Mrs. CLINTON, Mr. COBURN, Mr. COCHRAN, Mr. COLEMAN, Ms. COLLINS, Mr. CONRAD, Mr. CORNYN, Mr. CORZINE, Mr. CRAIG, Mr. CRAPO, Mr. DAYTON, Mr. DEMINT, Mr. DEWINE, Mr. DODD, Mrs. DOLE, Mr. DOMENICI, Mr. DORGAN, Mr. DURBIN, Mr. ENSIGN, Mr. ENZI, Mr. FEINGOLD, Mrs. FEINSTEIN, Mr. GRAHAM, Mr. GRASSLEY, Mr. GREGG, Mr. HAGEL, Mr. HARKIN, Mr. HATCH, Mrs. HUTCHISON, Mr. INHOFE, Mr. ISAKSON, Mr. JEFFORDS, Mr. JOHNSON, Mr. KENNEDY, Mr. KERRY, Mr. KOHL, Mr. KYL, Ms. LANDRIEU, Mr. LAUTENBERG, Mr. LEAHY, Mr. LEVIN, Mr. LIEBERMAN, Mrs. LINCOLN, Mr. LOTT, Mr. LUGAR, Mr. MARTINEZ, Mr. MCCAIN, Mr. MCCONNELL, Ms. MIKULSKI, Ms. MURKOWSKI, Mrs. MURRAY, Mr. NELSON of Florida, Mr. NELSON of Nebraska, Mr. OBAMA, Mr. PRYOR, Mr. REED, Mr. ROBERTS, Mr. ROCKEFELLER, Mr. SALAZAR, Mr. SANTORUM, Mr. SARBANES, Mr. SCHUMER, Mr. SESSIONS, Mr. SHELBY, Mr. SMITH, Ms. SNOWE, Mr. SPECTER, Ms. STABENOW, Mr. STEVENS, Mr. SUNUNU, Mr. TALENT, Mr. THOMAS, Mr. THUNE, Mr. VITTER, Mr. VOINOVICH, Mr. WARNER, and Mr. WYDEN):

S. Res. 300. A resolution relative to the death of Henry Ku'ualoha Giugni, former Sergeant-at-Arms of the United States Senate; considered and agreed to.

ADDITIONAL COSPONSORS

S. 331

At the request of Mr. JOHNSON, the name of the Senator from South Dakota (Mr. THUNE) was added as a cosponsor of S. 331, a bill to amend title 38, United States Code, to provide for an assured adequate level of funding for veterans health care.

S. 333

At the request of Mr. SANTORUM, the name of the Senator from California (Mrs. BOXER) was added as a cosponsor of S. 333, a bill to hold the current regime in Iran accountable for its threatening behavior and to support a transition to democracy in Iran.

S. 1496

At the request of Mr. CRAPO, the name of the Senator from Minnesota (Mr. COLEMAN) was added as a cosponsor of S. 1496, a bill to direct the Secretary of the Interior to conduct a pilot program under which up to 15 States may issue electronic Federal migratory bird hunting stamps.

S. 1516

At the request of Mr. LOTT, the names of the Senator from Pennsylvania (Mr. SPECTER), the Senator from Pennsylvania (Mr. SANTORUM), the Senator from Rhode Island (Mr. CHAFEE), the Senator from Arkansas (Mr. PRYOR), the Senator from Delaware (Mr. BIDEN) and the Senator from New York (Mr. SCHUMER) were added as cosponsors of S. 1516, a bill to reauthorize Amtrak, and for other purposes.

S. 1699

At the request of Mr. SPECTER, the names of the Senator from Oklahoma (Mr. COBURN) and the Senator from California (Mrs. FEINSTEIN) were added as cosponsors of S. 1699, a bill to amend title 18, United States Code, to provide criminal penalties for trafficking in counterfeit marks.

S. 1767

At the request of Ms. SNOWE, the name of the Senator from North Dakota (Mr. DORGAN) was added as a cosponsor of S. 1767, a bill to require the Federal Communications Commission to reevaluate the band plans for the upper 700 megaHertz band and the unauctioned portions of the lower 700 megaHertz band and reconfigure them to include spectrum to be licensed for small geographic areas.

S. 1791

At the request of Mr. SMITH, the name of the Senator from Idaho (Mr. CRAPO) was added as a cosponsor of S. 1791, a bill to amend the Internal Revenue Code of 1986 to allow a deduction for qualified timber gains.

S. 1848

At the request of Mr. SALAZAR, the name of the Senator from Nevada (Mr. REID) was added as a cosponsor of S. 1848, a bill to promote remediation of inactive and abandoned mines, and for other purposes.

S. 1947

At the request of Mr. SUNUNU, the name of the Senator from Georgia (Mr. ISAKSON) was added as a cosponsor of S. 1947, a bill to amend chapter 21 of title 38, United States Code, to enhance adaptive housing assistance for disabled veterans.

S. RES. 219

At the request of Mrs. FEINSTEIN, the name of the Senator from Massachusetts (Mr. KERRY) was added as a cosponsor of S. Res. 219, a resolution designating March 8, 2006, as ''Endangered Species Day,'' and encouraging the people of the United States to become educated about, and aware of, threats to species, success stories in species recovery, and the opportunity to promote species conservation worldwide.

AMENDMENT NO. 762

At the request of Mr. NELSON of Florida, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of amendment No. 762 proposed to S. 1042, an original bill to authorize appropriations for fiscal year 2006 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe personnel strengths for such fiscal year for the Armed Forces, and for other purposes.

AMENDMENT NO. 2346

At the request of Mr. INOUYE, the name of the Senator from Hawaii (Mr. AKAKA) was added as a cosponsor of amendment No. 2346 intended to be proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2350

At the request of Mrs. MURRAY, the name of the Senator from New York (Mrs. CLINTON) was added as a cosponsor of amendment No. 2350 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2353

At the request of Mrs. MURRAY, the name of the Senator from Illinois (Mr. OBAMA) was added as a cosponsor of amendment No. 2353 intended to be proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2356

At the request of Mrs. LINCOLN, the names of the Senator from Wisconsin (Mr. KOHL), the Senator from New Jersey (Mr. CORZINE) and the Senator from New York (Mrs. CLINTON) were added as cosponsors of amendment No. 2356 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2357

At the request of Mr. NELSON of Florida, the names of the Senator from Illinois (Mr. OBAMA) and the Senator from Wisconsin (Mr. FEINGOLD) were added as cosponsors of amendment No. 2357 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2360

At the request of Mr. LOTT, the names of the Senator from Pennsylvania (Mr. SANTORUM), the Senator from Massachusetts (Mr. KENNEDY), the Senator from Vermont (Mr. JEFFORDS), the Senator from Illinois (Mr. DURBIN) and the Senator from North Dakota (Mr. DORGAN) were added as cosponsors of amendment No. 2360 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2363

At the request of Mr. HARKIN, the name of the Senator from New York (Mrs. CLINTON) was added as a cosponsor of amendment No. 2363 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2371

At the request of Ms. SNOWE, the names of the Senator from New York (Mrs. CLINTON), the Senator from Massachusetts (Mr. KERRY) and the Senator from Connecticut (Mr. DODD) were added as cosponsors of amendment No. 2371 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2372

At the request of Mrs. MURRAY, the name of the Senator from New Jersey (Mr. CORZINE) was added as a cosponsor of amendment No. 2372 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2373

At the request of Mr. REED, the name of the Senator from Minnesota (Mr. DAYTON) was added as a cosponsor of amendment No. 2373 intended to be proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

At the request of Mr. CARPER, his name was added as a cosponsor of amendment No. 2373 intended to be proposed to S. 1932, supra.

AMENDMENT NO. 2380

At the request of Mr. LIEBERMAN, the name of the Senator from Illinois (Mr. OBAMA) was added as a cosponsor of amendment No. 2380 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

AMENDMENT NO. 2390

At the request of Mr. SMITH, the name of the Senator from Wisconsin (Mr. FEINGOLD) was added as a cosponsor of amendment No. 2390 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

At the request of Mr. KERRY, his name was added as a cosponsor of amendment No. 2390 proposed to S. 1932, supra.

AMENDMENT NO. 2400

At the request of Ms. CANTWELL, the name of the Senator from Minnesota (Mr. DAYTON) was added as a cosponsor of amendment No. 2400 proposed to S. 1932, an original bill to provide for reconciliation pursuant to section 202(a) of the concurrent resolution on the budget for fiscal year 2006 (H. Con. Res. 95).

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. BROWNBACK (for himself and Mr. INHOFE):

S. 1956. A bill to amend the Federal Food, Drug, and Cosmetic Act to create a new three-tiered approval system for drugs, biological products, and devices that is responsive to the needs of seriously ill patients, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. BROWNBACK. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1956

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 ''Access, Compassion, Care, and Ethics for Seriously Ill Patients Act'' or the ''ACCESS Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The necessity of placebo controlled studies has been questioned on both scientific and ethical grounds for seriously ill patients.

(2) The current standards of the Food and Drug Administration for approval of drugs, biological products, and devices deny the benefits of medical progress to seriously ill patients who face morbidity or death from their disease.

(3) Promising therapies intended to treat serious or life threatening conditions or diseases and which address unmet medical needs have received unjustified delays and denials of approval.

(4) Seriously ill patients have a right to access available investigational drugs, biological products, and devices.

(5) The current Food and Drug Administration and National Cancer Institute case-by-case exception for compassionate access must be required to permit all seriously ill patients access to available experimental therapies as a treatment option.

(6) The current emphasis on statistical analysis of clinical information needs to be balanced by a greater reliance on clinical evaluation of this information.

(7) Food and Drug Administration advisory committees should have greater representation of medical clinicians who represent the interests of seriously ill patients in early access to promising investigational therapies.

(8) The use of available investigational products for treatment is the responsibility of the physician and the patient.

(9) The use of combinations of available investigational and approved products for treatment is the responsibility of the physician and the patient.

(10) The development and approval of drugs, biological products, and devices intended to address serious or life-threatening conditions or diseases is often delayed by the inability of sponsors to obtain prompt meetings with the Food and Drug Administration and to obtain prompt resolution of scientific and regulatory issues related to the investigation and review of new technologies.

SEC. 3. TIERED APPROVAL SYSTEM FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended to read as follows:

''SEC. 506. TIERED APPROVAL SYSTEM.

''(a) IN GENERAL.—Notwithstanding any other provision of law, the sponsor of an investigational drug, biological product, or device may submit an application to the Secretary for Tier I or Tier II approval in accordance with this section.

''(b) TIER I APPROVAL.—

''(1) IN GENERAL.—

''(A) APPLICATION CONTENT.—A sponsor of an investigational drug, biological product, or device applying for Tier I approval of the product shall submit to the Secretary an application as described under section 505(b)(1) or 505(b)(2), section 351(a) of the Public Health Service Act, or section 510(k) or 515(c)(1), as applicable, which shall contain—

''(i) data and information from completed Phase I clinical investigations and any other nonclinical or clinical investigations;

''(ii) preliminary evidence that the product may be effective against a serious or life-threatening condition or disease, which evidence may be based on uncontrolled data such as case histories, information about the pharmacological mechanism of action, data from animal and computer models, comparison with historical data, or other preliminary information, and may be based on a small number of patients; and

''(iii) an assurance that the sponsor will continue clinical investigation to obtain Tier III approval.

''(B) LIMITATION.—Tier I approval shall be primarily based upon clinical evaluation, not statistical analysis.

''(2) DETERMINATION BY SECRETARY.—

''(A) IN GENERAL.—Not later than 30 days after the receipt of an application for Tier I approval, the Secretary shall either—

''(i) approve the application; or

''(ii) refer the application to the Accelerated Approval Advisory Committee.

''(B) RECOMMENDATION.—Within 90 days after receipt of an application for approval, the Accelerated Approval Advisory Committee shall issue a recommendation to the Secretary on whether the Secretary should approve the application.

''(C) FINAL DECISION.—Within 30 days after receipt of the recommendation from the Accelerated Approval Advisory Committee, the Secretary shall either approve the application or shall issue an order setting forth a detailed explanation of the reasons why the application was not approved and the specific data that the sponsor must provide so that the application may be approved.

''(3) APPEAL.—If the Secretary does not approve an application for which the Accelerated Approval Advisory Committee recommended approval, the sponsor of the application shall have the right to appeal the decision to the Commissioner of Food and Drugs. The Commissioner shall provide the sponsor with a hearing within 30 days following the nonapproval of the application and shall issue an order within 30 days following the hearing either concurring in the nonapproval or approving the application. The Commissioner shall not delegate the responsibility described in this paragraph to any other person.

''(4) CRITERIA.—In making a determination under paragraph (2), the Secretary shall consider whether the totality of the information available to the Secretary regarding the safety and effectiveness of an investigational drug, biological product, or device, as compared to the risk of morbidity or death from a condition or disease, indicates that a patient (who may be representative of a small patient subpopulation) may obtain more benefit than risk if treated with the drug, biological product, or device. If the potential risk to a patient of the condition or disease outweighs the potential risk of the product, and the product may possibly provide benefit to the patient, the Secretary shall approve the application.

''(5) PRODUCT LABELING.—The labeling approved by the Secretary for the drug, biological product, or device—

''(A) shall state that the product is intended for use by a patient whose physician has documented in writing that the patient has—

''(i) exhausted all treatment options approved by Secretary for the condition or disease for which the patient is a reasonable candidate; and

''(ii) unsuccessfully sought treatment, or obtained treatment that was not effective, with an investigational drug, biological product, or device for which such individual is a reasonable candidate (which may include consideration of the lack of a source of supply or geographic factors); and

''(B) shall state that every patient to whom the product is administered shall, as a