

significant because it makes you a stronger person by realizing the significance of self control, discipline, and restricting ones desires.

The last pillar is making the pilgrimage to Makkah, Saudi Arabia. This pilgrimage is called Hajj. The holiest mosque is in Makkah, Masjid-al-Haram. Hajj occurs only once a year during the twelfth month of the Islamic calendar. It is required that you perform Hajj at least once in your lifetime if one can financially afford it.

The prophet of Islam is Muhammad (peace be upon him). He was born in Makkah, Saudi Arabia in 570 BCE. In 610 BCE, the angel Gabriel carried the revelation from God and brought it down to Muhammad (peace be upon him). After a period of time, these revelations were placed into one book called the Qur'an.

I hope this information, though very basic, would at least provoke some thought process towards efforts to better understand Islam.

I appreciate very much Sanaa sending me this letter. I hope everyone in the Senate will become familiar with her letter and become familiar with the tenets of her religion.

I have been on the floor before, speaking about Islam and what a great religion it is. I have said before and I repeat that my wife's primary physicians are two members of the Islamic faith, her internist and the person who has performed surgery on her. I know them well. I have been in their homes. I have socialized with them. I have talked about very serious things with them. We have helped each other with family problems.

I have been to the new mosque with them in Las Vegas. They are wonderful people with great families. I have come to realize Islam is a good religion; it is a good way of life. Muslims maintain a good health code as their religion dictates, and they have great spiritual values as their religion dictates. It is too bad there are some people—evil people around the world—who would target the innocent in the name of Islam.

I believe that the strength of Islam, and the faith and fortitude of more than one billion Muslims around the world, will overcome these evil people and their evil deeds.

(The remarks of Mr. REID pertaining to the introduction of S. 1566 are located in today's RECORD under "Statements on Introduced Bills and Joint Resolutions.")

Mr. REID. Madam President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. ALLEN. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### EMILY COURIC

Mr. ALLEN. Madam President, I rise this afternoon on a very sad note. We lost a State senator from Virginia, Emily Couric.

For those who knew Emily Couric, and for those who worked with Emily Couric and followed her life and her battles, we all know we have lost a fine person. We have lost an articulate, passionate, and inspirational leader.

Emily Couric passed away today, October 18. She had been a State senator in the 25th District of Virginia since after her election in 1995. That is an area around Charlottesville, Albemarle County, Greene County, Madison County, Orange County, and Nelson County—generally the Piedmont area of Virginia.

She passed away of pancreatic cancer today in her home in Charlottesville.

She served in the State senate while I served as the Governor of the Commonwealth of Virginia.

She was recognized by all on both sides of the aisle as a leader—especially in her areas of greatest concern, which were health care and education.

Before serving in the State senate, she served on the school board in the city of Charlottesville, and indeed before getting elected to the State senate was chairman of the school board.

She had many accomplishments, such as establishing advanced mathematics and technology diploma seals for those high school graduates. Picture that—encouraging students to do even more than what is just enough to get by. But if they wanted to do even more, they could add an advanced mathematics and technology aspect to their education.

She was also a leader in supporting research and rehabilitation for victims of spinal cord injuries and traumatic brain injuries.

She was a leader in the Democrat Party in Virginia. Had she not contracted pancreatic cancer, she would right now certainly be running for Lieutenant Governor on the Democrat ticket. She explored that race. But she was diagnosed with cancer back in July of last year—2000. She was certainly regarded as a frontrunner and would not have had any opposition whatsoever in her party. I would certainly guess that she would probably have won very easily. But she had to withdraw from the race because she had to undergo treatment for the pancreatic cancer.

Nevertheless, she didn't want to get out of what she cared about, which was serving the people. Indeed, she served as the general chair of the Democrat Party of Virginia, and undertook that responsibility in December of 2000.

She served on many committees in the State senate, such as the Education and Health Committee, the Agriculture, Conservation and Natural Resources Committee, and the Rehabilitation and Social Services Committee.

She served in a variety of areas, but she did not just serve Virginia, she served the region. She served not only in the legislature, but on the Southern Regional Education Board and the Southern Legislative Conference Education Committee, as well as other policy committees.

As I said, prior to her election, she did serve on the Charlottesville School Board from 1985 to 1991, including one term as chairman. She served on a lot of community boards and organizations. She was a member of the Charlottesville Boys & Girls Club, the Charlottesville Area School Business Alliance, the Jefferson Area Board for Aging, the Virginia National Bank, the Virginia Festival of the Book, the Heritage Repertory Theater, Camp Holiday Trails, and various other activities in the community. Until her last breath, you knew her passion was for all these ideas, but especially those that would benefit youngsters with their health, their education, and their future opportunities.

She was born in Atlanta, GA. She moved to Virginia in 1951. She was a graduate of Yorktown High School in Arlington, VA, right across the river from us.

She received her bachelor of arts from Smith College and graduated with honors, magna cum laude, Phi Beta Kappa, and Sigma Xi from Smith College.

Expressing for my colleague and myself, and I think all Senators and anybody who knew Emily Couric, our prayers and thoughts are with her husband, Dr. George Beller of Charlottesville, VA, her son Ray Wadlow—he is a doctor—and her daughter-in-law Jessica of Philadelphia, PA; and her son Jeff Wadlow of Los Angeles, CA.

She is also survived by her parents Elinor and John Couric of Arlington, VA; her siblings, Clara Couric Batchelor, John Couric, Jr., and, of course, one we know and see every morning, Katie Couric; her step children, Michael Beller, Amy Beller, and Leslie Beller; and also seven nieces and nephews; and two step-grandchildren.

We will all miss Emily Couric. Regardless of our political parties, Emily Couric was an inspiration. Her life really embodied her true dedication to her fellow human beings.

Once she was diagnosed with this terrible cancer, she kept fighting. She did not give up. She is an inspiration and her spirit lives on. All of us have been blessed to have known her; and, indeed, future generations will have healthier, better lives because Emily Couric cared enough to devote a great deal of her lifetime to public service and the betterment of others.

Mr. WARNER. Will the Senator yield for a moment?

Mr. ALLEN. I am pleased to yield.

The PRESIDING OFFICER. The senior Senator from Virginia.

Mr. WARNER. Madam President, I associate myself with my colleague's remarks. I say to Senator ALLEN, indeed, you knew her very well. I had come to know her in later years.

The Presiding Officer might be interested in this little story. I had a chance to be with her about 6 or 8 months ago, it seems to me, when she won an award in Northern Virginia and I was sort of the toastmaster of that evening. We

had a very friendly conversation—as we often do.

I talked to her about my father, who had likewise died from cancer. He was a medical doctor who devoted his life to others. We engaged briefly in a conversation.

I said: It took great courage for you not to seek the Lieutenant Governor's post.

She acknowledged that, and then, with a twinkle in her eye—she was a very attractive woman, by the way—she said: Yes. I thought about the Lieutenant Governor post because that was going to be a way stop to come and have a campaign against you, Senator WARNER.

And she could have waged a campaign against this old Senator that would give him a wakeup call, for sure.

Our State has lost one of its shining stars, but that is God's will, and we must accept it. I share with the Senator our prayers for her family and her friends.

Mr. ALLEN. Thank you, Madam President.

The PRESIDING OFFICER. The Senator from Connecticut.

Mr. DODD. Madam President, I add my voice to that of the two Senators from Virginia. I did not know Emily Couric, but having listened to the distinguished junior Senator from Virginia speak about her, and the senior Senator, not only did Virginia lose someone of great value but the country did as well. I am sure her family and friends appreciate immensely the words spoken in this Chamber this afternoon. I am sure all of us would like to associate ourselves with them. We express our sympathies to them.

#### BEST PHARMACEUTICALS FOR CHILDREN ACT

Mr. DODD. Madam President, I ask unanimous consent that the Senate now proceed to the consideration of Calendar No. 184, S. 838; that the only amendment in order other than the committee-reported substitute be a Dodd-DeWine amendment; that the amendment be agreed to, the committee substitute, as amended, be agreed to, the bill, as amended, be read three times, passed, and the motion to reconsider be laid upon the table, with the above occurring with no intervening action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senate proceeded to consider the bill (S. 838) to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children, which had been reported from the Committee on Health, Education, Labor, and Pensions, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

#### SECTION 1. SHORT TITLE.

*This Act may be cited as the "Best Pharmaceuticals for Children Act".*

#### SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED DRUGS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) by striking subsection (b); and

(2) in subsection (c)—

(A) by inserting after "the Secretary" the following: "determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population"; and

(B) by striking "concerning a drug identified in the list described in subsection (b)".

#### SEC. 3. RESEARCH FUND FOR THE STUDY OF DRUGS LACKING EXCLUSIVITY.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended—

(1) by redesignating the second section 409C, relating to clinical research (42 U.S.C. 284k), as section 409G;

(2) by redesignating the second section 409D, relating to enhancement awards (42 U.S.C. 284l), as section 409H; and

(3) by adding at the end the following:

#### "SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS LACKING EXCLUSIVITY.

"(a) LIST OF DRUGS LACKING EXCLUSIVITY FOR WHICH PEDIATRIC STUDIES ARE NEEDED.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop, prioritize, and publish an annual list of approved drugs for which—

"(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); or

"(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); or

"(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

"(B) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

"(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

"(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

"(B) whether additional information is needed;

"(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and

"(D) whether reformulation of the drug is necessary;

"(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

"(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

"(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—

"(A) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Director of National Institutes of Health, may issue a written request (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list described in subsection (a) to all holders of an approved application for the drug under section

505 of the Federal Food, Drug, and Cosmetic Act. Such a request shall be made in accordance with section 505A of the Federal Food, Drug, and Cosmetic Act.

"(B) PUBLICATION OF REQUEST.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under subparagraph (A) within 30 days of the date on which a request was issued, the Secretary, acting through the Director of National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

"(C) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under subparagraph (B).

"(D) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the submission of responses to written requests under subparagraph (A).

"(2) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

"(3) REPORTING OF STUDIES.—

"(A) Upon completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

"(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain, and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

"(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (4).

"(4) REQUEST FOR LABELING CHANGES.—During the 180-day period after the date on which a report is submitted under paragraph (3)(A), the Commissioner of Food and Drugs shall—

"(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied; and

"(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

"(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

"(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.

"(5) DISPUTE RESOLUTION.—If, not later than the end of the 180-day period specified in paragraph (4), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph—

"(A) the Commissioner of Food and Drugs shall immediately refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee; and

"(B) not later than 90 days after receiving the referral, the Subcommittee shall—

"(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and