

# Facility Automation Management Engineering (FAME) Systems

33 Hoffman Avenue, Lake Hiawatha, NJ 07034 – Tel. 973263-4843

Tuesday, 3 January 2006

To Whom It May Concern:

This layman's commentary that follows this introductory letter presents the odious "pandemic flu" provisions of H.R. 2863, as enacted, and focuses on the "Public Readiness and Emergency Preparedness Act" as published in the Thomas listing of the enacted legislation that I visited as a part of my research in this area on Wednesday, 28 December 2005.

In general, to clearly differentiate between my comments and those of the bill's language, this commenter's remarks are written in an indented blue "News Gothic MT" font following the commented legislation's language, which is written in a "Times New Roman" font.

Quotes from federal laws and statutes (other than the one addressed in this commentary) will be quoted in a "Lydian" font.

Should anyone find any factual errors in this commenter's remarks, then this commenter requests that the factual error along with the appropriate documents that prove your point to this reviewer so that this commenter can learn from you, incorporate that new knowledge into his layman's understanding of the law, and, where indicated, appropriately correct this draft document.

Respectfully,

A handwritten signature in black ink that reads "Paul G. King". The signature is written in a cursive style with some capital letters.

Paul G. King, PhD, MS, BA  
Founder, **FAME Systems**

With minor revisions on 30 March 2006

Before commenting on the provisions in this legislation, this commenter is compelled to comment on the duplicitous manner in which these “pandemic” provisions were added to the House conference report after the House conferees voted and the manner in which the Senate, including many Senators with a clear conflict of interest, acted to pass these gifts to the pharmaceutical industry at the expense, monetary, health and constitutional rights, of the American public.

In this commenter’s view, all of those who cooperated to insert this document in the H.R. 2863 and/or signed the document, “DIVISION E—PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT” adding these provisions to H.R. 2863 on 17 December 2005 at 11:230 PM EST should *not* be reelected to any office federal, State, or local.

That list includes:

- Senators Christopher S. Bond (R-MO III), **Conrad Burns (R-MT I)**, Thad Cochran (R-MS II), Pete V. Domenici (R-NM II), **Bill Frist (R-TN I)**, Judd Gregg (R-NH III), **Kay Bailey Hutchinson (R-TX I)**, Daniel K. Inouye (D-HI III), Mitch McConnell (R-KY II), Richard C. Shelby (R-AS III), Arlen Specter (R-PA III), and Ted Stevens (R-AK II).
- Representatives Robert B. Aderholt (R-AL 4<sup>th</sup>), Henry Bonilla (R-TX 23<sup>rd</sup>), Norman D. Dicks (D-WA 6<sup>th</sup>), Chet Edwards (D-TX 17<sup>th</sup>), Rodney P. Frelinghuysen (R-NJ 11), Kay Granger (R-TX 12<sup>th</sup>), David L. Hobson (R-OH 7<sup>th</sup>), Marcy Kaptur (D-OH 9<sup>th</sup>), Jack Kingston (R-GA 1<sup>st</sup>), Jerry Lewis (R-CA 41<sup>st</sup>), John P. Murtha (D-PA 12<sup>th</sup>), Martin Olav Sabo (D-MN 5<sup>th</sup>), Todd Tiahrt (R-KS 4<sup>th</sup>), James T. Walsh (R-NY 25<sup>th</sup>), Roger F. Wicker (R-MS 1<sup>st</sup>), and C. W. Bill Young (R-FL 10<sup>th</sup>).

In addition, all Democrat and Republican Senators who have a significant stock holding or interest in any firm in the “Healthcare Establishment” and who voted for the “PREP” Act provisions should be targeted for replacement at their next election.

Those Senators are: “Allen (**R-Va. I**), Bayh (D-Ind. III), Bingaman (**D-N.M. I**), Bond (R-Mo. III), Boxer (D-Calif. III), Brownback (R-Kan. III), Burns (**R-Mont. I**), Carper (**D-Del. I**), Coburn (R-Okla. III), Cochran (R-Miss. II), Conrad (**D-N.D. I**), Crapo (R-Idaho III), Dayton (**D-Minn. I**), DeWine (**R-Ohio I**), Dole (R-N.C. II), Ensign (**R-Nev. I**), Feinstein (**D-Calif. I**), Frist (**R-Tenn. I**), Hatch (**R-Utah I**), Hutchison (**R-Texas I**), Inhofe (R-Okla. II), Isakson (R-Ga. III), Kerry (D-Mass. II), Kyl (**R-Ariz. I**), Landrieu (D-La. II), Lautenberg (D-N.J. II), Levin (D-Mich. II), Lieberman (**D-Conn. I**), Lott (**R-Miss. I**), Reed (D-R.I. II), Reid (D-Nev. III), Roberts (R-Kan. II), Stevens (R-Alaska II), Sununu (R-N.H. II), Talent (**R-Mo. I**), Vitter (R-La. III), Voinovich (R-Ohio III) and Warner (R-Va. II).” [**Note:** Bolded ones (class I) will be up for reelection in 2006; class II in 2008; and class III in 2010.]

Finally, because of the Republican Party’s strong ties to the Pharma, all Republican Representatives, including Tom Delay (R-TX 22<sup>nd</sup>) should be generally targeted for replacement (if possible, in the 2006 primary or, failing that, in the general elections of 2006.).

**A Draft Commentary on the Pandemic Flu Provisions Of HR 2863  
Focused on the “Public Readiness and Emergency Preparedness Act”**

**HURRICANES IN THE GULF OF MEXICO AND PANDEMIC INFLUENZA,  
2006**

That the following sums are appropriated, out of any money in the Treasury not otherwise appropriated, to address hurricanes in the Gulf of Mexico and pandemic influenza for the fiscal year ending September 30, 2006, and for other purposes, namely:

TITLE I ...

TITLE II

EMERGENCY SUPPLEMENTAL APPROPRIATIONS TO ADDRESS  
PANDEMIC INFLUENZA

CHAPTER 1 ...

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

SALARIES AND EXPENSES

For an additional amount for 'Food and Drug Administration, Salaries and Expenses', to prepare for and respond to an influenza pandemic, \$20,000,000, to remain available until September 30, 2007: *Provided*, That of the total amount appropriated \$18,000,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs, and \$2,000,000 shall be for other activities including the Office of the Commissioner and the Office of Management: *Provided further*, That the amounts provided under this heading are designated as an emergency requirement pursuant to section 402 of H. Con. Res. 95 (109th Congress), the concurrent resolution on the budget for fiscal year 2006.

\$18 million extra to CBER and ORA for preparing to respond to an influenza pandemic and \$2 million to the Office of Commissioner & Office of Management.

...

CHAPTER 6

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

## PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

For an additional amount for 'Public Health and Social Services Emergency Fund' to prepare for and respond to an influenza pandemic, including the development and purchase of vaccines, antivirals, and necessary medical supplies, and for planning activities, \$3,054,000,000, to remain available until expended:

\$3.054 billion to Public Health & Social Services Emergency Fund for preparing and responding to influenza pandemic – including develop & purchase vaccines, antivirals, and necessary medical supplies & for planning.

*Provided*, That \$350,000,000 shall be for Upgrading State and Local Capacity and \$50,000,000 shall be for laboratory capacity and research at the Centers for Disease Control and Prevention:

\$350 million to upgrade state & local capacity & \$50 million to CDC for lab capacity & research → leaving \$2.654 billion for the development and stockpiling of vaccines, anti-viral drugs and medical supplies, and for planning.

*Provided further*, That products purchased with these funds may, at the discretion of the Secretary, be deposited in the Strategic National Stockpile: *Provided further*, That notwithstanding section 496(b) of the Public Health Service Act, funds may be used for the construction or renovation of privately owned facilities for the production of pandemic influenza vaccines and other biologicals, where the Secretary finds such a contract necessary to secure sufficient supplies of such vaccines or biologicals: *Provided further*, That the Secretary may negotiate a contract with a vendor under which a State may place an order with the vendor for antivirals; may reimburse a State for a portion of the price paid by the State pursuant to such an order; and may use amounts made available herein for such reimbursement: *Provided further*, That funds appropriated herein and not specifically designated under this heading may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate, to be used for the purposes specified in this sentence: *Provided further*, That the amounts provided under this heading are designated as an emergency requirement pursuant to section 402 of H. Con. Res. 95 (109th Congress), the concurrent resolution on the budget for fiscal year 2006.

Essentially, this provision is a \$2.4-plus billion giveaway to the pharmaceutical industry, in which all amounts to be considered "emergency requirement" funds that can be spent essentially as the Secretary sees fit.

For an additional amount for 'Public Health and Social Services Emergency Fund' for activities related to pandemic influenza, including international activities and activities in foreign countries, related to preparedness planning, enhancing the pandemic influenza regulatory

science base, accelerating pandemic influenza disease surveillance, developing registries to monitor influenza vaccine distribution and use, and supporting pandemic influenza research, clinical trials and clinical trials infrastructure, \$246,000,000, of which \$150,000,000, to remain available until expended, shall be for the Centers for Disease Control and Prevention to carry out global and domestic disease surveillance, laboratory diagnostics, rapid response, and quarantine: *Provided*, That funds appropriated herein and not specifically designated under this heading may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate, to be used for the purposes specified in this sentence: *Provided further*, That the amounts provided under this heading are designated as an emergency requirement pursuant to section 402 of H. Con. Res. 95 (109th Congress), the concurrent resolution on the budget for fiscal year 2006.

This provision essentially provides \$96 million for clinical trials and clinical trials infrastructure; and \$150 million for global and domestic surveillance.

...

## CHAPTER 7

### DEPARTMENT OF VETERANS AFFAIRS

#### Veterans Health Administration

#### MEDICAL SERVICES

For an additional amount for 'Medical Services' for enhanced avian influenza surveillance programs, planning functions and preparations for the pandemic and to establish real-time surveillance data exchange with the Centers for Disease Control and Prevention, \$27,000,000: *Provided*, That the amount provided under this heading is designated as an emergency requirement pursuant to section 402 of H. Con. Res. 95 (109th Congress), the concurrent resolution on the budget for fiscal year 2006.

This provision provides \$27 million in "emergency" funds in fiscal 2006 to the Department of Veterans Affairs (VA) for surveillance, planning and preparations in the VA system

...

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

**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'.

The "P.R.E.P." (PREP) Act or 'PREPA.'

**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:

**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.

Not only does this language seem overly broad but it also seems to be unconstitutional abridgment of the State's right and duty to protect its citizens from harm. [Government will argue that this falls under the "commerce" clause and the "broad view" of homeland security even though it erodes public health security.]

(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.

Statute appears to be an illegal **ex post facto law** (U.S. Constitution, Article I Section 9) since the "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” does not contain the language “*after the date this statute becomes effective.*”

`(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.

Applies to “any claim for loss” causally related to essentially every aspect of a the “covered countermeasure” including its “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;

Unfortunately, “the effective period of the declaration that was issued ...” can be indefinite.

`(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

Appears to exclude uses of the “countermeasure” outside the scope of the “declaration” BUT →

`(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.

The “had a connection to such area specified in the declaration” language is overly broad and, potentially, negates any “outside of declaration” exemption.

`(4) APPLICABILITY OF CERTAIN CONDITIONS- With respect to immunity under paragraph (1) and subject to the other provisions of this section:

*Comments from the pen of Paul G. King, PhD, MS, BA*

`(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).

Persons who are manufacturers and distributors of covered countermeasures are immune even if the “countermeasure” is administered to other than covered individuals.

`(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).

Protects administrators from liability if the “covered person *reasonably* could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C)” – because the language leaves “*reasonably*” open to interpretation by the Secretary and not to the courts.

`(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.

This provision will require a non-covered person who is damaged to prove that a covered countermeasure was used outside of its approved usages **boundaries**.

`(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.

The “may in the future constitute such an emergency” (a public health emergency) would allow virtually any drug to be covered because the Secretary’s ability to make a determination is *not* restricted to *any* scientific or explicit definition of what constitutes a “public health emergency” or, worse, what constitutes “a credible risk that the disease, condition, or threat may in the future constitute such an emergency.”

`(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.

*Comments from the pen of Paul G. King, PhD, MS, BA*

`(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.

NO retroactive limitation of applicability of subsection (a) is granted but, *since the silence is deafening here*, retroactive increases in the applicability of subsection (a) seem to be allowed.

`(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.

**Title 5 U.S.C. Section 552(b)** states (**bolding** added for emphasis):

“This section does not apply to matters that are -

(1)(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

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- (4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;
- (5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;
- (6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
- (7) records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings, (B) would deprive a person of a right to a fair trial or an impartial adjudication, (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, (D) could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source, (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual;
- (8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or
- (9) geological and geophysical information and data, including maps, concerning wells.

**Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.** The amount of information deleted shall be indicated on the released portion of the record, unless including that indication would harm an interest protected by the exemption in this subsection under which the deletion is made. If technically feasible, the amount of the information deleted shall be indicated at the place in the record where such deletion is made.”

*Based on the preceding,* the Secretary is being exempted from having to disclose any information whatsoever with respect any “declaration” under the “PREP” Act – essentially fully protected from the general mandate to disclose information outside of that restricted by statute.

(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.

“Secretary shall consider the desirability of encouraging ...” without regard to safety or other costs to the public – another industry “perk.”

`(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.

This section seems to be an unconstitutional “carve out” whereby the actions of an administrative official in the Executive branch, the Secretary of HHS, a political appointee, is held to be above the law pursuant to any action he or she may elect with respect to a “declaration” for a covered countermeasure.

`(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.

Usurps the States rights to protect the health of their citizens without providing for any federal health safety protections in place of the States’ laws for such.

This section may be an unconstitutional usurpation of rights reserved to the States.

`(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.

Appropriate committees in Congress, but not Congress or the people, will be given the reasons for declarations and declaration revisions – reports should have been required to be published in the Federal Register.

(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.

Defines “willful misconduct” in a manner that justifies almost all conduct short of intentional murder.

(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.

This provision sets “willful misconduct” above any “standard of negligence” and above “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).

In case (1) is not protective enough, permits Secretary to “further restrict the scope of actions or omissions by a covered person that may qualify as `willful misconduct' for purposes of subsection (d),” which is the section that provides “**(d) Exception to Immunity of Covered Persons-**”

(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.

As long as regulations “will not adversely affect the public health,” the Secretary, a political appointee, is essentially

free to do as he or she pleases to restrict the scope of “permissible civil actions under subsection (d).”

`(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).

Since “ex post facto” times are not proscribed, retroactive regulations can be issued.

`(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.

Requires the Secretary to issue initial rules within 180 days.

This “fast tracking” is designed to minimize the risk of adverse comments from the public because the comment period(s) are shortened.

`(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.

The proof burden by the plaintiff is “clear and convincing evidence” of willful misconduct and that the proven willful misconduct caused “death or serious physical injury” – claims for serious mental injury are barred.

`(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.

Another “get out of jail free card” for program planners and qualified persons.

**(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.

Willful misconduct to be ignored if no "enforcement action" initiated or if an initiated "enforcement action" has been "terminated or finally resolved" by Secretary (FDA) or Attorney General (Justice Dept.).

Moreover, any legal action under "subsection (d)" is stayed while an "enforcement action" is pending – another loophole for the industry to escape liability for conduct that is "willful conduct."

**(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.

If the Secretary “declares” a “mandatory recall,” then, the firm(s) covered by the Secretary’s “declaration” escape falling under the enforcement action provisions “required” for “willful misconduct” by the firm(s) covered in said “declaration,” another loophole for the industry to escape liability.

`(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.

This provision defines “the sole exemption to the immunity from suit and liability of covered persons ...”

The cited statute [Title 28 USC Sec. 2679(b)(2)(B), last updated 01/19/04, states:

**TITLE 28 - JUDICIARY AND JUDICIAL PROCEDURE**

**PART VI - PARTICULAR PROCEEDINGS**

**CHAPTER 171 - TORT CLAIMS PROCEDURE**

**Sec. 2679. Exclusiveness of remedy**

(a) The authority of any federal agency to sue and be sued in its own name shall not be construed to authorize suits against such federal agency on claims which are cognizable under section 1346(b) of this title, and the remedies provided by this title in such cases shall be exclusive.

**(b)(1)** The remedy against the United States provided by sections 1346(b) and 2672 of this title for injury or loss of property, or personal injury or death arising or resulting from the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment is exclusive of any other civil action or proceeding for money damages by reason of the same subject matter against the employee whose act or omission gave rise to the claim or against the estate of such employee. Any other civil action or proceeding for money damages arising out of or relating to the same subject matter against the employee or the employee's estate is precluded without regard to when the act or omission occurred.

**(2) Paragraph (1) does not extend or apply to a civil action against an employee of the Government -**

**(A)** which is brought for a violation of the Constitution of the United States, or

**(B) which is brought for a violation of a statute of the United States under which such action against an individual is otherwise authorized.**

This, this section effectively exempts employees, including the Secretary, of the government from being held liable when their actions violate a “statute of the United States ...”

Thus, even if the Secretary’s actions are found to be a violation of a “statute of the United States,” his or her actions cannot be held civilly accountable for said actions.

**(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.

Only persons killed or **persons** suffering serious physical injury, or their **legal** representatives can bring an action.

`(e) Procedures for Suit-

`(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.

Suits limited to an already overloaded court, the “United States District Court for the District of Columbia” for which no provision is made for increased judges and resources to handle this increased responsibility thus ensuring slow progress and the court’s seeking to find technicalities to throw out otherwise meritorious suits.

In addition, this provision places additional financial burdens on those who live some distance from DC – further discouraging all but the upper middle class and the rich from bringing suit.

`(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.

This provision essentially boils down to, if the State’s laws are weaker than or the same as those in the DC court, then the State’s laws will apply.

However, when the State’s laws are stronger than the federal, the federal laws will apply.

Thus, ensuring that any finding for the plaintiff will be as stingy as possible.

`(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.

By requiring plaintiff to “plead with particularity,” this section further raises the bar against suit by requiring the plaintiff to be able to

establish with certainty the exact who, what, where, when, and how of “(A),” “(B),” and “(C).”

“(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.

Most important issue is that filing does not stop the “running of the statute of limitations” if the court rejects a plaintiff’s filing on the grounds that its “does not substantially comply with subparagraphs (B) and (C)” – another barrier to the plaintiff that favors the defendants by not stopping the running of the statute of limitations when the suit is filed but only when the court accepts the filing.

“(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.

Requires plaintiff to clearly state allegations and, should any such be overlooked, treats these 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

This provisions raises an additional barrier by requiring plaintiff to find an “outside expert physician” to certify and explain “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” – another barrier to the plaintiffs that again limits the ability of those who are not affluent to bring such suits even when there is clear proof of willful misconduct.

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

By requiring all medical records to be certified rather than simply “true copies” of records, this provision creates another barrier to the plaintiff’s being able to file a suit.

“(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).

Title 28 U.S.C. Sec. 1253, as of 1/19/04 states:

TITLE 28 - JUDICIARY AND JUDICIAL PROCEDURE

PART IV - JURISDICTION AND VENUE

CHAPTER 81 - SUPREME COURT

Sec. 1253. Direct appeals from decisions of three-judge courts

Except as otherwise provided by law, any party may appeal to the Supreme Court from an order granting or denying, after notice and hearing, an interlocutory or permanent injunction in any civil action, suit or proceeding required by any Act of Congress to be heard and determined by a district court of three judges.

Title 28 U.S.C. Sec. 2284(b)(3) states:

TITLE 28 - JUDICIARY AND JUDICIAL PROCEDURE

PART VI - PARTICULAR PROCEEDINGS

CHAPTER 155 - INJUNCTIONS; THREE-JUDGE COURTS

Sec. 2284. Three-judge court; when required; composition; procedure

*Comments from the pen of Paul G. King, PhD, MS, BA*

- (a) A district court of three judges shall be convened when otherwise required by Act of Congress, or when an action is filed challenging the constitutionality of the apportionment of congressional districts or the apportionment of any statewide legislative body.
- (b) In any action required to be heard and determined by a district court of three judges under subsection (a) of this section, the composition and procedure of the court shall be as follows:
  - (1) Upon the filing of a request for three judges, the judge to whom the request is presented shall, unless he determines that three judges are not required, immediately notify the chief judge of the circuit, who shall designate two other judges, at least one of whom shall be a circuit judge. The judges so designated, and the judge to whom the request was presented, shall serve as members of the court to hear and determine the action or proceeding.
  - (2) If the action is against a State, or officer or agency thereof, at least five days' notice of hearing of the action shall be given by registered or certified mail to the Governor and attorney general of the State.
  - (3) A single judge may conduct all proceedings except the trial, and enter all orders permitted by the rules of civil procedure except as provided in this subsection. He may grant a temporary restraining order on a specific finding, based on evidence submitted, that specified irreparable damage will result if the order is not granted, which order, unless previously revoked by the district judge, shall remain in force only until the hearing and determination by the district court of three judges of an application for a preliminary injunction. A single judge shall not appoint a master, or order a reference, or hear and determine any application for a preliminary or permanent injunction or motion to vacate such an injunction, or enter judgment on the merits. Any action of a single judge may be reviewed by the full court at any time before final judgment.

This section prohibits a) direct appeals to the Supreme Court of decisions by a 3-judge panel forcing plaintiffs to first proceed through the full Appeals Court panel (a further disincentive to plaintiffs) and b) a single judge from conducting all pre-trial proceedings (a stipulation designed to slow case progress, another disincentive for all but the wealthiest to pursue a case).

**(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.

Prohibits any discovery until after all motions, including appeals of motions, are decided.

- (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.

This provision severely limits discovery and leaves it to the court's discretion subject to a finding that the "likely benefits" of discovery "equal or exceed the burden or cost for the responding party."

#### `(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.

This section provides that awards under subsection (d) are 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).

This section prohibits "providers of collateral source benefits" from trying to recover from "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.

This section defines collateral source benefits.

`(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.

This section defines and limits awards of “noneconomic damages.”

`(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.

This section provides sanctions who “have violated Rule 11 or are responsible for the violation” – another provision designed to further discourage lawsuits under subsection (d) of this legislation.

`(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).

This section specifically assigns jurisdiction of interlocutory appeals to the US Court of Appeals for the District of Columbia.

`(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).

This section preserves US government’s freedom to act or not act as it sees fit without being limited by these provisions.

`(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.

This section severs any provision declared unconstitutional from the other provisions of this legislation.

`(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.

This section excludes those products covered under the NVICP from being affected by this legislation.

`(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.

This provision broadly defines a “covered countermeasure” under this statute.

`(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).

This provision defines a “covered person” as “(A) the United States” or “(B) a person or entity that is—, (i) a manufacturer ..., (ii) a distributor ..., (iii) a program planner ..., (iv) a qualified persons who prescribed, administered, or dispensed” a “covered countermeasure” including in “(B)(v)” those who are the officials, agents, or employees of the direct actors described in “(B)(i)” through “(B)(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.

This provision broadly defines a “distributor” to include retail pharmacies.

`(4) MANUFACTURER- The term `manufacturer' includes--

`(A) a contractor or subcontractor of a manufacturer;

`(B) a supplier or licensor 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.

This provision broadly defines a “manufacturer” under this statute.

`(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.

This provision broadly defines a “person” under this statute.

`(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).

This provision broadly defines a “program planner” under this statute.

`(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--

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- `(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.

This provision broadly defines a “qualified pandemic or epidemic product” under this statute.

- `(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).

This provision broadly defines a “qualified person” under this statute.

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

Section 319F-2(c)(1)(B) of PL 108-276, the Project Bioshield Law of 2004, states:

**“SEC. 319F-2. STRATEGIC NATIONAL STOCKPILE.**

“(a) Strategic National Stockpile.--

- “(1) In general.--The Secretary, in coordination with the Secretary of Homeland Security (referred to in this section as the ‘Homeland Security Secretary’), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.
- “(2) Procedures.--The Secretary, in managing the stockpile under paragraph (1), shall--
  - “(A) consult with the working group under section 319F(a);
  - “(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;
  - “(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

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- "(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;
  - "(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure;
  - "(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;
  - "(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety; and
  - "(H) ensure the adequate physical security of the stockpile.
- "(b) Smallpox Vaccine Development.--
- "(1) In general.--The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.
  - "(2) Rule of construction.--Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).
- "(c) Additional Authority Regarding Procurement of Certain Biomedical Countermeasures; Availability of Special Reserve Fund.--
- "(1) In general.--
- "(A) Use of fund.--A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund under paragraph (10).
  - "(B) Security countermeasure.--For purposes of this subsection, the term 'security countermeasure' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that--
    - "(i)(I) the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;
    - "(ii) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and
    - "(iii)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; or
    - "(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for

approval or licensing within eight years after the date of a determination under paragraph (5); or  
“(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.

“(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.**

“(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.

This provision sets up an unfunded fund for those willfully harmed – another unfunded or underfunded federally mandate like the “no child shall be left behind” legislation.

“(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.

This section guarantees no payouts until the “Fund” is funded thus delaying any payouts for an indeterminate period.

“(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.

Rather than restating compensations limits, this provision simply adopts the applicable portions of the compensation structure provided in the smallpox provisions.

`(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.

Unlike the statutes for smallpox, benefits not limited as they are for smallpox injuries.

`(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.

Sets out and limits eligibility and compensation to those cases where there is “compelling, reliable, valid, medical and scientific evidence” of harm and willful misconduct.

`(5) COVERED COUNTERMEASURE INJURY TABLE-

`(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.

Like the NVICP, this legislation requires the Secretary to set up a table with injury and onset windows for each covered countermeasure.

`(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.**

Again, Secretary's decisions here are exempt from any judicial review whatsoever.

These "no judicial review" provisions seem to be an overreaching upon the part of the legislative and executive branches of government and, on that basis, would seem to be unconstitutional on their face.

`(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.*

This section speaks of the Secretary making sure that there are State, local and DHHS plans to administer or use a covered countermeasure and to educate public to "contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part", but not to their safety risks.

`(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*

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*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

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`(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.'

Overall, this section (the "PREP" Act) seems to be unconstitutional because it bars all right to a trial by jury for a loss – seemingly violating the 7<sup>th</sup> Amendment of the U.S. Constitution since the right to a trial is not guaranteed but rests on the 'whim' of the Secretary of HHS.

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'.

Speaker of the House of Representatives.

Vice President of the United States and  
President of the Senate.

*END*

### **Commenter's Recommendations**

Based on this commenter's understanding of the various sections, the action that Americans should demand is that the "Public Readiness and Emergency Preparedness Act" of 2005 must be repealed in full *because* no industry should have a *federal indulgence* to gratify their desire for profit by knowingly engaging in actions that will maim and kill some members of the public as long as their maiming and murderous actions do not rise to the level of "willful misconduct"

The "Public Readiness and Emergency Preparedness Act" of 2005 essentially sanctions the maiming and killing of some Americans without legal recourse so that the industry can be protected from the industry's less-than-safe and unsafe and/or less-than-effective or ineffective products whenever the government grants them an indulgence (issues a declaration) to maim and kill with no legal liability for the industry and limited chances for civil compensation for the harm or loss from the government (essentially, from the taxpayers). [**Note:** The government's projected smallpox vaccine's death rate was 1 in a million, the observed death rate for the about 38,000 who "voluntarily" took the smallpox inoculation was about 1 in 12,000. Similarly, the anthrax vaccine was so harmful that the Defense Department hid an additional 20,000 severe adverse event reactions from the public, Congress and the FDA in order to get the FDA to declare the vaccine safe even though its **serious** adverse reaction rate exceeds 1% of those inoculated.]

If the industry's products are so harmful that they need this protection, then the public should, as the first responders have for the smallpox vaccine that has caused at least 10 times the harm and 100 times the deaths as the government predicted, refuse to "volunteer" (because these countermeasures programs are "represented" to be voluntary programs).

If the industry's products are safe, then, it should be obvious that no such liability protection is needed.

Either repeal this legislation or prepare for mass refusals by the population – similar to the refusal by first providers to be inoculated with a smallpox vaccine that has a 1 in 100 chance of causing severe harm or death.