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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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Vaccine Accessibility for Children and Seniors Act of 2005'' or the ''VACS Act of 2005''.

SEC. 2. FINDINGS; PURPOSE.

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

(1) Vaccines represent one of the most significant public health advances in history. They have saved millions of lives and prevented millions of disabilities.

(2) Vaccines are now available for preventing once common childhood diseases, such as polio, chicken pox, and measles, and for preventing diseases responsible for high rates of sickness and death among adults, including influenza, pneumonia, and hepatitis.

(3) Vaccines reduce future medical costs and prevent the need for more expensive drugs. Vaccines not only provide a health benefit to the individual receiving the vaccine, they benefit others in the community by reducing their chances of exposure to a disease.

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

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

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

(6) In October 2004, the Secretary of Health and Human Services announced a flu vaccine shortage in the United States. The Secretary indicated that the souring of the vaccine manufacturing marketplace was due, in part, to ''costly liability lawsuits''.

(7) The Congress intervened in 1986 by creating a no-fault compensation system called the National Vaccine Injury Compensation Program, which was intended to lower the legal risk to vaccine manufacturers, encourage a stable supply of vaccine, and ensure that injured patients are rapidly and appropriately compensated.

(8) Under the National Vaccine Injury Compensation Program, individuals who believe they have been injured by a vaccine may file a claim in the United States Court of Federal Claims. If found eligible, they can receive unlimited economic damages for medical expenses, rehabilitation expenses, and lost earnings, as well as pain and suffering damages subject to a $250,000 cap. Over 1,800 claims have been paid totaling over $1,500,000,000 for vaccine-related injuries and complications under the

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

(9) Notwithstanding the intent of the National Vaccine Injury Compensation Program, vaccine companies still face significant and expensive litigation exposure, in part, because—

(A) the National Vaccine Injury Compensation Program allows all individuals to ''opt out'' of this system and pursue individual and class action lawsuits in State and Federal courts;

(B) trial attorneys continually seek to bypass the the Program and elect to go to trial by alleging that a particular vaccine is not covered under the Program, or that the Program does not apply to certain preservatives, components, or ingredients of any such vaccine; and

(C) the Program does not preclude an individual who is otherwise ineligible to file a claim under the Program (such as family members of injured individuals) from pursuing civil litigation.

(10) To ensure that litigation involving federally approved vaccines is based on valid scientific

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

(11) To ensure that injured patients with legitimate claims are more rapidly and fairly compensated by the National Vaccine Injury Compensation Program in a less adversarial manner so as to avoid the need for traditional civil litigation, it is imperative that the Secretary of Health and Human Services and the Attorney General of the United States, in consultation with the Advisory Commission on Childhood Vaccines, jointly study and submit a report to the Congress within one year regarding their recommendations.

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

(1) establish reasonable legal reforms that will facilitate the manufacture of vital, life-saving vaccines;

(2) establish certain legal rules and procedures to better assure that litigation involving federally approved vaccines is based on valid scientific evidence;

(3) discourage frivolous litigation; and

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

SEC. 3. FEDERAL COURT REMEDY.

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

''(a) FEDERAL CAUSE OF ACTION.—

''(1) IN GENERAL.—There shall exist a Federal cause of action for claims arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988. The substantive law for decision in any such action shall be derived from this section and, unless inconsistent with or preempted by Federal law, from the law, including choice of law principles, of the State in which such vaccine was administered. Except for a proceeding for compensation under the National Vaccine Injury Compensation Program, the cause of

action established by this paragraph shall constitute the exclusive cause of action or remedy for any vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, including any related injury or loss sustained by any person (including any relative or other third party).

''(2) JURISDICTION.—Except for a proceeding in the United States Court of Federal Claims pursuant to section 2112, the district courts of the United States shall have original and exclusive jurisdiction over all actions for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, including any related injury or loss sustained by any person (including any relative or other third party). If any civil action subject to this section is brought or is pending in a State court, and the action is not dismissed by the State court, the action may be removed at any time before final judgment by any defendant to the district court of the United States for the district and division embracing the place where such action is pending. An order remanding an action removed pursuant to this subsection is an appealable order. Except as provided herein, the removal of any such action shall proceed in accordance

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

''(3) STATE ACTIONS.—All State causes of action for damages arising from, or equitable relief relating to, a vaccine-related injury or death associated with a vaccine administered after October 1, 1988, including for any related injury or loss sustained by any person (including any relative or other third party) are hereby preempted.

''(4) VACCINE DEFINED.—For purposes of this section, the term 'vaccine' includes any preservative, ingredient, or component of a vaccine.''.

SEC. 4. SANCTIONS FOR FRIVOLOUS VACCINE LITIGATION; 3-STRIKES RULE FOR SUSPENDING ATTORNEYS WHO COMMIT MULTIPLE RULE 11 VIOLATIONS.

(a) MANDATORY SUSPENSION.—Whenever a district court of the United States in connection with an action for damages arising from a vaccine-related injury or death associated with a vaccine administered after October 1, 1988 (in this section referred to as a ''vaccine suit''), determines that an attorney has violated Rule 11 of the Federal Rules of Civil Procedure, the court shall determine the number of times that the attorney has violated that rule in connection with a vaccine suit in that district court

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

(1) shall suspend that attorney from the practice of law in that district court for 1 year; and

(2) may suspend that attorney from the practice of law in that district court for any additional period that the court considers appropriate.

(b) APPEAL; STAY.—An attorney has the right to appeal a suspension under subsection (a). While such an appeal is pending, the suspension shall be stayed.

(c) REINSTATEMENT.—To be reinstated to the practice of law in a district court of the United States after completion of a suspension under subsection (a), the attorney must first petition the court for reinstatement under such procedures and conditions as the court may prescribe.

SEC. 5. TRIAL PROCEDURE.

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

(1) in subsection (a)—

(A) by striking ''three'' and inserting ''four''; and

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

ing any relative or other third party),'' after ''the effective date of this part'';

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

(3) by inserting after subsection (a) the following:

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

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

(5) in subsection (d) (as so redesignated), by striking ''second'' and inserting ''third''; and

(6) in subsection (e) (as so redesignated), by striking ''third'' and inserting ''fourth''.

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

SEC. 6. TRANSITION RULES.

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

(b) FAILURE TO FILE NOTICE.—If no notice is filed for a claim described in subsection (a) within the 30-day period described in such subsection, and the claim is pending in State court, the claim shall be dismissed with prejudice.

(c) NOTICE FILED.—If a notice is filed for a claim described in subsection (a) within such 30-day period described in such subsection, and the claim is pending in State court prior to the entry of final judgment, any plaintiff or defendant may remove the action to the district court of the United States for the district and division embracing the place where such action is pending by filing

a notice of removal signed pursuant to Rule 11 of the Federal Rules of Civil Procedure and containing a short and plain statement of the grounds for removal, together with a copy of all process, pleadings, and orders served or previously filed in such action. Promptly after the filing of such notice of removal, the removing party shall give written notice thereof to all other parties and shall file a copy of the notice with the clerk of such State court, which shall effect the removal, and the State court shall proceed no further unless the case is remanded. An order remanding an action removed pursuant to this subsection is an appealable order. Except as provided herein, the removal of any such action shall proceed in accordance with sections 1446 through 1451 of title 28, United States Code. If a case is not properly removed within 40 days of the date of the enactment of this Act, any claim subject to subsection (a) that remains pending in State court or that is remanded to State court shall be promptly dismissed with prejudice.

SEC. 7. STUDY AND REPORT.

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

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

the need the for civil litigation, and to avoid the rancor and substantial delays often associated with traditional litigation.

(2) Although the National Vaccine Injury Compensation Program maintains it has an excellent record of promptly and appropriately compensating valid claims, recent reports of some individuals seeking compensation under the Program allege that some legitimate claims have taken 5 to 10 years to resolve, the process has become more adversarial, the Program has made claims harder to prove, and the process has drifted toward full-blown litigation and away from Congress' intent as a positive alternative to tort litigation.

(b) STUDY.—After considering the findings in subsection (a), and after consulting with the Advisory Commission on Childhood Vaccines, the Secretary of Health and Human Services and the Attorney General of the United States shall, not later than 1 year after the date of the enactment of this Act, jointly submit a report to the appropriate committees of the Congress concerning their recommendations to ensure that injured patients with legitimate claims are rapidly and appropriately compensated in a less adversarial manner.

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