

like arthritis, rheumatism, but it attacks every system of the body.

I urge all of my colleagues, Mr. Speaker, to join with me in cosponsoring H.R. 1111.

COMMENTS BY VICE PRESIDENT GORE REGARDING SOLUTION FOR GLOBAL WARMING

(Mr. PITTS asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. PITTS. Mr. Speaker, I rise to express outrage at the recent comments made by Vice President AL GORE to the effect that abortion is the solution for global warming.

I would like to enter into the RECORD a letter many of us in Congress will be sending him today. Let me read a portion of it.

Mr. Gore, as the father of four children, surely you see the value of your own children to our society. Since we are sure you do not regard your own children as a threat to our environment, it is difficult to understand why you would regard a large African, Asian, or Latin American family as an environmental threat.

Your statements contain a crucial fallacy of logic; namely, that human life is incompatible with sound environmental policy. We believe it is practically and morally essential that these two goals be pursued together. A pristine environment will be of no use to the millions of children who would be sacrificed to the policies you endorse.

You accused those who oppose abortion as part of U.S.-funded population control programs of creating controversy needlessly. Let us be clear; it is not our reaffirmation of human dignity that ought to be controversial but, rather, the violence and degradation inflicted upon women and children through these programs.

Mr. Speaker, I urge the Members of the House to seek environmental health for our world without endangering the lives of defenseless children.

The letter referred to follows:

Hon. ALBERT GORE,
The White House,
Washington, DC.

DEAR VICE PRESIDENT GORE: We write to express our concern over the comments you made to TV weather forecasters on climate control at the White House on October 1, 1997. Your conviction that abortion programs in developing countries are crucial to saving the environment is directly at odds with the American commitment to protecting human life.

Mr. Gore, as the father of four children, surely you see the value of your own children to our society. Since we are sure you do not regard your own children as a threat to our environment, it is difficult to understand why you would regard a large African, Asian, or Latin American family as an environmental threat.

Your statements contain a crucial fallacy of logic, namely that human life is incompatible with sound environmental policy. We believe it is practically and morally essential that these two goals be pursued together. A pristine environment will be of no use to the millions of children who would be sacrificed to the policies you endorse.

You accused those who oppose abortion as part of U.S.-funded population control programs of creating "controversy" needlessly.

Let us be clear: it is not our reaffirmation of human dignity that ought to be controversial, but rather the violence and degradation inflicted upon women and children through these programs.

Mr. Vice President, we urge you to seek environmental health for our world without endangering the lives of defenseless children. I hope that you and others in the Administration will bear in mind that when it comes to solving the problems of our planet, human beings are our first natural resource.

MILITARY CONSTRUCTION CUT AT DYESS AFB, TEXAS

(Mr. STENHOLM asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. STENHOLM. Mr. Speaker, yesterday the President used his new-found line item veto authority to cut a number of congressionally and Defense Department approved military construction projects at military installations around the United States.

Among those projects eliminated was a squadron operations facility at Dyess Air Force Base in Abilene, TX. With one stroke of his pen, he has eliminated the means of building a facility needed to serve the 500 to 1,000 men and women who will make up the 13th Bomber Squadron in the year 2000.

One of the reasons given for vetoing this project is that it did not meet the so-called quality of life requirement for funding military construction projects. I do not know what the President's definition of quality of life is, but I do know that there are currently no existing facilities to house the 13th Bomber Squadron.

Without this facility, the 500 to 1,000 men and women of the 13th Bomber Squadron will be denied the tools they need to do their job. How will this add to their quality of life or their ability to discharge their duties?

This is a programmed project. The appropriate committees of the House and Senate saw the value of this project and funded it for the good of the Air Force and our national security.

Mr. President, you were wrong to veto this project.

ERRONEOUS INFORMATION CAUSES BAD DECISIONS

(Mr. SKEEN asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. SKEEN. Mr. Speaker, imagine working where buildings do not meet current safety regulations, the heating and cooling systems do not work, the septic tanks are failing, facilities are crumbling, adequate fire detection and suppression systems do not exist, and in one instance a building is a breeding ground for the hantavirus due to rat infestation.

What am I describing? The White House? No. It is difficult to imagine, but these working conditions do exist

for approximately 200 men and women who work at the military launch complexes in southern New Mexico. These are people who are protecting our national interest by testing vital national defense systems, such as the Patriot Missile, one of the most widely recognized and successful systems.

Yesterday, by saying "no" to improving working conditions, when the President vetoed portions of the military construction legislation, he said "no" to the women and men by denying them the opportunity to perform their duties in the safest facilities possible.

I am introducing legislation today that will restore funding for this and other meritorious projects. The President's decision was misguided. This is not about deficit reduction. This is about the President taking the "Washington knows best" approach and ignoring the judgment of individuals who are closest to the problems.

AL GORE'S STATEMENTS MADE AT WEATHER FORECASTERS' MEETING

(Mr. SHIMKUS asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. SHIMKUS. Mr. Speaker, I too rise today to take exception to the statements made by Vice President AL GORE last Wednesday in a meeting of the weather forecasters.

In this speech, Vice President GORE claimed that overpopulation was a major cause of worldwide environmental problems and global warming. But what was indefensible were the solutions which he offered for the still disputed problem of global warming.

The Vice President praised President Clinton for the repeal of the Mexico City policy, which permitted hundreds of millions of tax dollars to flow to organizations which perform or actively promote abortion as a method of family planning in Third World countries.

According to the Washington Times, Mr. GORE also stated that industrialized nations have stabilized their populations through birth control, abortion, and a reduction in child mortality rates but that world population would grow if developing nations are not targeted now.

Has the Vice President's environmental extremism gone so far that he now advocates the worldwide killing of innocent babies as the solution to the still unproven problem of global warming?

TODAY IS GREAT DAY FOR CONGRESS

(Mr. BARTON of Texas asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. BARTON of Texas. Mr. Speaker, today is a great day for the Congress. It shows that the system does work.

There are going to be two bills on the suspension calendar that I worked on very hard for the last several years.

The first bill is a comprehensive FDA reform bill to reform the Food and Drug Administration. It is the culmination of a series of 3 years of work on a bipartisan basis to bring the American people the safest food and the most technologically advanced drugs and medical devices in the world.

The second bill is the suspension bill that will ratify low-level nuclear waste compact between my State, Texas, and the great States of Maine and Vermont. Again, this bill is a culmination of 5 years of work between those States' Governors and State delegations on a bipartisan basis.

So we are going to have two bills on the floor today, both good public policy, and I would encourage all of my colleagues to vote for them.

FOOD AND DRUG ADMINISTRATION REGULATORY MODERNIZATION ACT OF 1997

Mr. BLILEY. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1411) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes, as amended.

The Clerk read as follows:

H.R. 1411

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

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Food and Drug Administration Regulatory Modernization Act of 1997".

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

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

Sec. 1. Short title; references; table of contents.

TITLE I—IMPROVING REGULATION OF DRUGS

- Sec. 101. Fees relating to drugs.
- Sec. 102. Pediatric studies of drugs.
- Sec. 103. Expediting study and approval of fast track drugs.
- Sec. 104. Expanded access to investigational therapies.
- Sec. 105. Information program on clinical trials for serious or life-threatening diseases.
- Sec. 106. Dissemination of information on new uses.
- Sec. 107. Studies and reports.
- Sec. 108. Approval of supplemental applications for approved products.
- Sec. 109. Health care economic information.
- Sec. 110. Clinical investigations.
- Sec. 111. Manufacturing changes for drugs.
- Sec. 112. Streamlining clinical research on drugs.
- Sec. 113. Data requirements for drugs.
- Sec. 114. Content and review of applications.

- Sec. 115. Scientific advisory panels.
- Sec. 116. Dispute resolution.
- Sec. 117. Informal agency statements.
- Sec. 118. Positron emission tomography.
- Sec. 119. Requirements for radiopharmaceuticals.
- Sec. 120. Modernization of regulation.
- Sec. 121. Pilot and small scale manufacture.
- Sec. 122. Insulin and antibiotics.
- Sec. 123. FDA mission and annual report.
- Sec. 124. Information system.
- Sec. 125. Education and training.
- Sec. 126. Centers for education and research on drugs.
- Sec. 127. Harmonization.
- Sec. 128. Environmental impact review.
- Sec. 129. National uniformity.
- Sec. 130. FDA study of mercury compounds in drugs and food.
- Sec. 131. Notification of discontinuance of a life saving product.

TITLE II—IMPROVING REGULATION OF DEVICES

- Sec. 201. Dispute resolution.
- Sec. 202. Investigational device exemptions; expanded access.
- Sec. 203. Special review for certain devices.
- Sec. 204. Expanding humanitarian use of devices.
- Sec. 205. Device standards.
- Sec. 206. Scope of review.
- Sec. 207. Premarket notification.
- Sec. 208. Classification panels.
- Sec. 209. Premarket approval.
- Sec. 210. Accreditation for accredited persons.
- Sec. 211. Preamendment devices.
- Sec. 212. Device tracking.
- Sec. 213. Postmarket surveillance.
- Sec. 214. Harmonization.
- Sec. 215. Reports.
- Sec. 216. Practice of medicine.
- Sec. 217. Clarification of definition.
- Sec. 218. Labeling and advertising regarding compliance with statutory requirements.
- Sec. 219. FDA mission and annual report.
- Sec. 220. Information system.
- Sec. 221. Noninvasive blood glucose meter.
- Sec. 222. Rule of construction.

TITLE III—IMPROVING REGULATION OF FOOD

- Sec. 301. Flexibility for regulations regarding claims.
- Sec. 302. Petitions for claims.
- Sec. 303. Health claims for food products.
- Sec. 304. Nutrient content claims.
- Sec. 305. Referral statements.
- Sec. 306. Disclosure of irradiation.
- Sec. 307. Irradiation petition.
- Sec. 308. Glass and ceramic ware.
- Sec. 309. Food contact substances.
- Sec. 310. Margarine.
- Sec. 311. Effective date.

TITLE I—IMPROVING REGULATION OF DRUGS

SEC. 101. FEES RELATING TO DRUGS.

- (a) FINDINGS.—Congress finds that—
- (1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;
 - (2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;
 - (3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—
- (A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in the letters of _____, and _____, from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth at ____ Cong. Rec. _____ (daily ed. _____, 1997).

(b) DEFINITIONS.—Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

(A) by striking "Service Act, and" and inserting "Service Act,;" and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.;"

(2) in the second sentence of paragraph (3)—

(A) by striking "Service Act, and" and inserting "Service Act,;" and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.;"

(3) in paragraph (4), by striking "without" and inserting "without substantial";

(4) by amending the first sentence of paragraph (5) to read as follows:

"(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other and at which one or more prescription drug products are manufactured in final dosage form."

(5) in paragraph (7)(A)—

(A) by striking "employees under contract" and all that follows through "Administration," the second time it occurs and inserting "contractors of the Food and Drug Administration,;" and

(B) by striking "and committees," and inserting "and committees and to contracts with such contractors,;"

(6) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking "August of" and inserting "April of"; and

(ii) by striking "August 1992" and inserting "April 1997";

(B) in subparagraph (B), by striking "1992" and inserting "1997"; and

(C) by striking the second sentence; and

(7) by adding at the end the following:

"(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—