a drug, biological product or device if, after notice and an opportunity for comment, the Secretary determines that—

''(A) with respect to the particular type of human tissue—

''(i) the tissue is subject to a patient registry or other retrospective data requirement under which the collection of information has been required for at least 5 years (or such other time period as agreed to by the Secretary and the registered person); and

''(ii) the information received from such patient registry or other retrospective data requirement is insufficient to confirm the safety and clinical benefit from the use of such tissue; or

''(B) a particular type of human tissue should be reclassified because it presents an imminent hazard to public health.

''(2) UPON SECRETARIAL ACTION.—The Secretary may reclassify a human drug, biological product or medical device as human tissue if the Secretary determines, after notice and an opportunity for comment, that such previous classification is not necessary to protect public health.

''(3) UPON PETITION.—The Secretary may reclassify a drug, biological product, medical device, or human tissue upon the petition of the sponsor of such drug, biological product or device, or the registered person for such human tissue, if, after notice and an opportunity to comment, the Secretary finds that such reclassification is consistent with the protection of public health.

''(g) ENFORCEMENT.—

''(1) IN GENERAL.—If the Secretary determines that any person has violated any provision of this section or any regulations promulgated under this section, and the Secretary determines that the violation constitutes a significant risk to the public health, the Secretary may issue an order that such person cease distribution of human tissue, or that human tissue recovered, processed, stored or distributed by such person be retained, recalled, or destroyed. After receipt of such an order, the person in possession of the human tissue shall not distribute or dispose of the human tissue in any manner inconsistent with the provisions of the order.

''(2) HEARING.—A person subject to the order under paragraph (1) may obtain an informal hearing regarding the order if the person requests such a hearing not later than 5 days after receiving the order. If the person does make such a request within such period, the Secretary shall conduct the hearing within 30 days after receiving the request and shall issue an order not later than 15 days after the hearing is conducted. Such order shall be considered a final order of the Secretary.

''(h) INSPECTION.—Each person registered under subsection (b) shall be subject to inspection under section 704 of the Federal Food, Drug, and Cosmetic Act. The Secretary may, with the concurrence of the registered person, authorize an inspection be conducted by any person specifically accredited by the Secretary to conduct such inspection under section 712 of such Act.

''(i) CORD BLOOD.—

''(1) IN GENERAL.—This section (including provisions regarding reclassification) shall apply with respect to cord blood to the same extent and in the same manner as this section applies with respect to human tissue.

''(2) IMPLEMENTATION.—The Secretary shall implement this section with respect to cord blood under regulations promulgated after notice and opportunity to comment.

''(j) EYES.—The Secretary shall not regulate eyes until such time as the Secretary makes a finding under this section that voluntary regulation under generally accepted standards is inadequate to protect the public health.''.

(c) TRANSITION.—The requirements of the interim regulation, promulgated by the Secretary of Health and Human Services on December 11, 1993, shall remain in effect until amended or withdrawn by the Secretary. Any modifications to such regulations after the date of the enactment of this Act are subject to this Act and the amendments made by this Act.

(d) EFFECTIVE DATE.—The amendment made by subsection (c) shall take effect on June 30, 1997.

(e) CONFORMING AMENDMENTS.—

(1) ADULTERATION PROVISION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended—

(A) in the first sentence by striking ''drug or device'' and inserting ''drug, device or human tissue''; and

(B) by adding at the end thereof the following:

''(j) if it is human tissue and it is recovered, processed, stored, or distributed by—

''(1) a registered person under section 352A of the Public Health Service Act whose failure to comply with standards constitutes a threat to public health; or

''(2) a person who is required under such section to register but has failed to do so.''.

(2) MISBRANDING PROVISIONS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended:

(A) in the section heading, by striking ''MISBRANDED DRUGS AND DEVICES'' and inserting the following: ''MISBRANDED DRUGS, DEVICES, AND HUMAN TISSUE''; and

(B) in the first sentence, by striking ''drug or device'' and inserting ''drug, device or human tissue''.

(3) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end thereof the following:

''(v) The adulteration or misbranding of any human tissue.''.

(4) SEIZURE.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended

(A) in subsection (a)(2)(D), by inserting ''or human tissue'' after ''device''; and

(B) in the first sentence of subsection (d)(1), by striking ''or cosmetic'' and inserting ''cosmetic, or human tissue''.

(5) INSPECTION.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended—

(A) in the first sentence, by inserting ''human tissue,'' after ''device,'' each place such appears; and

(B) in the second sentence, by inserting ''human tissue,'' after ''drugs,'' each place such appears.

THE NEED FOR BALLAST MANAGEMENT—H.R. 4283

● Mr. GLENN. I thank the Senator from South Dakota for his efforts in responding to the urgent national need for ballast management to prevent unintentional introduction of nonnative species into U.S. waters. As you know, some Senators raised concerns about the initial House-passed version of the National Invasive Species Act [H.R. 3217] because it does not give assurance that onerous requirements will not be imposed upon vessels that exercise the safety exemption from national ballast exchange requirements. This version, [H.R. 4283], rectifies that problem. The Great Lakes Program which already leaves sole discretion over safety to the ship master, and already requires alternatives if high seas exchange is not possible, will not be affected by this amendment. I ask the Senator, is it his opinion that the Coast Guard will actively seek to identify alternatives of which vessels may avail themselves in other coastal regions, and will it request vessels to conduct these alternative precautions on a voluntary basis in the new national program?

Mr. PRESSLER. As Chairman of the Senate Committee on Commerce, Science and Transportation that has jurisdiction of the U.S. Coast Guard, I would expect the Coast Guard to actively seek alternatives applicable to other regions, routinely identify those alternatives to ballast exchange for vessels which use the safety exemption, and encourage their use prior to discharging unexchanged water in the port of call.

Mr. GLENN. I also ask the Senator, if he believes that the Coast Guard will keep careful records regarding the extent to which the safety exemption is utilized, under what circumstances, and the extent to which vessels attempt in good faith to use alternatives that may be identified?

Mr. PRESSLER. Yes, I expect the Coast Guard to include each of those items in its reporting requirements, and to include a careful assessment of those matters in its report to Congress so that Congress can make decisions regarding the impact of this exemption and the need for revision of the law.

Mr. GLENN. As I mentioned, the Great Lakes Program currently requires alternatives to ballast exchange if high seas exchange is not possible due to safety concerns. While these alternatives are not overly onerous, I can understand industry's concern in other regions where the alternatives have not yet been developed.

A cooperative relationship between the Committee of Environment and Public Works at the Committee on Commerce, Science and Transportation is crucial to the passage of this legislation and its effective implementation. I hope that these two Committees that share jurisdiction over this issue continue to work together to evaluate progress under the National Invasive Species Act.

Mr. PRESSLER. I look forward to a continued cooperative relationship between the two committees as well as with the bill author and cosponsors.

Mr. GLENN. H.R. 4283 includes an exemption from the National Ballast Management Program for crude oil tankers engaged in coastwise trade. While the majority of this trade is conducted between Hawaii and Alaska, the risk to receiving waters of ballast water from these vessels may be significant. As the Senator knows, there is concern that fish pathogens may have been transported to Alaskan waters via this trade. I would hope that every effort will be made to study the baseline conditions of the Prince William Sound ecosystem to assure that invasive species problems in fact have

not been arising from this trade, and will not arise in the future.

Mr. PRESSLER. I join the Senator in urging such a study.●

CHILDREN'S HEALTH INSURANCE FOR LONG-TERM DEVELOPMENT ACT

● Mr. KERREY. Mr. President, on September 30, 1996, I introduced S. 2167, the Children's Health Insurance for Long-Term Development Act—the CHILD bill. In simple terms, this legislation will require private health plans to cover all necessary health and screening services for infants and children through age 3. But it has a broader purpose. It will close the gap between two entities that serve America's children, the health system and the school system, by addressing an important health risk that has implications for children's education achievements and later development.

A significant body of research demonstrates that the first 3 years of life are critical to children's development—mentally, physically, and emotionally. In particular, during the first 3 years of life the human brain and central nervous system undergo their most rapid period of neurological development. This time period—the infant neurological risk exposure period—provides both a substantial risk and an important opportunity. If we can ensure that children receive the health care, parenting and environmental influences they need during their first 3 years, we can give our children a strong start in life. If, however, we neglect their physical and mental development during this crucial period, we have lost an important opportunity to promote learning and prevent damage to brain functioning.

Obviously, there are many influences on a child's early development, such as parental influence and childrearing practices, comprehensive health care, environment, mental stimulation, and community support. As a Nation, we have an opportunity and an obligation to provide children with a safe, healthy, stimulating environment during their early years. This bill takes an important step toward this goal.

First, this legislation identifies a critical period in children's development—the Infant Neurological Risk Exposure Period [INREP]. Brain and nervous system development during this period has a long-lasting impact on the child's life. I hope that by singling out this particular time-frame, this legislation will focus greater attention on improving health care and supportive services during infancy and early childhood.

Second, this bill will require private health insurers to cover comprehensive preventive and curative services through age 3. These third-party payors will therefore be financially responsible for the care children need to be adequately monitored and treated through this important developmental period.

I was startled to learn that 86 percent of children who are privately insured are not covered for comprehensive well-child care. Children who receive health coverage through the Medicaid Program are covered for a comprehensive array of well-child care, diagnostic assessments and treatment services through the EPSDT program, yet most children who are privately insured do not have similar coverage. Health screenings and periodic check-ups provide an important opportunity for physicians to ensure that a child's neurological development is progressing along normal patterns—and to intervene as appropriate if it is not.

This comprehensive approach will also address other problems in pediatric health care, such as ensuring that children are completely covered for immunizations through this time period. This coverage will counter current immunization trends that leave 60 percent of children in most States with incomplete immunizations at age 2.

I should also emphasize that this bill, by its very nature, cannot help children who are uninsured. We need to pursue further legislation that addresses this important problem. In a recent study on children's health insurance, the GAO noted that the proportion of children who are uninsured—14.2 percent, or 10 million children—is at the highest level since 1987. This decline in children's health insurance coverage has been concentrated among low-income children.

Mr. President, all children should have health insurance that covers their complete developmental needs. We are the wealthiest, most powerful, and most advanced Nation on this planet. But it is discouraging that we still have so far to go when it comes to caring for our own children.

My friend and respected colleague Senator JOHN KERRY has offered one approach to this problem using sliding-scale subsidies; we should explore this option and others in order to ensure that America's infants and young children achieve their highest potential. My proposal represents the first step toward this important goal—the next step is health coverage for all children.

Mr. President, I ask that the text of S. 2167 be printed in the RECORD.

The bill follows:

S. 2167

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 ''Children's Health Insurance for Long-Term Development Act of 1996''.

SEC. 2. PURPOSE.

The purpose of this act is to provide health insurance coverage for children during the Infant Neurological Risk Exposure Period (INREP). The INREP extends through age 3 and encompasses the period of most rapid neurological changes in young children. Health coverage will improve children's health, and, through routine health supervision, promote parents' caregiving skills through these critical years.

SEC. 3 FINDINGS.

Congress finds that—

(1) 86 percent of children with private health insurance are under-insured with respect to well-child care;

(2) because the human brain develops rapidly until the age of 3, children need regular screenings and follow-up care to detect neurological abnormalities and ensure normal development;

(3) regular pediatric visits enable physicians to provide guidance on parental activities, such as reading, that stimulate the brain development of infants; and

(4) children deserve health care coverage that promotes normal brain and nervous system development.

SEC. 4. DEFINITIONS.

As used in this Act:

(1) BENEFICIARY.—The term ''beneficiary'' has the meaning given such term under section 3(8) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(8)).

(2) CHILD.—The term ''child'' means an individual who is age 3 or younger.

(3) EMPLOYEE HEALTH BENEFIT PLAN.—

(A) IN GENERAL.—The term ''employee health benefit plan'' means any employee welfare benefit plan, governmental plan, or church plan (as defined under paragraphs (1), (32), and (33) of section 3 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002 (1), (32), and (33))) that provides or pays for health benefits (such as provider and hospital benefits) for participants and beneficiaries whether—

(i) directly;

(ii) through a health plan offered by a health plan issuer as defined in paragraph (6); or

(iii) otherwise.

(B) RULE OF CONSTRUCTION.—An employee health benefit plan shall not be construed to be a health plan or a health plan issuer.

(C) ARRANGEMENTS NOT INCLUDED.—Such term does not include the following, or any combination thereof:

(i) Coverage only for accident, or disability income insurance, or any combination thereof.

(ii) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act (42 U.S.C. 1395ss(g)(1))).

(iii) Coverage issued as a supplement to liability insurance.

(iv) Liability insurance, including general liability insurance and automobile liability insurance.

(v) Workers' compensation or similar insurance.

(vi) Automobile medical payment insurance.

(vii) Coverage for a specified disease or illness.

(viii) Hospital or fixed indemnity insurance.

(ix) Short-term limited duration insurance.

(x) Credit-only, dental-only, or vision-only insurance.

(xi) A health insurance policy providing benefits only for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

(4) GROUP PURCHASER.—The term ''group purchaser'' means any person (as defined in section 3(9) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(9))) or entity that purchases or pays for health benefits (such as provider or hospital benefits) on behalf of participants or beneficiaries in connection with an employee health benefit plan.

(5) HEALTH PLAN.—