

pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions; and"; and

(iii) in subparagraph (C), by inserting "(including drugs and biological products) and medical devices" after "therapeutics".

SEC. 7. STUDIES.

(a) POSTMARKET STUDIES.—Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) in subsection (a)—

(A) by inserting ", or as a condition to approval of an application (or a supplement to an application) or a product development protocol under section 515 or as a condition to clearance of a premarket notification report under section 510(k)," after "The Secretary may by order"; and

(B) by inserting ", that is expected to have significant use in pediatric populations," after "health consequences"; and

(2) in subsection (b)—

(A) by striking "(b) SURVEILLANCE APPROVAL.—Each" and inserting the following: "(b) SURVEILLANCE APPROVAL.—"

"(1) IN GENERAL.—Each";

(B) by striking "The Secretary, in consultation" and inserting "Except as provided in paragraph (2), the Secretary, in consultation";

(C) by striking "Any determination" and inserting "Except as provided in paragraph (2), any determination"; and

(D) by adding at the end the following:

"(2) LONGER STUDIES FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device."

(b) DATABASE.—

(1) IN GENERAL.—

(A) ESTABLISHMENT.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall establish a publicly accessible database of studies of medical devices that includes all studies and surveillances, described in paragraph (2)(A), that were in progress on the date of enactment of this Act or that began after such date.

(B) ACCESSIBILITY.—Information included in the database under subparagraph (A) shall be in language reasonably accessible and understood by individuals without specific expertise in the medical field.

(2) STUDIES AND SURVEILLANCES.—

(A) INCLUDED.—The database described in paragraph (1) shall include—

(i) all postmarket surveillances ordered under section 522(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l(a)) or agreed to by the manufacturer; and

(ii) all other studies completed by the manufacturer with respect to a medical device after—

(I) the premarket approval of such device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e);

(II) the clearance of a premarket notification report under section 510(k) of such Act (21 U.S.C. 360(k)) with respect to such device; or

(III) submission of an application under section 520(m) of such Act (21 U.S.C. 360j(m)) with respect to such device.

(B) EXCLUDED.—The database described in paragraph (1) shall not include any studies with respect to a medical device that were completed prior to the initial approval of such device.

(3) CONTENTS OF STUDY AND SURVEILLANCE.—For each study or surveillance included in the database described in paragraph (1), the database shall include—

(A) information on the status of the study or surveillance;

(B) basic information about the study or surveillance, including the purpose, the primary and secondary outcomes, and the population targeted;

(C) the expected completion date of the study or surveillance;

(D) public health notifications, including safety alerts; and

(E) any other information the Secretary of Health and Human Services determines appropriate to protect the public health.

(4) ONCE COMPLETED OR TERMINATED.—In addition to the information described in paragraph (3), once a study or surveillance has been completed or if a study or surveillance is terminated, the database shall also include—

(A) the actual date of completion or termination;

(B) if the study or surveillance was terminated, the reason for termination;

(C) if the study or surveillance was submitted but not accepted by the Food and Drug Administration because the study or surveillance did not meet the requirements for such study or surveillance, an explanation of the reasons and any follow-up action required;

(D) information about any labeling changes made to the device as a result of the study or surveillance findings;

(E) information about any other decisions or actions of the Food and Drug Administration that result from the study or surveillance findings;

(F) lay and technical summaries of the study or surveillance results and key findings, or an explanation as to why the results and key findings do not warrant public availability;

(G) a link to any peer reviewed articles on the study or surveillance; and

(H) any other information the Secretary of Health and Human Services determines appropriate to protect the public health.

(5) PUBLIC ACCESS.—The database described in paragraph (1) shall be—

(A) accessible to the general public; and

(B) easily searchable by multiple criteria, including whether the study or surveillance involves pediatric populations.

(c) MEDICAL DEVICE CODING.—The Secretary of Health and Human Services, in consultation with the Commissioner of Food and Drugs, shall adopt voluntary national standards for medical device coding. In adopting voluntary national standards for medical device coding, the Secretary of Health and Human Services shall coordinate with other efforts by the Secretary to adopt and implement standards for the electronic exchange of health information.

Mr. DEWINE. Mr. President, today I join my colleague Senator DODD to introduce a bill designed to help protect our Nation's children. Simply put, our bill would help ensure that our children have access to lifesaving medical devices that are designed specifically for their small bodies. Since the beginning of my career, my No. 1 priority has been to ensure that our children are healthy and safe. There is no other issue more important to me.

Today, many medical devices used by pediatricians are not designed for children. That means that doctors have to fit adult sized devices into children's bodies. This is not right. We need to

encourage the development of devices that are sized appropriately for children. According to pediatricians, medical devices sized appropriately for children are developed sometimes 5 to 10 years behind those for adults. The Pediatric Medical Device Safety and Improvement Act takes a step towards fixing this problem by providing incentives for manufacturers to develop devices for children while also ensuring the safety of new products once on the market.

By introducing this bill, we are saying that we care about our children. We are saying that we care that children have access to lifesaving medical devices that are designed specifically for their small bodies. We are saying that we know we can do better for our children and this bill will do just that.

We all want to see better health care options for our sick children. I believe that with this bill we are taking the first step to resolve a serious national health problem. While this legislation obviously will not pass this year, I know that Senator DODD will continue to work on it next year and encourage my Republican colleagues to take a close look at this bill and support it in the 110th Congress.

I ask unanimous consent that the text of the bill be printed in the RECORD.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 624—TO HONOR THE MEMORY OF ARNOLD "RED" AUERBACH

Mr. KENNEDY (for himself and Mr. KERRY) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 624

Whereas Arnold "Red" Auerbach was born on September 20, 1917, in Brooklyn, New York, the son of immigrants from Minsk, Russia;

Whereas Red started playing basketball as a public school student in Brooklyn and later became a star guard for Eastern District High School, making all-scholastic second team in his senior year;

Whereas Red started his coaching career at St. Albans Preparatory School and Roosevelt High School in Washington, D.C., before serving in the United States Navy from 1943 to 1946;

Whereas, in 1946, Red began his professional coaching career with the Washington Capitols in the Basketball Association of America (BAA) and led the team to the 1947 and 1949 division titles, then joined the Boston Celtics as coach in 1950 after the BAA merged with the National Basketball Association (NBA);

Whereas Red's record of success on the basketball court and in the Celtics' front office is unmatched;

Whereas, during Red's 16 years coaching the Boston Celtics, the team won 9 NBA championships, with a record 8 in a row;

Whereas, when Red retired from coaching in 1966 to become General Manager of the Celtics, he had won more games than any other coach in NBA history with 1,037 victories and had won almost two-thirds of the

games he coached over a 20-year NBA coaching career;

Whereas during his nearly 57-year tenure with the Celtics as Head Coach, General Manager, Vice Chairman of the Board, and President, Red was the architect of one of the greatest dynasties in the history of professional sports;

Whereas Red infused the Celtics organization with the values of teamwork, respect, tenacity, and loyalty, creating a culture known as "Celtic Pride" that will be forever associated with the Boston Celtics franchise;

Whereas Red's imprint on the Celtics, the NBA, and the game of basketball is permanent and visible today in innovations that Red developed, including the "sixth man" role and fast break style of play;

Whereas Red was an effective and tireless ambassador for the game of basketball, both in the United States and overseas, conducting clinics, barnstorming with the Celtics, starring in the successful television series "Red on Roundball", writing 7 books on basketball, including the influential "Basketball For The Player, The Coach, and The Fan", and participating with Celtics great and Hall of Famer Larry Bird in the instructional video, "Winning Basketball";

Whereas Red received numerous awards and honors in recognition of his extraordinary achievements, such as selection as the NBA Coach of the Year in 1965, induction into the Naismith Memorial Basketball Hall of Fame in 1969, designation as the NBA Executive of the Year in 1980, and selection as "The Greatest Coach in the History of the NBA" by the Professional Basketball Writers' Association of America in 1980;

Whereas Red's lighting of his cigar in the closing moments of an imminent Celtics' victory became an enduring symbol of success in Boston and around the world;

Whereas Red's legacy extends beyond the game of basketball and includes his important contributions to the advancement of a colorblind society through his decisions to draft the NBA's first African-American player, Chuck Cooper, in 1950, hire the first African-American head coach in professional sports, Bill Russell, in 1966, and field the first starting lineup in the NBA consisting entirely of African-American players in 1964; and

Whereas the name Red Auerbach will forever be synonymous with winning, intensity, integrity, and charitable causes: Now, therefore, be it

Resolved, That it is the sense of the Senate that—

(1) Arnold "Red" Auerbach was a basketball genius who embodied the values of creativity, determination, versatility, and commitment to helping the less fortunate;

(2) Red Auerbach was a leader in the effort to remove racial barriers and allow merit to prevail in professional sports, through his decisions to draft, hire, and prominently feature African-Americans on the Boston Celtics basketball team; and

(3) Red Auerbach's place among the greatest coaches and executives of all time is assured, his contributions to the betterment of society will always endure, and his life exemplifies the very best ideals of the United States.

SENATE RESOLUTION 625—EXTENDING THE AUTHORITY FOR THE SENATE NATIONAL SECURITY WORKING GROUP

Mr. FRIST (for himself and Mr. REID) submitted the following resolution; which was considered and agreed to:

S. RES. 625

Resolved, That Senate Resolution 105 of the One Hundred First Congress, 1st session (agreed to on April 13, 1989), as amended by Senate Resolution 149 of the One Hundred Third Congress, 1st session (agreed to on October 5, 1993), as further amended by Senate Resolution 75 of the One Hundred Sixth Congress, 1st session (agreed to on March 25, 1999), as further amended by Senate Resolution 383 of the One Hundred Sixth Congress, 2d session (agreed to on October 27, 2000), as further amended by Senate Resolution 355 of the One Hundred Seventh Congress, 2d session (agreed to on November 13, 2002), and as further amended by Senate Resolution 480 of the One Hundred Eighth Congress, 2d session (agreed to November 20, 2004), is further amended in section 4 by striking "2006" and inserting "2008".

AMENDMENTS SUBMITTED & PROPOSED

SA 5212. Mr. ENSIGN (for Mr. ENZI (for himself and Mr. KENNEDY)) proposed an amendment to the bill H.R. 6143, to amend title XXVI of the Public Health Service Act to revise and extend the program for providing life-saving care for those with HIV AIDS.

SA 5213. Mr. FRIST (for Mr. INHOFE (for himself, Mr. CHAFEE, and Mr. JEFFORDS)) proposed an amendment to the bill H.R. 4588, to reauthorize grants for and require applied water supply research regarding the water resources research and technology institutes established under the Water Resources Research Act of 1984.

SA 5214. Mr. FRIST (for Mr. INHOFE (for himself, Mr. JEFFORDS, Mr. BOND, and Mr. BAUCUS)) proposed an amendment to the bill S. 2735, to amend the National Dam Safety Program Act to reauthorize the national dam safety program, and for other purposes.

SA 5215. Mr. FRIST proposed an amendment to the concurrent resolution H. Con. Res. 430, recognizing the accomplishments of the American Council of Young Political Leaders for providing 40 years of international exchange programs, increasing international dialogue, and enhancing global understanding, and commemorating its 40th anniversary.

SA 5216. Mr. FRIST (for Mr. AKAKA) proposed an amendment to the bill S. 1876, to provide that attorneys employed by the Department of Justice shall be eligible for compensatory time off for travel under section 5550b of title 5, United States Code.

SA 5217. Mr. FRIST (for Mr. SPECTER (for himself, Mr. LEAHY, Mr. REID, Mr. CORNYN, and Mr. DURBIN)) proposed an amendment to the bill H.R. 1751, to amend title 18, United States Code, to protect judges, prosecutors, witnesses, victims, and their family members, and for other purposes.

SA 5218. Mr. FRIST (for Mr. STEVENS) proposed an amendment to the bill S. 2653, to direct the Federal Communications Commission to make efforts to reduce telephone rates for Armed Forces personnel deployed overseas.

SA 5219. Mr. FRIST (for Mr. ENZI) proposed an amendment to the bill H.R. 864, to provide for programs and activities with respect to the prevention of underage drinking.

SA 5220. Mr. FRIST (for Mr. STEVENS) proposed an amendment to the bill H.R. 4075, to amend the Marine Mammal Protection Act of 1972 to provide for better understanding and protection of marine mammals, and for other purposes.

SA 5221. Mr. FRIST (for Mr. STEVENS) proposed an amendment to the bill H.R. 4075, supra.

SA 5222. Mr. WYDEN (for himself, Ms. CANTWELL, Mr. SMITH, and Mrs. MURRAY)

submitted an amendment intended to be proposed by him to the bill H.R. 4388, to amend the Internal Revenue Code of 1986 to extend certain expiring provisions, and for other purposes; which was ordered to lie on the table.

SA 5223. Mr. FRIST (for Ms. COLLINS) proposed an amendment to the bill S. 3821, to authorize certain athletes to be admitted temporarily into the United States to compete or perform in an athletic league, competition, or performance.

TEXT OF AMENDMENTS

SA 5212. Mr. ENSIGN (for Mr. ENZI (for himself and Mr. KENNEDY)) proposed an amendment to the bill H.R. 6143, to amend title XXVI of the Public Health Service Act to revise and extend the program for providing life-saving care for those with HIV AIDS; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Ryan White HIV/AIDS Treatment Modernization Act of 2006".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—EMERGENCY RELIEF FOR ELIGIBLE AREAS

Sec. 101. Establishment of program; general eligibility for grants.

Sec. 102. Type and distribution of grants; formula grants.

Sec. 103. Type and distribution of grants; supplemental grants.

Sec. 104. Timeframe for obligation and expenditure of grant funds.

Sec. 105. Use of amounts.

Sec. 106. Additional amendments to part A.

Sec. 107. New program in part A; transitional grants for certain areas ineligible under section 2601.

Sec. 108. Authorization of appropriations for part A.

TITLE II—CARE GRANTS

Sec. 201. General use of grants.

Sec. 202. AIDS Drug Assistance Program.

Sec. 203. Distribution of funds.

Sec. 204. Additional amendments to subpart I of part B.

Sec. 205. Supplemental grants on basis of demonstrated need.

Sec. 206. Emerging communities.

Sec. 207. Timeframe for obligation and expenditure of grant funds.

Sec. 208. Authorization of appropriations for subpart I of part B.

Sec. 209. Early diagnosis grant program.

Sec. 210. Certain partner notification programs; authorization of appropriations.

TITLE III—EARLY INTERVENTION SERVICES

Sec. 301. Establishment of program; core medical services.

Sec. 302. Eligible entities; preferences; planning and development grants.

Sec. 303. Authorization of appropriations.

Sec. 304. Confidentiality and informed consent.

Sec. 305. Provision of certain counseling services.

Sec. 306. General provisions.

TITLE IV—WOMEN, INFANTS, CHILDREN, AND YOUTH

Sec. 401. Women, infants, children, and youth.

Sec. 402. GAO Report.

TITLE V—GENERAL PROVISIONS

Sec. 501. General provisions.