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—

"(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.

"(b) DECLARATION BY SECRETARY.—

"(1) AUTHORITY TO ISSUE DECLARATION.—Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk

that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

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

"(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;

"(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which period or periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);

"(C) the population or populations of individuals for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);

"(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and

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

"(3) EFFECTIVE PERIOD OF DECLARATION.—

"(A) FLEXIBILITY OF PERIOD.—The Secretary may, in describing periods under paragraph (2)(B), have different periods for different covered persons to address different logistical, practical or other differences in responsibilities.

"(B) ADDITIONAL TIME TO BE SPECIFIED.—In each declaration under paragraph (1), the Secretary, after consulting, to the extent the Secretary deems appropriate, with the manufacturer of the covered countermeasure, shall also specify a date that is after the ending date specified under paragraph (2)(B) and that allows what the Secretary determines is—

"(i) a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and

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

"(C) ADDITIONAL PERIOD FOR CERTAIN STRATEGIC NATIONAL STOCKPILE COUNTERMEASURES.—With respect to a covered countermeasure that is in the stockpile under section 319F-2, if such countermeasure was the subject of a declaration under paragraph (1) at the time that it was obtained for the stockpile, the effective period of such declaration shall include a period when the countermeasure is administered or used pursuant to a distribution or release from the stockpile.

"(4) AMENDMENTS TO DECLARATION.—The Secretary may through publication in the Federal Register amend any portion of a declaration under paragraph (1). Such an amendment shall not retroactively limit the applicability of subsection (a) with respect to the administration or use of the covered countermeasure involved.

"(5) CERTAIN DISCLOSURES.—In publishing a declaration under paragraph (1) in the Federal Register, the Secretary is not required to disclose any matter described in section 552(b) of title 5, United States Code.

"(6) FACTORS TO BE CONSIDERED.—In deciding whether and under what circumstances or conditions to issue a declaration under paragraph (1) with respect to a covered countermeasure, the Secretary shall 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 such countermeasure.

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

"(8) PREEMPTION OF STATE LAW.—During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

"(A) is different from, or is in conflict with, any requirement applicable under this section; and

"(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this Act, or under the Federal Food, Drug, and Cosmetic Act.

"(9) REPORT TO CONGRESS.—Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that

provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

"(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.

"(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.

"(2) AUTHORITY TO PROMULGATE REGULATORY DEFINITION.—

"(A) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as 'willful misconduct' for purposes of subsection (d).

"(B) FACTORS TO BE CONSIDERED.—In promulgating the regulations under this paragraph, the Secretary, in consultation with the Attorney General, shall consider the need to define the scope of permissible civil actions under subsection (d) in a way that will not adversely affect the public health.

"(C) TEMPORAL SCOPE OF REGULATIONS.—The regulations under this paragraph may specify the temporal effect that they shall be given for purposes of subsection (d).

Deadline.

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

"(3) PROOF OF WILLFUL MISCONDUCT.—In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

"(4) DEFENSE FOR ACTS OR OMISSIONS TAKEN PURSUANT TO SECRETARY'S DECLARATION.—Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in 'willful misconduct' as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration

under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

"(5) EXCLUSION FOR REGULATED ACTIVITY OF MANUFACTURER OR DISTRIBUTOR.—

"(A) IN GENERAL.—If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this Act or by the Federal Food, Drug, and Cosmetic Act, such act or omission shall not constitute 'willful misconduct' for purposes of subsection (d) if—

"(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

"(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

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

"(B) DEFINITIONS.—For purposes of this paragraph, the following terms have the following meanings:

"(i) ENFORCEMENT ACTION.—The term 'enforcement action' means a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act, or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act or of a licensure under section 351 of this Act.

"(ii) COVERED REMEDY.—The term 'covered remedy' means an outcome—

"(I) that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act, or a suspension or withdrawal of an approval or clearance under chapter 5 of such Act or of a licensure under section 351 of this Act; and

"(II) that results from a final determination by a court or from a final agency action.

"(iii) FINAL.—The terms 'final' and 'finally'—

"(I) with respect to a court determination, or to a final resolution of an enforcement action that is a court determination, mean a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and

"(II) with respect to an agency action, or to a final resolution of an enforcement action that is an agency action, mean an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal.

"(C) RULES OF CONSTRUCTION.—

"(i) IN GENERAL.—Nothing in this paragraph shall be construed—

"(I) to affect the interpretation of any provision of the Federal Food, Drug, and Cosmetic Act, of this Act, or of any other applicable statute or regulation; or

"(II) to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this Act, under the Federal Food, Drug, and Cosmetic Act, under title 18 of the United States Code, or under any other applicable statute or regulation.

"(ii) MANDATORY RECALLS.—A mandatory recall called for in the declaration is not a Food and Drug Administration enforcement action.

"(d) EXCEPTION TO IMMUNITY OF COVERED PERSONS.—

"(1) IN GENERAL.—Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, United States Code, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

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

"(e) PROCEDURES FOR SUIT.—

Records. Courts, U.S. District of Columbia.

"(1) EXCLUSIVE FEDERAL JURISDICTION.—Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

"(2) GOVERNING LAW.—The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

"(3) PLEADING WITH PARTICULARITY.—In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including—

"(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

"(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

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

"(4) VERIFICATION, CERTIFICATION, AND MEDICAL RECORDS.—

"(A) IN GENERAL.—In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

"(B) VERIFICATION REQUIREMENT.—

"(i) IN GENERAL.—The complaint shall include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the deponent, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

"(ii) IDENTIFICATION OF MATTERS ALLEGED UPON INFORMATION AND BELIEF.—Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

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

"(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and

"(ii) certified medical records documenting such injury or death and such proximate causal connection.

"(5) THREE-JUDGE COURT.—Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial. Section 1253 of title 28, United States Code, and paragraph (3) of subsection

(b) of section 2284 of title 28, United States Code, shall not apply to actions under subsection (d).

"(6) CIVIL DISCOVERY.—

"(A) TIMING.—In an action under subsection (d), no discovery shall be allowed—

"(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

"(ii) in the event such a motion is filed, before the court has ruled on such motion; and

"(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

"(B) STANDARD.—Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

"(7) REDUCTION IN AWARD OF DAMAGES FOR COLLATERAL SOURCE BENEFITS.—

"(A) IN GENERAL.—In an action under subsection (d), the amount of an award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

"(B) PROVIDER OF COLLATERAL SOURCE BENEFITS NOT TO HAVE LIEN OR SUBROGATION.—No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

"(C) COLLATERAL SOURCE BENEFIT DEFINED.—For purposes of this paragraph, the term 'collateral source benefit' means any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to—

"(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

"(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

"(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or

"(iv) any other publicly or privately funded program.

"(8) NONECONOMIC DAMAGES.—In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term 'noneconomic damages' means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

"(9) RULE 11 SANCTIONS.—Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

"(10) INTERLOCUTORY APPEAL.—The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

"(f) ACTIONS BY AND AGAINST THE UNITED STATES.—Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of title 28, United States Code (relating to tort claims procedure).

"(g) SEVERABILITY.—If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

"(h) RULE OF CONSTRUCTION CONCERNING NATIONAL VACCINE INJURY COMPENSATION PROGRAM.—Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the National Vaccine Injury Compensation Program under title XXI of this Act.

"(i) DEFINITIONS.—In this section:

"(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)); or

"(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), 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 of the Federal Food, Drug, and Cosmetic Act.

"(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.

"(5) PERSON.—The term 'person' includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

"(6) PROGRAM PLANNER.—The term 'program planner' means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

"(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), 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; or

"(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); and

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

"(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; or

"(iii) authorized for emergency use in accordance with section 564 of the Federal Food, Drug, and Cosmetic Act.

"(8) QUALIFIED PERSON.—The term 'qualified person', when used with respect to the administration or use of a covered countermeasure, means—

"(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

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

"(9) SECURITY COUNTERMEASURE.—The term 'security countermeasure' has the meaning given such term in section 319F–2(c)(1)(B).

"(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.".

SEC. 3. COVERED COUNTERMEASURE PROCESS.

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

"SEC. 319F–4. COVERED COUNTERMEASURE PROCESS. 42 USC 247d–6e.

"(a) ESTABLISHMENT OF FUND.—Upon the issuance by the Secretary of a declaration under section 319F–3(b), there is hereby established in the Treasury an emergency fund designated as the 'Covered Countermeasure Process Fund' 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.

"(b) PAYMENT OF COMPENSATION.—

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

"(2) ELEMENTS OF COMPENSATION.—The compensation that shall be provided pursuant to paragraph (1) shall have the same elements, and be in the same amount, as is prescribed by sections 264, 265, and 266 in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 266(a)(2)(B) shall not apply.

"(3) RULE OF CONSTRUCTION.—Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by section 266.

"(4) DETERMINATION OF ELIGIBILITY AND COMPENSATION.—Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 262 (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

"(5) COVERED COUNTERMEASURE INJURY TABLE.—

Regulations.

"(A) IN GENERAL.—The Secretary shall by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply. The Secretary may only identify such covered injuries, for purpose of inclusion on the table, where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury.

"(B) AMENDMENTS.—The provisions of section 263 (other than a provision of subsection (a)(2) of such section that relates to accidental vaccinia inoculation) shall apply to the table established under this section.

"(C) JUDICIAL REVIEW.—No court of the United States, or of any State, shall have subject matter jurisdiction to

review, whether by mandamus or otherwise, any action by the Secretary under this paragraph.

"(6) MEANINGS OF TERMS.—In applying sections 262, 263, 264, 265, and 266 for purposes of this section—

"(A) the terms 'vaccine' and 'smallpox vaccine' shall be deemed to mean a covered countermeasure;

"(B) the terms 'smallpox vaccine injury table' and 'table established under section 263' shall be deemed to refer to the table established under paragraph (4); and

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

"(c) VOLUNTARY PROGRAM.—The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 319F–3 and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

"(d) EXHAUSTION; EXCLUSIVITY; ELECTION.—

"(1) EXHAUSTION.—Subject to paragraph (5), a covered individual may not bring a civil action under section 319F–3(d) against a covered person (as such term is defined in section 319F–3(i)(2)) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 319F–3(d).

"(2) TOLLING OF STATUTE OF LIMITATIONS.—The time limit for filing a civil action under section 319F–3(d) for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a).

"(3) RULE OF CONSTRUCTION.—This section shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, United States Code, to exhaust administrative remedies.

"(4) EXCLUSIVITY.—The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 319F–3.

"(5) ELECTION.—If under subsection (a) the Secretary determines that a covered individual qualifies for compensation, the individual has an election to accept the compensation or to bring an action under section 319F–3(d). If such individual elects to accept the compensation, the individual may not bring such an action.

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

"(1) COVERED COUNTERMEASURE.—The term 'covered countermeasure' has the meaning given such term in section 319F–3.

"(2) COVERED INDIVIDUAL.—The term 'covered individual', with respect to administration or use of a covered countermeasure pursuant to a declaration, means an individual—

"(A) who is in a population specified in such declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or

"(B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A).

"(3) COVERED INJURY.—The term 'covered injury' means serious physical injury or death.

"(4) DECLARATION.—The term 'declaration' means a declaration under section 319F–3(b).

"(5) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury.".

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

Approved December 30, 2005.

LEGISLATIVE HISTORY—H.R. 2863:

HOUSE REPORTS: Nos. 109–119 (Comm. on Appropriations) and 109–359 (Comm. of Conference).
SENATE REPORTS: No. 109–141 (Comm. on Appropriations).
CONGRESSIONAL RECORD, Vol. 151 (2005):
June 20, considered and passed House.
Sept. 29, 30, Oct. 3–7, considered and passed Senate, amended.
Dec. 19, House agreed to conference report.
Dec. 21, Senate agreed to conference report.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 41 (2005):
Dec. 30, Presidential statement.

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