-2 the following section:

13 **“SEC. 319F-3. TARGETED LIABILITY PROTECTIONS FOR**
14 **PANDEMIC AND EPIDEMIC PRODUCTS AND**
15 **SECURITY COUNTERMEASURES.**

16 **“(a) LIABILITY PROTECTIONS.—**

17 **“(1) IN GENERAL.—**Subject to the other provi-
18 sions of this section, a covered person shall be im-
19 mune from suit and liability under Federal and
20 State law with respect to all claims for loss caused
21 by, arising out of, relating to, or resulting from the
22 administration to or the use by an individual of a
23 covered countermeasure if a declaration under sub-



1 section (b) has been issued with respect to such
2 countermeasure.

3 “(2) SCOPE OF CLAIMS FOR LOSS.—

4 “(A) LOSS.—For purposes of this section,
5 the term ‘loss’ means any type of loss,
6 including—

7 “(i) death;

8 “(ii) physical, mental, or emotional in-
9 jury, illness, disability, or condition;

10 “(iii) fear of physical, mental, or emo-
11 tional injury, illness, disability, or condi-
12 tion, including any need for medical moni-
13 toring; and

14 “(iv) loss of or damage to property,
15 including business interruption loss.

16 Each of clauses (i) through (iv) applies without
17 regard to the date of the occurrence, presen-
18 tation, or discovery of the loss described in the
19 clause.

20 “(B) SCOPE.—The immunity under para-
21 graph (1) applies to any claim for loss that has
22 a causal relationship with the administration to
23 or use by an individual of a covered counter-
24 measure, including a causal relationship with
25 the design, development, clinical testing or in-



1 vestigation, manufacture, labeling, distribution,
2 formulation, packaging, marketing, promotion,
3 sale, purchase, donation, dispensing, pre-
4 scribing, administration, licensing, or use of
5 such countermeasure.

6 “(3) CERTAIN CONDITIONS.—Subject to the
7 other provisions of this section, immunity under
8 paragraph (1) with respect to a covered counter-
9 measure applies only if—

10 “(A) the countermeasure was administered
11 or used during the effective period of the dec-
12 laration that was issued under subsection (b)
13 with respect to the countermeasure;

14 “(B) the countermeasure was administered
15 or used for the category or categories of dis-
16 eases, health conditions, or threats to health
17 specified in the declaration; and

18 “(C) in addition, in the case of a covered
19 person who is a program planner or qualified
20 person with respect to the administration or use
21 of the countermeasure, the countermeasure was
22 administered to or used by an individual who—

23 “(i) was in a population specified by
24 the declaration; and



1 “(ii) was at the time of administration
2 physically present in a geographic area
3 specified by the declaration or had a con-
4 nection to such area specified in the dec-
5 laration.

6 “(4) APPLICABILITY OF CERTAIN CONDI-
7 TIONS.—With respect to immunity under paragraph
8 (1) and subject to the other provisions of this sec-
9 tion:

10 “(A) In the case of a covered person who
11 is a manufacturer or distributor of the covered
12 countermeasure involved, the immunity applies
13 without regard to whether such countermeasure
14 was administered to or used by an individual in
15 accordance with the conditions described in
16 paragraph (3)(C).

17 “(B) In the case of a covered person who
18 is a program planner or qualified person with
19 respect to the administration or use of the cov-
20 ered countermeasure, the scope of immunity in-
21 cludes circumstances in which the counter-
22 measure was administered to or used by an in-
23 dividual in circumstances in which the covered
24 person reasonably could have believed that the
25 countermeasure was administered or used in ac-



1 cordance with the conditions described in para-
2 graph (3)(C).

3 “(5) EFFECT OF DISTRIBUTION METHOD.—The
4 provisions of this section apply to a covered counter-
5 measure regardless of whether such countermeasure
6 is obtained by donation, commercial sale, or any
7 other means of distribution, except to the extent
8 that, under paragraph (2)(E) of subsection (b), the
9 declaration under such subsection provides that sub-
10 section (a) applies only to covered countermeasures
11 obtained through a particular means of distribution.

12 “(6) REBUTTABLE PRESUMPTION.—For pur-
13 poses of paragraph (1), there shall be a rebuttable
14 presumption that any administration or use, during
15 the effective period of the emergency declaration by
16 the Secretary under subsection (b), of a covered
17 countermeasure shall have been for the category or
18 categories of diseases, health conditions, or threats
19 to health with respect to which such declaration was
20 issued.

21 “(b) DECLARATION BY SECRETARY.—

22 “(1) AUTHORITY TO ISSUE DECLARATION.—
23 Subject to paragraph (2), if the Secretary makes a
24 determination that a disease or other health condi-
25 tion or other threat to health constitutes a public



1 health emergency, or that there is a credible risk
2 that the disease, condition, or threat may in the fu-
3 ture constitute such an emergency, the Secretary
4 may make a declaration, through publication in the
5 Federal Register, recommending, under conditions
6 as the Secretary may specify, the manufacture, test-
7 ing, development, distribution, administration, or use
8 of one or more covered countermeasures, and stating
9 that subsection (a) is in effect with respect to the
10 activities so recommended.

11 “(2) CONTENTS.—In issuing a declaration
12 under paragraph (1), the Secretary shall identify,
13 for each covered countermeasure specified in the
14 declaration—

15 “(A) the category or categories of diseases,
16 health conditions, or threats to health for which
17 the Secretary recommends the administration
18 or use of the countermeasure;

19 “(B) the period or periods during which,
20 including as modified by paragraph (3), sub-
21 section (a) is in effect, which period or periods
22 may be designated by dates, or by milestones or
23 other description of events, including factors
24 specified in paragraph (6);



1 “(C) the population or populations of indi-
2 viduals for which subsection (a) is in effect with
3 respect to the administration or use of the
4 countermeasure (which may be a specification
5 that such subsection applies without geographic
6 limitation to all individuals);

7 “(D) the geographic area or areas for
8 which subsection (a) is in effect with respect to
9 the administration or use of the countermeasure
10 (which may be a specification that such sub-
11 section applies without geographic limitation),
12 including, with respect to individuals in the
13 populations identified under subparagraph (C),
14 a specification, as determined appropriate by
15 the Secretary, of whether the declaration ap-
16 plies only to individuals physically present in
17 such areas or whether in addition the declara-
18 tion applies to individuals who have a connec-
19 tion to such areas, which connection is de-
20 scribed in the declaration; and

21 “(E) whether subsection (a) is effective
22 only to a particular means of distribution as
23 provided in subsection (a)(5) for obtaining the
24 countermeasure, and if so, the particular means
25 to which such subsection is effective.



1 “(3) EFFECTIVE PERIOD OF DECLARATION.—

2 “(A) FLEXIBILITY OF PERIOD.—The Sec-
3 retary may, in describing periods under para-
4 graph (2)(B), have different periods for dif-
5 ferent covered persons to address different
6 logistical, practical or other differences in re-
7 sponsibilities.

8 “(B) ADDITIONAL TIME TO BE SPECI-
9 FIED.—In each declaration under paragraph
10 (1), the Secretary, after consulting, to the ex-
11 tent the Secretary deems appropriate, with the
12 manufacturer of the covered countermeasure,
13 shall also specify a date that is after the ending
14 date specified under paragraph (2)(B) and that
15 allows what the Secretary determines is—

16 “(i) a reasonable period for the manu-
17 facturer to arrange for disposition of the
18 covered countermeasure, including the re-
19 turn of such product to the manufacturer;
20 and

21 “(ii) a reasonable period for covered
22 persons to take such other actions as may
23 be appropriate to limit administration or
24 use of the covered countermeasure.



1 “(C) ADDITIONAL PERIOD FOR CERTAIN
2 STRATEGIC NATIONAL STOCKPILE COUNTER-
3 MEASURES.—With respect to a covered counter-
4 measure that is in the stockpile under section
5 319F-2, if such countermeasure was the subject
6 of a declaration under paragraph (1) at the
7 time that it was obtained for the stockpile, the
8 effective period of such declaration shall include
9 a period when the countermeasure is adminis-
10 tered or used pursuant to a distribution or re-
11 lease from the stockpile.

12 “(4) AMENDMENTS TO DECLARATION.—The
13 Secretary may through publication in the Federal
14 Register amend any portion of a declaration under
15 paragraph (1). Such an amendment shall not retro-
16 actively limit the applicability of subsection (a) with
17 respect to the administration or use of the covered
18 countermeasure involved.

19 “(5) CERTAIN DISCLOSURES.—In publishing a
20 declaration under paragraph (1) in the Federal Reg-
21 ister, the Secretary is not required to disclose any
22 matter described in section 552(b) of title 5, United
23 States Code.

24 “(6) FACTORS TO BE CONSIDERED.—In decid-
25 ing whether and under what circumstances or condi-



1 tions to issue a declaration under paragraph (1)
2 with respect to a covered countermeasure, the Sec-
3 retary shall consider the desirability of encouraging
4 the design, development, clinical testing or investiga-
5 tion, manufacture, labeling, distribution, formula-
6 tion, packaging, marketing, promotion, sale, pur-
7 chase, donation, dispensing, prescribing, administra-
8 tion, licensing, and use of such countermeasure.

9 “(7) JUDICIAL REVIEW.—No court of the
10 United States, or of any State, shall have subject
11 matter jurisdiction to review, whether by mandamus
12 or otherwise, any action by the Secretary under this
13 subsection.

14 “(8) PREEMPTION OF STATE LAW.—During the
15 effective period of a declaration under subsection
16 (b), or at any time with respect to conduct under-
17 taken in accordance with such declaration, no State
18 or political subdivision of a State may establish, en-
19 force, or continue in effect with respect to a covered
20 countermeasure any provision of law or legal re-
21 quirement that—

22 “(A) is different from, or is in conflict
23 with, any requirement applicable under this sec-
24 tion; and



1 “(B) relates to the design, development,
2 clinical testing or investigation, formulation,
3 manufacture, distribution, sale, donation, pur-
4 chase, marketing, promotion, packaging, label-
5 ing, licensing, use, any other aspect of safety or
6 efficacy, or the prescribing, dispensing, or ad-
7 ministration by qualified persons of the covered
8 countermeasure, or to any matter included in a
9 requirement applicable to the covered counter-
10 measure under this section or any other provi-
11 sion of this Act, or under the Federal Food,
12 Drug, and Cosmetic Act.

13 “(9) REPORT TO CONGRESS.—Within 30 days
14 after making a declaration under paragraph (1), the
15 Secretary shall submit to the appropriate committees
16 of the Congress a report that provides an expla-
17 nation of the reasons for issuing the declaration and
18 the reasons underlying the determinations of the
19 Secretary with respect to paragraph (2). Within 30
20 days after making an amendment under paragraph
21 (4), the Secretary shall submit to such committees
22 a report that provides the reasons underlying the de-
23 termination of the Secretary to make the amend-
24 ment.

25 “(c) DEFINITION OF WILLFUL MISCONDUCT.—



1 “(1) DEFINITION.—

2 “(A) IN GENERAL.—Except as the mean-
3 ing of such term is further restricted pursuant
4 to paragraph (2), the term ‘willful misconduct’
5 shall, for purposes of subsection (d), denote an
6 act or omission that is taken—

7 “(i) intentionally to achieve a wrong-
8 ful purpose;

9 “(ii) knowingly without legal or fac-
10 tual justification; and

11 “(iii) in disregard of a known or obvi-
12 ous risk that is so great as to make it
13 highly probable that the harm will out-
14 weigh the benefit.

15 “(B) RULE OF CONSTRUCTION.—The cri-
16 terion stated in subparagraph (A) shall be con-
17 strued as establishing a standard for liability
18 that is more stringent than a standard of neg-
19 ligence in any form or recklessness.

20 “(2) AUTHORITY TO PROMULGATE REGU-
21 LATORY DEFINITION.—

22 “(A) IN GENERAL.—The Secretary, in con-
23 sultation with the Attorney General, shall pro-
24 mulgate regulations, which may be promulgated
25 through interim final rules, that further restrict



1 the scope of actions or omissions by a covered
2 person that may qualify as 'willful misconduct'
3 for purposes of subsection (d).

4 "(B) FACTORS TO BE CONSIDERED.—In
5 promulgating the regulations under this para-
6 graph, the Secretary, in consultation with the
7 Attorney General, shall consider the need to de-
8 fine the scope of permissible civil actions under
9 subsection (d) in a way that will not adversely
10 affect the public health.

11 "(C) TEMPORAL SCOPE OF REGULA-
12 TIONS.—The regulations under this paragraph
13 may specify the temporal effect that they shall
14 be given for purposes of subsection (d).

15 "(D) INITIAL RULEMAKING.—Within 180
16 days after the enactment of the Public Readiness and
17 Emergency Preparedness Act, the Secretary, in consultation with the Attorney General, shall commence and complete an initial
18 rulemaking process under this paragraph.

19 "(3) PROOF OF WILLFUL MISCONDUCT.—In an
20 action under subsection (d), the plaintiff shall have
21 the burden of proving by clear and convincing evidence
22 willful misconduct by each covered person
23
24



1 sued and that such willful misconduct caused death
2 or serious physical injury.

3 “(4) DEFENSE FOR ACTS OR OMISSIONS TAKEN
4 PURSUANT TO SECRETARY’S DECLARATION.—Not-
5 withstanding any other provision of law, a program
6 planner or qualified person shall not have engaged
7 in ‘willful misconduct’ as a matter of law where such
8 program planner or qualified person acted consistent
9 with applicable directions, guidelines, or rec-
10 ommendations by the Secretary regarding the ad-
11 ministration or use of a covered countermeasure that
12 is specified in the declaration under subsection (b),
13 provided either the Secretary, or a State or local
14 health authority, was provided with notice of infor-
15 mation regarding serious physical injury or death
16 from the administration or use of a covered counter-
17 measure that is material to the plaintiff’s alleged
18 loss within 7 days of the actual discovery of such in-
19 formation by such program planner or qualified per-
20 son.

21 “(5) EXCLUSION FOR REGULATED ACTIVITY OF
22 MANUFACTURER OR DISTRIBUTOR.—

23 “(A) IN GENERAL.—If an act or omission
24 by a manufacturer or distributor with respect to
25 a covered countermeasure, which act or omis-



1 sion is alleged under subsection (e)(3)(A) to
2 constitute willful misconduct, is subject to regu-
3 lation by this Act or by the Federal Food,
4 Drug, and Cosmetic Act, such act or omission
5 shall not constitute 'willful misconduct' for pur-
6 poses of subsection (d) if—

7 “(i) neither the Secretary nor the At-
8 torney General has initiated an enforce-
9 ment action with respect to such act or
10 omission; or

11 “(ii) such an enforcement action has
12 been initiated and the action has been ter-
13 minated or finally resolved without a cov-
14 ered remedy.

15 Any action or proceeding under subsection (d)
16 shall be stayed during the pendency of such an
17 enforcement action.

18 “(B) DEFINITIONS.—For purposes of this
19 paragraph, the following terms have the fol-
20 lowing meanings:

21 “(i) ENFORCEMENT ACTION.—The
22 term 'enforcement action' means a crimi-
23 nal prosecution, an action seeking an in-
24 junction, a seizure action, a civil monetary
25 proceeding based on willful misconduct, a



1 mandatory recall of a product because vol-
2 untary recall was refused, a proceeding to
3 compel repair or replacement of a product,
4 a termination of an exemption under sec-
5 tion 505(i) or 520(g) of the Federal Food,
6 Drug, and Cosmetic Act, a debarment pro-
7 ceeding, an investigator disqualification
8 proceeding where an investigator is an em-
9 ployee or agent of the manufacturer, a rev-
10 ocation, based on willful misconduct, of an
11 authorization under section 564 of such
12 Act, or a suspension or withdrawal, based
13 on willful misconduct, of an approval or
14 clearance under chapter V of such Act or
15 of a licensure under section 351 of this
16 Act.

17 “(ii) COVERED REMEDY.—The term
18 ‘covered remedy’ means an outcome—

19 “(I) that is a criminal conviction,
20 an injunction, or a condemnation, a
21 civil monetary payment, a product re-
22 call, a repair or replacement of a
23 product, a termination of an exemp-
24 tion under section 505(i) or 520(g) of
25 the Federal Food, Drug, and Cos-



1 metic Act, a debarment, an investi-
2 gator disqualification, a revocation of
3 an authorization under section 564 of
4 such Act, or a suspension or with-
5 drawal of an approval or clearance
6 under chapter 5 of such Act or of a
7 licensure under section 351 of this
8 Act; and

9 “(II) that results from a final de-
10 termination by a court or from a final
11 agency action.

12 “(iii) FINAL.—The terms ‘final’ and
13 ‘finally’—

14 “(I) with respect to a court de-
15 termination, or to a final resolution of
16 an enforcement action that is a court
17 determination, mean a judgment from
18 which an appeal of right cannot be
19 taken or a voluntary or stipulated dis-
20 missal; and

21 “(II) with respect to an agency
22 action, or to a final resolution of an
23 enforcement action that is an agency
24 action, mean an order that is not sub-
25 ject to further review within the agen-



1 cy and that has not been reversed, va-
2 cated, enjoined, or otherwise nullified
3 by a final court determination or a
4 voluntary or stipulated dismissal.

5 “(C) RULES OF CONSTRUCTION.—

6 “(i) IN GENERAL.—Nothing in this
7 paragraph shall be construed—

8 “(I) to affect the interpretation
9 of any provision of the Federal Food,
10 Drug, and Cosmetic Act, of this Act,
11 or of any other applicable statute or
12 regulation; or

13 “(II) to impair, delay, alter, or
14 affect the authority, including the en-
15 forcement discretion, of the United
16 States, of the Secretary, of the Attor-
17 ney General, or of any other official
18 with respect to any administrative or
19 court proceeding under this Act,
20 under the Federal Food, Drug, and
21 Cosmetic Act, under title 18 of the
22 United States Code, or under any
23 other applicable statute or regulation.

24 “(ii) MANDATORY RECALLS.—A man-
25 datory recall called for in the declaration is



1 not a Food and Drug Administration en-
2 forcement action.

3 “(d) EXCEPTION TO IMMUNITY OF COVERED PER-
4 SONS.—

5 “(1) IN GENERAL.—Subject to subsection (f),
6 the sole exception to the immunity from suit and li-
7 ability of covered persons set forth in subsection (a)
8 shall be for an exclusive Federal cause of action
9 against a covered person for death or serious phys-
10 ical injury proximately caused by willful misconduct,
11 as defined pursuant to subsection (c), by such cov-
12 ered person. For purposes of section 2679(b)(2)(B)
13 of title 28, United States Code, such a cause of ac-
14 tion is not an action brought for violation of a stat-
15 ute of the United States under which an action
16 against an individual is otherwise authorized.

17 “(2) PERSONS WHO CAN SUE.—An action
18 under this subsection may be brought for wrongful
19 death or serious physical injury by any person who
20 suffers such injury or by any representative of such
21 a person.

22 “(e) PROCEDURES FOR SUIT.—

23 “(1) EXCLUSIVE FEDERAL JURISDICTION.—
24 Any action under subsection (d) shall be filed and



1 maintained only in the United States District Court
2 for the District of Columbia.

3 “(2) GOVERNING LAW.—The substantive law
4 for decision in an action under subsection (d) shall
5 be derived from the law, including choice of law
6 principles, of the State in which the alleged willful
7 misconduct occurred, unless such law is inconsistent
8 with or preempted by Federal law, including provi-
9 sions of this section.

10 “(3) PLEADING WITH PARTICULARITY.—In an
11 action under subsection (d), the complaint shall
12 plead with particularity each element of the plain-
13 tiff’s claim, including—

14 “(A) each act or omission, by each covered
15 person sued, that is alleged to constitute willful
16 misconduct relating to the covered counter-
17 measure administered to or used by the person
18 on whose behalf the complaint was filed;

19 “(B) facts supporting the allegation that
20 such alleged willful misconduct proximately
21 caused the injury claimed; and

22 “(C) facts supporting the allegation that
23 the person on whose behalf the complaint was
24 filed suffered death or serious physical injury.



1 “(4) VERIFICATION, CERTIFICATION, AND MED-
2 ICAL RECORDS.—

3 “(A) IN GENERAL.—In an action under
4 subsection (d), the plaintiff shall verify the com-
5 plaint in the manner stated in subparagraph
6 (B) and shall file with the complaint the mate-
7 rials described in subparagraph (C). A com-
8 plaint that does not substantially comply with
9 subparagraphs (B) and (C) shall not be accept-
10 ed for filing and shall not stop the running of
11 the statute of limitations.

12 “(B) VERIFICATION REQUIREMENT.—

13 “(i) IN GENERAL.—The complaint
14 shall include a verification, made by affi-
15 davit of the plaintiff under oath, stating
16 that the pleading is true to the knowledge
17 of the deponent, except as to matters spe-
18 cifically identified as being alleged on in-
19 formation and belief, and that as to those
20 matters the plaintiff believes it to be true.

21 “(ii) IDENTIFICATION OF MATTERS
22 ALLEGED UPON INFORMATION AND BE-
23 LIEF.—Any matter that is not specifically
24 identified as being alleged upon the infor-
25 mation and belief of the plaintiff, shall be



1 regarded for all purposes, including a
2 criminal prosecution, as having been made
3 upon the knowledge of the plaintiff.

4 “(C) MATERIALS REQUIRED.—In an action
5 under subsection (d), the plaintiff shall file with
6 the complaint—

7 “(i) an affidavit, by a physician who
8 did not treat the person on whose behalf
9 the complaint was filed, certifying, and ex-
10 plaining the basis for such physician’s be-
11 lief, that such person suffered the serious
12 physical injury or death alleged in the com-
13 plaint and that such injury or death was
14 proximately caused by the administration
15 or use of a covered countermeasure; and

16 “(ii) certified medical records docu-
17 menting such injury or death and such
18 proximate causal connection.

19 “(5) THREE-JUDGE COURT.—Any action under
20 subsection (d) shall be assigned initially to a panel
21 of three judges. Such panel shall have jurisdiction
22 over such action for purposes of considering motions
23 to dismiss, motions for summary judgment, and
24 matters related thereto. If such panel has denied
25 such motions, or if the time for filing such motions



1 has expired, such panel shall refer the action to the
2 chief judge for assignment for further proceedings,
3 including any trial. Section 1253 of title 28, United
4 States Code, and paragraph (3) of subsection (b) of
5 section 2284 of title 28, United States Code, shall
6 not apply to actions under subsection (d).

7 “(6) CIVIL DISCOVERY.—

8 “(A) TIMING.—In an action under sub-
9 section (d), no discovery shall be allowed—

10 “(i) before each covered person sued
11 has had a reasonable opportunity to file a
12 motion to dismiss;

13 “(ii) in the event such a motion is
14 filed, before the court has ruled on such
15 motion; and

16 “(iii) in the event a covered person
17 files an interlocutory appeal from the de-
18 nial of such a motion, before the court of
19 appeals has ruled on such appeal.

20 “(B) STANDARD.—Notwithstanding any
21 other provision of law, the court in an action
22 under subsection (d) shall permit discovery only
23 with respect to matters directly related to mate-
24 rial issues contested in such action, and the
25 court shall compel a response to a discovery re-

1 quest (including a request for admission, an in-
2 terrogatory, a request for production of docu-
3 ments, or any other form of discovery request)
4 under Rule 37, Federal Rules of Civil Proce-
5 dure, only if the court finds that the requesting
6 party needs the information sought to prove or
7 defend as to a material issue contested in such
8 action and that the likely benefits of a response
9 to such request equal or exceed the burden or
10 cost for the responding party of providing such
11 response.

12 “(7) REDUCTION IN AWARD OF DAMAGES FOR
13 COLLATERAL SOURCE BENEFITS.—

14 “(A) IN GENERAL.—In an action under
15 subsection (d), the amount of an award of dam-
16 ages that would otherwise be made to a plaintiff
17 shall be reduced by the amount of collateral
18 source benefits to such plaintiff.

19 “(B) PROVIDER OF COLLATERAL SOURCE
20 BENEFITS NOT TO HAVE LIEN OR SUBROGA-
21 TION.—No provider of collateral source benefits
22 shall recover any amount against the plaintiff
23 or receive any lien or credit against the plain-
24 tiff’s recovery or be equitably or legally sub-



1 rogated to the right of the plaintiff in an action
2 under subsection (d).

3 “(C) COLLATERAL SOURCE BENEFIT DE-
4 FINED.—For purposes of this paragraph, the
5 term ‘collateral source benefit’ means any
6 amount paid or to be paid in the future to or
7 on behalf of the plaintiff, or any service, prod-
8 uct, or other benefit provided or to be provided
9 in the future to or on behalf of the plaintiff, as
10 a result of the injury or wrongful death, pursu-
11 ant to—

12 “(i) any State or Federal health, sick-
13 ness, income-disability, accident, or work-
14 ers’ compensation law;

15 “(ii) any health, sickness, income-dis-
16 ability, or accident insurance that provides
17 health benefits or income-disability cov-
18 erage;

19 “(iii) any contract or agreement of
20 any group, organization, partnership, or
21 corporation to provide, pay for, or reim-
22 burse the cost of medical, hospital, dental,
23 or income disability benefits; or

24 “(iv) any other publicly or privately
25 funded program.



1 “(8) NONECONOMIC DAMAGES.—In an action
2 under subsection (d), any noneconomic damages may
3 be awarded only in an amount directly proportional
4 to the percentage of responsibility of a defendant for
5 the harm to the plaintiff. For purposes of this para-
6 graph, the term ‘noneconomic damages’ means dam-
7 ages for losses for physical and emotional pain, suf-
8 fering, inconvenience, physical impairment, mental
9 anguish, disfigurement, loss of enjoyment of life, loss
10 of society and companionship, loss of consortium,
11 hedonic damages, injury to reputation, and any
12 other nonpecuniary losses.

13 “(9) RULE 11 SANCTIONS.—Whenever a district
14 court of the United States determines that there has
15 been a violation of Rule 11 of the Federal Rules of
16 Civil Procedure in an action under subsection (d),
17 the court shall impose upon the attorney, law firm,
18 or parties that have violated Rule 11 or are respon-
19 sible for the violation, an appropriate sanction,
20 which may include an order to pay the other party
21 or parties for the reasonable expenses incurred as a
22 direct result of the filing of the pleading, motion, or
23 other paper that is the subject of the violation, in-
24 cluding a reasonable attorney’s fee. Such sanction
25 shall be sufficient to deter repetition of such conduct



1 or comparable conduct by others similarly situated,
2 and to compensate the party or parties injured by
3 such conduct.

4 “(10) INTERLOCUTORY APPEAL.—The United
5 States Court of Appeals for the District of Columbia
6 Circuit shall have jurisdiction of an interlocutory ap-
7 peal by a covered person taken within 30 days of an
8 order denying a motion to dismiss or a motion for
9 summary judgment based on an assertion of the im-
10 munity from suit conferred by subsection (a) or
11 based on an assertion of the exclusion under sub-
12 section (c)(5).

13 “(f) ACTIONS BY AND AGAINST THE UNITED
14 STATES.—Nothing in this section shall be construed to ab-
15 rogate or limit any right, remedy, or authority that the
16 United States or any agency thereof may possess under
17 any other provision of law or to waive sovereign immunity
18 or to abrogate or limit any defense or protection available
19 to the United States or its agencies, instrumentalities, of-
20 ficers, or employees under any other law, including any
21 provision of chapter 171 of title 28, United States Code
22 (relating to tort claims procedure).

23 “(g) SEVERABILITY.—If any provision of this section,
24 or the application of such provision to any person or cir-
25 cumstance, is held to be unconstitutional, the remainder



1 of this section and the application of such remainder to
2 any person or circumstance shall not be affected thereby.

3 “(h) RULE OF CONSTRUCTION CONCERNING NA-
4 TIONAL VACCINE INJURY COMPENSATION PROGRAM.—
5 Nothing in this section, or any amendment made by the
6 Public Readiness and Emergency Preparedness Act, shall
7 be construed to affect the National Vaccine Injury Com-
8 pensation Program under title XXI of this Act.

9 “(i) DEFINITIONS.—In this section:

10 “(1) COVERED COUNTERMEASURE.—The term
11 ‘covered countermeasure’ means—

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

14 “(B) a security countermeasure (as defined
15 in section 319F-2(c)(1)(B)); or

16 “(C) a drug (as such term is defined in
17 section 201(g)(1) of the Federal Food, Drug,
18 and Cosmetic Act (21 U.S.C. 321(g)(1)), bio-
19 logical product (as such term is defined by sec-
20 tion 351(i) of this Act), or device (as such term
21 is defined by section 201(h) of the Federal
22 Food, Drug and Cosmetic Act (21 U.S.C.
23 321(h)) that is authorized for emergency use in
24 accordance with section 564 of the Federal
25 Food, Drug, and Cosmetic Act.



1 “(2) COVERED PERSON.—The term ‘covered
2 person’, when used with respect to the administra-
3 tion or use of a covered countermeasure, means—

4 “(A) the United States; or

5 “(B) a person or entity that is—

6 “(i) a manufacturer of such counter-
7 measure;

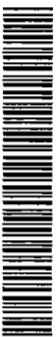
8 “(ii) a distributor of such counter-
9 measure;

10 “(iii) a program planner of such coun-
11 termeasure;

12 “(iv) a qualified person who pre-
13 scribed, administered, or dispensed such
14 countermeasure; or

15 “(v) an official, agent, or employee of
16 a person or entity described in clause (i),
17 (ii), (iii), or (iv).

18 “(3) DISTRIBUTOR.—The term ‘distributor’
19 means a person or entity engaged in the distribution
20 of drugs, biologics, or devices, including but not lim-
21 ited to manufacturers; repackers; common carriers;
22 contract carriers; air carriers; own-label distributors;
23 private-label distributors; jobbers; brokers; ware-
24 houses, and wholesale drug warehouses; independent
25 wholesale drug traders; and retail pharmacies.



1 “(4) MANUFACTURER.—The term ‘manufac-
2 turer’ includes—

3 “(A) a contractor or subcontractor of a
4 manufacturer;

5 “(B) a supplier or licensor of any product,
6 intellectual property, service, research tool, or
7 component or other article used in the design,
8 development, clinical testing, investigation, or
9 manufacturing of a covered countermeasure;
10 and

11 “(C) any or all of the parents, subsidiaries,
12 affiliates, successors, and assigns of a manufac-
13 turer.

14 “(5) PERSON.—The term ‘person’ includes an
15 individual, partnership, corporation, association, en-
16 tity, or public or private corporation, including a
17 Federal, State, or local government agency or de-
18 partment.

19 “(6) PROGRAM PLANNER.—The term ‘program
20 planner’ means a State or local government, includ-
21 ing an Indian tribe, a person employed by the State
22 or local government, or other person who supervised
23 or administered a program with respect to the ad-
24 ministration, dispensing, distribution, provision, or
25 use of a security countermeasure or a qualified pan-



1 demic or epidemic product, including a person who
 2 has established requirements, provided policy guid-
 3 ance, or supplied technical or scientific advice or as-
 4 sistance or provides a facility to administer or use
 5 a covered countermeasure in accordance with a dec-
 6 laration under subsection (b).

7 “(7) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
 8 UCT.—The term ‘qualified pandemic or epidemic
 9 product’ means a drug (as such term is defined in
 10 section 201(g)(1) of the Federal Food, Drug, and
 11 Cosmetic Act (21 U.S.C. 321(g)(1)), biological prod-
 12 uct (as such term is defined by section 351(i) of this
 13 Act), or device (as such term is defined by section
 14 201(h) of the Federal Food, Drug and Cosmetic Act
 15 (21 U.S.C. 321(h)) that is—

16 “(A)(i) a product manufactured, used, de-
 17 signed, developed, modified, licensed, or
 18 procured—

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

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

23 “(ii) a product manufactured, used, de-
 24 signed, developed, modified, licensed, or pro-
 25 cured to diagnose, mitigate, prevent, treat, or



1 cure a serious or life-threatening disease or con-
2 dition caused by a product described in clause
3 (i); and

4 “(B)(i) approved or cleared under chapter
5 V of the Federal Food, Drug, and Cosmetic Act
6 or licensed under section 351 of this Act;

7 “(ii) the object of research for possible use
8 as described by subparagraph (A) and is the
9 subject of an exemption under section 505(i) or
10 520(g) of the Federal Food, Drug, and Cos-
11 metic Act; or

12 “(iii) authorized for emergency use in ac-
13 cordance with section 564 of the Federal Food,
14 Drug, and Cosmetic Act.

15 “(8) QUALIFIED PERSON.—The term ‘qualified
16 person’, when used with respect to the administra-
17 tion or use of a covered countermeasure, means—

18 “(A) a licensed health professional or other
19 individual who is authorized to prescribe, ad-
20 minister, or dispense such countermeasures
21 under the law of the State in which the coun-
22 termeasure was prescribed, administered, or
23 dispensed; or



1 “(B) a person within a category of persons
2 so identified in a declaration by the Secretary
3 under subsection (b).

4 “(9) SECURITY COUNTERMEASURE.—The term
5 ‘security countermeasure’ has the meaning given
6 such term in section 319F-2(c)(1)(B).

7 “(10) SERIOUS PHYSICAL INJURY.—The term
8 ‘serious physical injury’ means an injury that—

9 “(A) is life threatening;

10 “(B) results in permanent impairment of a
11 body function or permanent damage to a body
12 structure; or

13 “(C) necessitates medical or surgical inter-
14 vention to preclude permanent impairment of a
15 body function or permanent damage to a body
16 structure.”.

17 **SEC. 3. COVERED COUNTERMEASURE PROCESS.**

18 Part B of title III of the Public Health Service Act
19 is further amended by inserting after section 319F-3 (as
20 added by section 2) the following new section:

21 **“SEC. 319F-4. COVERED COUNTERMEASURE PROCESS.**

22 “(a) ESTABLISHMENT OF FUND.—Upon the issuance
23 by the Secretary of a declaration under section 319F-3(b),
24 there is hereby established in the Treasury ^{an emergency} fund des-
25 ignated as the ‘Covered Countermeasure Process Fund’



1 ~~for purposes of providing timely, uniform, and adequate~~
 2 ~~compensation to eligible individuals for covered injuries di-~~
 3 ~~rectly caused by the administration or use of a covered~~
 4 ~~countermeasure pursuant to such declaration, which Fund~~
 5 ~~shall consist of such amounts, as may be provided by law~~
 6 ~~after the establishment of such Fund.~~

Unused
34a

7 “(b) PAYMENT OF COMPENSATION.—

designated as
emergency appropriations,
is and only
when Congress
designates such
funds as
emergency
appropriations.

8 “(1) IN GENERAL.—If the Secretary issues a
 9 declaration under 319F-3(b), the Secretary shall,
 10 after amounts have by law been provided for the
 11 Fund under subsection (a), provide compensation to
 12 an eligible individual for a covered injury directly
 13 caused by the administration or use of a covered
 14 countermeasure pursuant to such declaration.

15 “(2) ELEMENTS OF COMPENSATION.—The com-
 16 pensation that shall be provided pursuant to para-
 17 graph (1) shall have the same elements, and be in
 18 the same amount, as is prescribed by sections 264,
 19 265, and 266 in the case of certain individuals in-
 20 jured as a result of administration of certain coun-
 21 termeasures against smallpox, except that section
 22 266(a)(2)(B) shall not apply.

23 “(3) RULE OF CONSTRUCTION.—Neither rea-
 24 sonable and necessary medical benefits nor lifetime
 25 total benefits for lost employment income due to per-



34a

for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H.Con.Res.95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.

1 manent and total disability shall be limited by sec-
2 tion 266.

3 “(4) DETERMINATION OF ELIGIBILITY AND
4 COMPENSATION.—Except as provided in this section,
5 the procedures for determining, and for reviewing a
6 determination of, whether an individual is an eligible
7 individual, whether such individual has sustained a
8 covered injury, whether compensation may be avail-
9 able under this section, and the amount of such
10 compensation shall be those stated in section 262
11 (other than in subsection (d)(2) of such section), in
12 regulations issued pursuant to that section, and in
13 such additional or alternate regulations as the Sec-
14 retary may promulgate for purposes of this section.
15 In making determinations under this section, other
16 than those described in paragraph (5)(A) as to the
17 direct causation of a covered injury, the Secretary
18 may only make such determination based on compel-
19 ling, reliable, valid, medical and scientific evidence.

20 “(5) COVERED COUNTERMEASURE INJURY
21 TABLE.—

22 “(A) IN GENERAL.—The Secretary shall by
23 regulation establish a table identifying covered
24 injuries that shall be presumed to be directly
25 caused by the administration or use of a cov-



1 ered countermeasure and the time period in
2 which the first symptom or manifestation of
3 onset of each such adverse effect must manifest
4 in order for such presumption to apply. The
5 Secretary may only identify such covered inju-
6 ries, for purpose of inclusion on the table,
7 where the Secretary determines, based on com-
8 pelling, reliable, valid, medical and scientific
9 evidence that administration or use of the cov-
10 ered countermeasure directly caused such cov-
11 ered injury.

12 “(B) AMENDMENTS.—The provisions of
13 section 263 (other than a provision of sub-
14 section (a)(2) of such section that relates to ac-
15 cidental vaccinia inoculation) shall apply to the
16 table established under this section.

17 “(C) JUDICIAL REVIEW.—No court of the
18 United States, or of any State, shall have sub-
19 ject matter jurisdiction to review, whether by
20 mandamus or otherwise, any action by the Sec-
21 retary under this paragraph.

22 “(6) MEANINGS OF TERMS.—In applying sec-
23 tions 262, 263, 264, 265, and 266 for purposes of
24 this section—



1 “(A) the terms ‘vaccine’ and ‘smallpox vac-
2 cine’ shall be deemed to mean a covered coun-
3 termeasure;

4 “(B) the terms ‘smallpox vaccine injury
5 table’ and ‘table established under section 263’
6 shall be deemed to refer to the table established
7 under paragraph (4); and

8 “(C) other terms used in those sections
9 shall have the meanings given to such terms by
10 this section.

11 “(c) VOLUNTARY PROGRAM.—The Secretary shall
12 ensure that a State, local, or Department of Health and
13 Human Services plan to administer or use a covered coun-
14 termeasure is consistent with any declaration under 319F-
15 3 and any applicable guidelines of the Centers for Disease
16 Control and Prevention and that potential participants are
17 educated with respect to contraindications, the voluntary
18 nature of the program, and the availability of potential
19 benefits and compensation under this part.

20 “(d) EXHAUSTION; EXCLUSIVITY; ELECTION.—

21 “(1) EXHAUSTION.—Subject to paragraph (5),
22 a covered individual may not bring a civil action
23 under section 319F-3(d) against a covered person
24 (as such term is defined in section 319F-3(i)(2))
25 unless such individual has exhausted such remedies



1 as are available under subsection (a), except that if
2 amounts have not by law been provided for the Fund
3 under subsection (a), or if the Secretary fails to
4 make a final determination on a request for benefits
5 or compensation filed in accordance with the require-
6 ments of this section within 240 days after such re-
7 quest was filed, the individual may seek any remedy
8 that may be available under section 319F-3(d).

9 “(2) TOLLING OF STATUTE OF LIMITATIONS.—
10 The time limit for filing a civil action under section
11 319F-3(d) for an injury or death shall be tolled dur-
12 ing the pendency of a claim for compensation under
13 subsection (a).

14 “(3) RULE OF CONSTRUCTION.—This section
15 shall not be construed as superseding or otherwise
16 affecting the application of a requirement, under
17 chapter 171 of title 28, United States Code, to ex-
18 haust administrative remedies.

19 “(4) EXCLUSIVITY.—The remedy provided by
20 subsection (a) shall be exclusive of any other civil ac-
21 tion or proceeding for any claim or suit this section
22 encompasses, except for a proceeding under section
23 319F-3.

24 “(5) ELECTION.—If under subsection (a) the
25 Secretary determines that a covered individual quali-

1 fies for compensation, the individual has an election
2 to accept the compensation or to bring an action
3 under section 319F-3(d). If such individual elects to
4 accept the compensation, the individual may not
5 bring such an action.

6 “(e) DEFINITIONS.—For purposes of this section, the
7 following terms shall have the following meanings:

8 “(1) COVERED COUNTERMEASURE.—The term
9 ‘covered countermeasure’ has the meaning given
10 such term in section 319F-3.

11 “(2) COVERED INDIVIDUAL.—The term ‘cov-
12 ered individual’, with respect to administration or
13 use of a covered countermeasure pursuant to a dec-
14 laration, means an individual—

15 “(A) who is in a population specified in
16 such declaration, and with respect to whom the
17 administration or use of the covered counter-
18 measure satisfies the other specifications of
19 such declaration; or

20 “(B) who uses the covered countermeasure,
21 or to whom the covered countermeasure is ad-
22 ministered, in a good faith belief that the indi-
23 vidual is in the category described by subpara-
24 graph (A).




1 “(3) COVERED INJURY.—The term ‘covered in-
2 jury’ means serious physical injury or death.

3 “(4) DECLARATION.—The term ‘declaration’
4 means a declaration under section 319F-3(b)

5 “(5) ELIGIBLE INDIVIDUAL.—The term ‘eligible
6 individual’ means an individual who is determined,
7 in accordance with subsection (b), to be a covered
8 individual who sustains a covered injury.”.



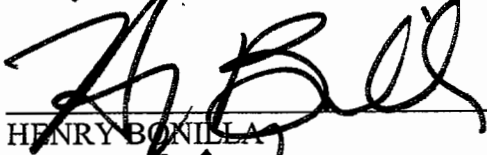
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C. W. BILL YOUNG



DAVID L. HOBSON



HENRY BONILLA



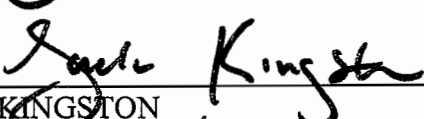
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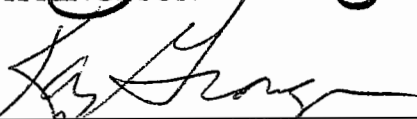
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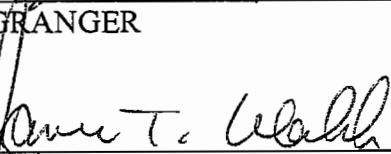
ROGER F. WICKER



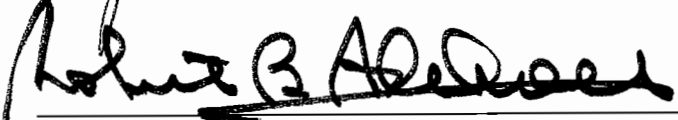
JACK KINGSTON



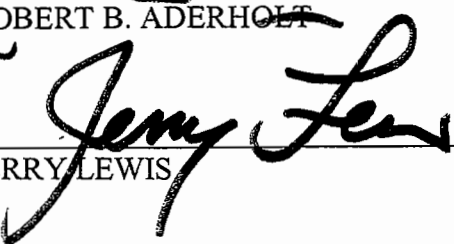
KAY GRANGER



JAMES T. WALSH



ROBERT B. ADERHOLT



JERRY LEWIS

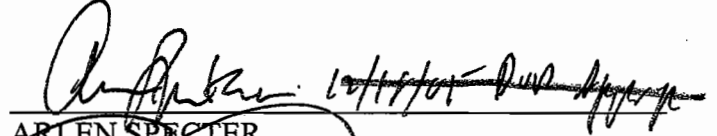
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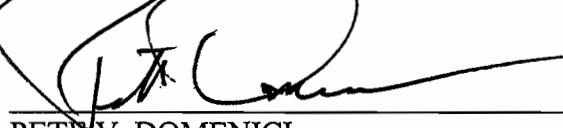
TED STEVENS



THAD COCHRAN



ARLEN SPECTER



PETE V. DOMENICI



CHRISTOPHER S. BOND



MITCH MC CONNELL



RICHARD C. SHELBY



JUDD GREGG



KAY BAILEY HUTCHISON



CONRAD BURNS



DANIEL K. INOUYE

JOHN P. MURTHA

except for ANWR
act

NORMAN D. DICKS

except for 1%
cut in Div.

MARTIN OLAY SABO

except for Division
C and Division B as to
1% cut and Avian Flu
section

PETER J. VISCIOSKY

except for Division
B and C as to 1% cut,
avian flu and
ANWR provision

JAMES P. MORAN

except for:

- ANWR provision
- Divisions B and C as to
1% cut and avian
flu

MARCY KAPTUR

except for
1% cut

CHET EDWARDS

DAVID R. OBEY

except for
Division C, Division
B as to 1% cut
and Avian Flu
section

EXCEPT ANWR & ACROSS THE BOARD CUT +

Robert C. Byrd
AVIAN FLU
VACCINE
LIABILITY AND
COMPENSATION PROVISIONS

ROBERT C. BYRD

PATRICK J. LEAHY

TOM HARKIN

except on ANWR
: 1% cut +
AVIAN FLU VACCINE
LIABILITY AND
COMPENSATION
PROVISIONS

BYRON L. DORGAN

RICHARD J. DURBIN

HARRY REED

except ANWR
+ 1% cut +
AVIAN FLU VACCINE
LIABILITY AND
COMPENSATION
PROVISIONS

DIANNE FEINSTEIN

except ANWR: 1% ATB cut

BARBARA A. MILULSKI

AVIAN FLU VACCINE
LIABILITY AND COMPENSATION
PROVISIONS