

109TH CONGRESS
1ST SESSION

H. R. 650

To establish reasonable legal reforms that will facilitate the manufacture of vital, life-saving vaccines, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2005

Mr. KELLER introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish reasonable legal reforms that will facilitate the manufacture of vital, life-saving vaccines, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Vaccine Accessibility
5 for Children and Seniors Act of 2005” or the “VACS Act
6 of 2005”.

7 **SEC. 2. FINDINGS; PURPOSE.**

8 (a) FINDINGS.—The Congress finds as follows:

1 (1) Vaccines represent one of the most signifi-
2 cant public health advances in history. They have
3 saved millions of lives and prevented millions of dis-
4 abilities.

5 (2) Vaccines are now available for preventing
6 once common childhood diseases, such as polio,
7 chicken pox, and measles, and for preventing dis-
8 eases responsible for high rates of sickness and
9 death among adults, including influenza, pneumonia,
10 and hepatitis.

11 (3) Vaccines reduce future medical costs and
12 prevent the need for more expensive drugs. Vaccines
13 not only provide a health benefit to the individual re-
14 ceiving the vaccine, they benefit others in the com-
15 munity by reducing their chances of exposure to a
16 disease.

17 (4) The threat of litigation, coupled with the
18 high cost of manufacturing a vaccine, has forced
19 many manufacturers to limit or cease production of
20 life-saving vaccines.

21 (5) In 1967, there were 26 companies in the
22 United States making these vital vaccines. A litiga-
23 tion crisis in the 1980's drove many companies away
24 from the vaccine business. Today, there are only 4
25 companies that make the vast majority of vaccines

1 used in the United States, making the system fragile
2 and limiting access to vaccines.

3 (6) In October 2004, the Secretary of Health
4 and Human Services announced a flu vaccine short-
5 age in the United States. The Secretary indicated
6 that the souring of the vaccine manufacturing mar-
7 ketplace was due, in part, to “costly liability law-
8 suits”.

9 (7) The Congress intervened in 1986 by cre-
10 ating a no-fault compensation system called the Na-
11 tional Vaccine Injury Compensation Program, which
12 was intended to lower the legal risk to vaccine man-
13 ufacturers, encourage a stable supply of vaccine, and
14 ensure that injured patients are rapidly and appro-
15 priately compensated.

16 (8) Under the National Vaccine Injury Com-
17 pensation Program, individuals who believe they
18 have been injured by a vaccine may file a claim in
19 the United States Court of Federal Claims. If found
20 eligible, they can receive unlimited economic dam-
21 ages for medical expenses, rehabilitation expenses,
22 and lost earnings, as well as pain and suffering dam-
23 ages subject to a \$250,000 cap. Over 1,800 claims
24 have been paid totaling over \$1,500,000,000 for vac-
25 cine-related injuries and complications under the

1 National Vaccine Injury Compensation Program,
2 with many awards amounting to more than
3 \$1,000,000 each, and some as high as \$7,500,000.

4 (9) Notwithstanding the intent of the National
5 Vaccine Injury Compensation Program, vaccine com-
6 panies still face significant and expensive litigation
7 exposure, in part, because—

8 (A) the National Vaccine Injury Com-
9 pensation Program allows all individuals to
10 “opt out” of this system and pursue individual
11 and class action lawsuits in State and Federal
12 courts;

13 (B) trial attorneys continually seek to by-
14 pass the the Program and elect to go to trial
15 by alleging that a particular vaccine is not cov-
16 ered under the Program, or that the Program
17 does not apply to certain preservatives, compo-
18 nents, or ingredients of any such vaccine; and

19 (C) the Program does not preclude an indi-
20 vidual who is otherwise ineligible to file a claim
21 under the Program (such as family members of
22 injured individuals) from pursuing civil litiga-
23 tion.

24 (10) To ensure that litigation involving feder-
25 ally approved vaccines is based on valid scientific

1 evidence and does not undermine the Federal public
2 health policy of creating and developing life saving
3 vaccines, it is imperative that any litigation involving
4 vaccines, and related preservatives, ingredients, and
5 components, that takes place outside of the National
6 Vaccine Injury Compensation Program shall take
7 place exclusively in the district courts of the United
8 States, where all procedures and expert testimony
9 shall be subject to the rules and requirements set
10 forth by the United States Supreme Court in
11 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509
12 U.S. 579, 113 S.Ct. 2786 (1993).

13 (11) To ensure that injured patients with legiti-
14 mate claims are more rapidly and fairly compensated
15 by the National Vaccine Injury Compensation Pro-
16 gram in a less adversarial manner so as to avoid the
17 need for traditional civil litigation, it is imperative
18 that the Secretary of Health and Human Services
19 and the Attorney General of the United States, in
20 consultation with the Advisory Commission on Child-
21 hood Vaccines, jointly study and submit a report to
22 the Congress within one year regarding their rec-
23 ommendations.

24 (b) PURPOSES.—The purposes of this Act are to—

1 (1) establish reasonable legal reforms that will
2 facilitate the manufacture of vital, life-saving vac-
3 cines;

4 (2) establish certain legal rules and procedures
5 to better assure that litigation involving federally ap-
6 proved vaccines is based on valid scientific evidence;

7 (3) discourage frivolous litigation; and

8 (4) ensure that injured patients are rapidly and
9 fairly compensated in the appropriate forum.

10 **SEC. 3. FEDERAL COURT REMEDY.**

11 Section 2122 of the Public Health Service Act (42
12 U.S.C 300aa-22) is amended by striking subsection (a)
13 and inserting the following:

14 “(a) FEDERAL CAUSE OF ACTION.—

15 “(1) IN GENERAL.—There shall exist a Federal
16 cause of action for claims arising from a vaccine-re-
17 lated injury or death associated with the administra-
18 tion of a vaccine after October 1, 1988. The sub-
19 stantive law for decision in any such action shall be
20 derived from this section and, unless inconsistent
21 with or preempted by Federal law, from the law, in-
22 cluding choice of law principles, of the State in
23 which such vaccine was administered. Except for a
24 proceeding for compensation under the National
25 Vaccine Injury Compensation Program, the cause of

1 action established by this paragraph shall constitute
2 the exclusive cause of action or remedy for any vac-
3 cine-related injury or death associated with the ad-
4 ministration of a vaccine after October 1, 1988, in-
5 cluding any related injury or loss sustained by any
6 person (including any relative or other third party).

7 “(2) JURISDICTION.—Except for a proceeding
8 in the United States Court of Federal Claims pursu-
9 ant to section 2112, the district courts of the United
10 States shall have original and exclusive jurisdiction
11 over all actions for damages arising from a vaccine-
12 related injury or death associated with the adminis-
13 tration of a vaccine after October 1, 1988, including
14 any related injury or loss sustained by any person
15 (including any relative or other third party). If any
16 civil action subject to this section is brought or is
17 pending in a State court, and the action is not dis-
18 missed by the State court, the action may be re-
19 moved at any time before final judgment by any de-
20 fendant to the district court of the United States for
21 the district and division embracing the place where
22 such action is pending. An order remanding an ac-
23 tion removed pursuant to this subsection is an ap-
24 pealable order. Except as provided herein, the re-
25 moval of any such action shall proceed in accordance

1 with sections 1446 through 1451 of title 28, United
2 States Code.

3 “(3) STATE ACTIONS.—All State causes of ac-
4 tion for damages arising from, or equitable relief re-
5 lating to, a vaccine-related injury or death associated
6 with a vaccine administered after October 1, 1988,
7 including for any related injury or loss sustained by
8 any person (including any relative or other third
9 party) are hereby preempted.

10 “(4) VACCINE DEFINED.—For purposes of this
11 section, the term ‘vaccine’ includes any preservative,
12 ingredient, or component of a vaccine.”.

13 **SEC. 4. SANCTIONS FOR FRIVOLOUS VACCINE LITIGATION;**
14 **3-STRIKES RULE FOR SUSPENDING ATTOR-**
15 **NEYS WHO COMMIT MULTIPLE RULE 11 VIO-**
16 **LATIONS.**

17 (a) MANDATORY SUSPENSION.—Whenever a district
18 court of the United States in connection with an action
19 for damages arising from a vaccine-related injury or death
20 associated with a vaccine administered after October 1,
21 1988 (in this section referred to as a “vaccine suit”), de-
22 termines that an attorney has violated Rule 11 of the Fed-
23 eral Rules of Civil Procedure, the court shall determine
24 the number of times that the attorney has violated that
25 rule in connection with a vaccine suit in that district court

1 during that attorney’s career. If the court determines that
2 the number is 3 or more, the district court of the United
3 States—

4 (1) shall suspend that attorney from the prac-
5 tice of law in that district court for 1 year; and

6 (2) may suspend that attorney from the prac-
7 tice of law in that district court for any additional
8 period that the court considers appropriate.

9 (b) APPEAL; STAY.—An attorney has the right to ap-
10 peal a suspension under subsection (a). While such an ap-
11 peal is pending, the suspension shall be stayed.

12 (c) REINSTATEMENT.—To be reinstated to the prac-
13 tice of law in a district court of the United States after
14 completion of a suspension under subsection (a), the attor-
15 ney must first petition the court for reinstatement under
16 such procedures and conditions as the court may pre-
17 scribe.

18 **SEC. 5. TRIAL PROCEDURE.**

19 (a) IN GENERAL.—Section 2123 of the Public Health
20 Service Act (42 U.S.C. 300aa–23) is amended—

21 (1) in subsection (a)—

22 (A) by striking “three” and inserting
23 “four”; and

24 (B) by inserting “, including any related
25 injury or loss sustained by any person (includ-

1 ing any relative or other third party),” after
2 “the effective date of this part”;

3 (2) by redesignating subsections (b), (c), (d)
4 and (e) as subsections (c), (d), (e) and (f);

5 (3) by inserting after subsection (a) the fol-
6 lowing:

7 “(b) CAUSATION IN FACT.—The first stage of such
8 civil action shall be held to determine whether competent
9 and reliable scientific evidence demonstrates that the
10 plaintiff’s alleged vaccine-related injury or death was
11 caused in fact by the vaccine.”;

12 (4) in subsection (c) (as so redesignated), by
13 striking “The first” and inserting “If the trier of
14 fact finds that the alleged vaccine-related injury or
15 death was caused in fact by the vaccine, a second”;

16 (5) in subsection (d) (as so redesignated), by
17 striking “second” and inserting “third”; and

18 (6) in subsection (e) (as so redesignated), by
19 striking “third” and inserting “fourth”.

20 (b) CONFORMING AMENDMENT.—Subparagraph (A)
21 of section 2122(b)(2) of the Public Health Service Act (42
22 U.S.C. 300aa–22) is amended by striking “2123(d)(2)”
23 and inserting “2123(e)(2)”.

1 **SEC. 6. TRANSITION RULES.**

2 (a) NOTICE.—If on the date of the enactment of this
3 Act, any State law claim for damages arising from, or eq-
4 uitable relief relating to, a vaccine-related injury or death
5 associated with a vaccine administered after October 1,
6 1988, including any related injury or loss sustained by any
7 person (including any relative or other third party), is
8 pending in any State or Federal court prior to the entry
9 of final judgment, the plaintiff may, within 30 days of
10 such date of enactment, file a notice with the court in
11 which the claim is pending electing to treat the State law
12 claim as a Federal law claim arising under section 2122
13 of the Public Health Service Act, as amended by section
14 3, and subject to the amendments made by this Act.

15 (b) FAILURE TO FILE NOTICE.—If no notice is filed
16 for a claim described in subsection (a) within the 30-day
17 period described in such subsection, and the claim is pend-
18 ing in State court, the claim shall be dismissed with preju-
19 dice.

20 (c) NOTICE FILED.—If a notice is filed for a claim
21 described in subsection (a) within such 30-day period de-
22 scribed in such subsection, and the claim is pending in
23 State court prior to the entry of final judgment, any plain-
24 tiff or defendant may remove the action to the district
25 court of the United States for the district and division em-
26 bracing the place where such action is pending by filing

1 a notice of removal signed pursuant to Rule 11 of the Fed-
2 eral Rules of Civil Procedure and containing a short and
3 plain statement of the grounds for removal, together with
4 a copy of all process, pleadings, and orders served or pre-
5 viously filed in such action. Promptly after the filing of
6 such notice of removal, the removing party shall give writ-
7 ten notice thereof to all other parties and shall file a copy
8 of the notice with the clerk of such State court, which shall
9 effect the removal, and the State court shall proceed no
10 further unless the case is remanded. An order remanding
11 an action removed pursuant to this subsection is an ap-
12 pealable order. Except as provided herein, the removal of
13 any such action shall proceed in accordance with sections
14 1446 through 1451 of title 28, United States Code. If a
15 case is not properly removed within 40 days of the date
16 of the enactment of this Act, any claim subject to sub-
17 section (a) that remains pending in State court or that
18 is remanded to State court shall be promptly dismissed
19 with prejudice.

20 **SEC. 7. STUDY AND REPORT.**

21 (a) FINDINGS.—The Congress finds as follows:

22 (1) The Congress intended the National Vac-
23 cine Injury Compensation Program to be a flexible,
24 no-fault, less adversarial system to handle claims in
25 a quick, easy, and generous manner so as to avoid

1 the need the for civil litigation, and to avoid the ran-
2 cor and substantial delays often associated with tra-
3 ditional litigation.

4 (2) Although the National Vaccine Injury Com-
5 pensation Program maintains it has an excellent
6 record of promptly and appropriately compensating
7 valid claims, recent reports of some individuals seek-
8 ing compensation under the Program allege that
9 some legitimate claims have taken 5 to 10 years to
10 resolve, the process has become more adversarial,
11 the Program has made claims harder to prove, and
12 the process has drifted toward full-blown litigation
13 and away from Congress' intent as a positive alter-
14 native to tort litigation.

15 (b) STUDY.—After considering the findings in sub-
16 section (a), and after consulting with the Advisory Com-
17 mission on Childhood Vaccines, the Secretary of Health
18 and Human Services and the Attorney General of the
19 United States shall, not later than 1 year after the date
20 of the enactment of this Act, jointly submit a report to
21 the appropriate committees of the Congress concerning
22 their recommendations to ensure that injured patients
23 with legitimate claims are rapidly and appropriately com-
24 pensated in a less adversarial manner.

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