

think there is a lot of strong bipartisan interest and support for this—is the whole question of this humanitarian crisis in Afghanistan.

The reports are there are about 7.5 million people who go hungry. We do not know how many hundreds of thousands could starve to death this winter if we do not get food to people.

The problem is, though there has been a lot of discussion about the airdrops, maybe a half of 1 percent, maybe 1 percent at best, doesn't do the job. The only way we can get the food to people is through the truck convoys, and now not nearly enough of this is happening.

Different organizations, the NGOs, the nongovernment organizations, food relief organizations, are all saying on present course they may be able to get enough food for half the people who need it at best. In 3 or 4 weeks there will be cold winter weather, and we will see pictures of innocent, starving Afghan children. That is a fact.

The resolution calls upon our Government to take stronger measures, with a more focused effort to get the food to people. That will be complicated. Part of it involves people who will still be trying to leave Afghanistan. Some of the neighboring countries have to open up their borders. Those people have been stopped at the borders. Then there are the people who don't leave. And the conditions in the refugee camps have to be dramatically improved.

The fact is, the people who don't leave are the poorest of the poor. They are the elderly, the infirmed; they are the children. They are the ones about whom we all worry. There have been intermittent reports—quite often when you try to confirm it, it is not clear what happened—that the Taliban itself has taken some of the food. Many organizations are saying with the bombing the truck convoys can't go through.

I am not making an argument for cessation of bombing. I argue it be as targeted as possible and to avoid in every way possible bombing innocent people. There has to be a way, whether it is the creation of safe corridors, coordinated with military activity or whatever to get these truck convoys in to get the food to people. Time is not neutral. We are going to deeply regret if we don't take these steps.

The resolution expresses the sense of the Senate regarding the urgent need to provide humanitarian assistance to the civilians of Afghanistan. Well before the terrorist attack of September 11, this was the site of great hunger and displacement in the world.

Whereas, after more than 20 years of conflict, 3 years of severe drought and the repressive policies of the Taliban regime, 4 million Afghans have sought refuge in neighboring countries, and Afghan women have one of the highest maternal mortality rates in the world,

and one in four children dies before the child's fifth birthday; whereas the United Nations High Commissioner for Refugees estimates that 1,500,000 additional Afghans could seek to flee the country in the coming months due to the military conflict; whereas all six countries neighboring Afghanistan have closed their borders to refugees both on security grounds and are also saying they can't provide for the refugees economically; whereas 7,500,000 people inside Afghanistan face critical food shortages or risk starvation by winter's end and are partially or fully dependent on outside assistance for survival, and of these people 70 percent are women and children; whereas the United Nations World Food Program, which we commonly call the WFP, which distributes most of the food within Afghanistan, estimates that food stocks in the country are critically short and WFP overland food shipments inside and outside the border of Afghanistan have been disrupted due to security concerns over United States military strikes; whereas the airdrops of food cannot meet the humanitarian needs of the Afghan people—and there is more to it, but I do not have the time—and that the most effective delivery is the overland convoys of food; whereas the President has announced a \$320 million initiative to respond to the humanitarian needs in Afghanistan and for Afghan refugees in neighboring countries; whereas the United States is the largest donor of humanitarian assistance, be it resolved—and this is what I am hoping to get a strong vote on—it is the sense of the Senate that, A, Afghanistan's neighbors should reopen their borders to allow for safe passage of refugees, and the international community must be prepared to contribute to the economic costs incurred by the flight of desperate Afghan civilians; B, as the United States engages in military action in Afghanistan, it must work to deliver assistance particularly through overland truck convoys and safe humanitarian access to affected populations in partnership with humanitarian agencies—that is critical—and C, the United States should contribute to efforts by the international community to provide long-term sustainable reconstruction and development assistance for the people of Afghanistan, including efforts to protect the basic human rights of women and children.

I announce this resolution today, which will be in the form of an amendment on the first vehicle for a vote, because it is critically important for the Senate to go on record with an intense and focused effort because it is who we are. It is our values to make sure these truck convoys can go forward and we can get the food to people.

A, it is who we are as a nation. It is about the values we live by and, frankly, B, it is national interest. If you

have juxtaposed with military actions pictures of starving Afghan children in the winter to come, that will be used against us. We know it will be used against us. We do not want to see that happen.

I am hoping there will be a strong message from the Senate to work with the administration, to work with the NGOs, to work with the food relief organizations. We have to put a focus on this.

SENATE RESOLUTION 173—CONDEMNING VIOLENCE AND DISCRIMINATION AGAINST IRANIAN-AMERICANS IN THE WAKE OF THE SEPTEMBER 11, 2001 TERRORIST ATTACKS

Mr. HATCH submitted the following resolution; which was considered and agreed to:

S. RES. 173

Whereas all Americans are united in condemning, in the strongest possible terms, the terrorists who planned and carried out the attacks against the United States on September 11, 2001, and in pursuing all those responsible for those attacks and their sponsors until they are brought to justice;

Whereas Iranian-Americans form a vibrant, peaceful, and law-abiding part of America's people;

Whereas Iranian-Americans stand resolutely in support of the commitment of our Government to bring the terrorists and those that harbor them to justice;

Whereas Iranian-Americans, as do all Americans, condemn acts of violence and prejudice against any American; and

Whereas the Senate is seriously concerned by the number of crimes against Americans of Middle Eastern descent, including Iranian-Americans, all across the Nation that have been reported in the wake of the tragic events that unfolded on September 11, 2001: Now, therefore, be it

Resolved, That the Senate—

(1) declares that, in the quest to identify, locate, and bring to justice the perpetrators and sponsors of the terrorist attacks on the United States on September 11, 2001, the civil rights and civil liberties of all Americans, including Iranian-Americans, should be protected;

(2) condemns bigotry and any acts of violence or discrimination against any Americans, including Iranian-Americans;

(3) calls upon local and Federal law enforcement authorities to work to prevent and prosecute crimes against all Americans, including Iranian-Americans.

AMENDMENTS SUBMITTED AND PROPOSED

SA 1905. Mr. DODD (for himself and Mr. DEWINE) proposed an amendment to the bill S. 838, to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

SA 1906. Mr. HATCH submitted an amendment intended to be proposed by him to the bill S. 838, supra; which was ordered to lie on the table.

SA 1907. Mr. REID (for Mr. DURBIN) proposed an amendment to the concurrent resolution S. Con. Res. 74, condemning bigotry and violence against Sikh-Americans in the

wake of terrorist attacks in New York City and Washington, D.C. on September 11, 2001.

SA 1908. Mr. REID (for Mr. DURBIN) proposed an amendment to the concurrent resolution S. Con. Res. 74, supra.

TEXT OF AMENDMENTS

SA 1905. Mr. DODD (for himself and Mr. DEWINE) proposed an amendment to the bill S. 838, to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children; as follows:

Strike all after the enacting clause and insert 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"; 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.

"(a) LIST OF DRUGS 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));

"(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));

"(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.); or

"(iv) there is a referral for inclusion on the list under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)); and

"(B) in the case of a drug referred to in clause (i), (ii), or (iii) of subparagraph (A), 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 and prioritizing 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.—The Commissioner of Food and Drugs, in consultation with the Director of the 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)(1)(A) (except clause (iv)) 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.

"(2) REQUESTS FOR CONTRACT PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (1) within 30 days of the date on which a request was issued, or if a referral described in subsection (a)(1)(A)(iv) is made, the Secretary, acting through the Director of the 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.

"(3) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under paragraph (2).

"(4) 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 paragraph (1).

"(5) 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.

"(6) REPORTING OF STUDIES.—

"(A) IN GENERAL.—On 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 the 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 (subject to section 505A(d)(4)(D)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(D)) 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 (7).

"(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(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;

"(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.

"(8) DISPUTE RESOLUTION.—

"(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), 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, the Commissioner of Food and Drugs may refer the request to the Pediatric Advisory Committee.

"(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee 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

"(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

"(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

"(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

"(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under section 502 when a drug lacks appropriate pediatric labeling.

"(12) RECOMMENDATION FOR FORMULATION CHANGES.—If a pediatric study completed under public contract indicates that a formulation change is necessary and the Secretary agrees, the Secretary shall send a nonbinding letter of recommendation regarding that change to each holder of an approved application.

"(d) AUTHORIZATION OF APPROPRIATIONS.—