

MEASURES INDEFINITELY POSTPONED—S. 2828, S. 2840, S. 2918, S. 2929, S. 2931

Mr. REID. Mr. President, I ask unanimous consent that the following calendar items be indefinitely postponed: Calendar Nos. 711, 712, 713, 714, and 715.

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

Mr. REID. Mr. President, for the information of the Senate, these items are Senate-numbered items and are Post Office designations. The House version of the bills have passed the Senate and been signed into law.

#### SUPPORTING GOALS OF RED RIBBON WEEK IN PROMOTING DRUG-FREE COMMUNITIES

Mr. REID. Mr. President, I ask unanimous consent that the HELP Committee be discharged from further consideration of H. Con. Res. 84, and that the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the concurrent resolution by title.

The legislative clerk read as follows:

A concurrent resolution (H. Con. Res. 84) supporting the goals of Red Ribbon Week in promoting drug-free communities.

There being no objection, the Senate proceeded to consider the concurrent resolution.

Mr. REID. Mr. President, I ask unanimous consent that the concurrent resolution and the preamble be agreed to en bloc; that the motions to reconsider be laid upon the table en bloc, without any intervening action or debate; and that any statements relating to the concurrent resolution be printed in the RECORD.

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

The concurrent resolution (H. Con. Res. 84) was agreed to.

The preamble was agreed to.

#### DRUG COMPETITION ACT OF 2001

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 431, S. 754.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 754) to enhance competition for prescription drugs by increasing the ability of the Department of Justice and Federal Trade Commission to enforce existing antitrust laws regarding brand name drugs and generic drugs.

There being no objection, the Senate proceeded to consider the bill which had been reported from the Committee on the Judiciary, with an amendment to strike all after the enacting clause and insert in lieu thereof the following: [Strike the part shown in black brackets and insert the part shown in *Italic*.]

S. 754

*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 "Drug Competition Act of 2001".]

#### SEC. 2. FINDINGS.

[Congress finds that—

(1) prescription drug costs are increasing at an alarming rate and are a major worry of senior citizens and American families;

(2) there is a potential for drug companies owning patents on brand-name drugs to enter into private financial deals with generic drug companies in a manner that could tend to restrain trade and greatly reduce competition and increase prescription drug costs for American citizens; and

(3) enhancing competition between generic drug manufacturers and brand name manufacturers can significantly reduce prescription drug costs to American families.

#### SEC. 3. PURPOSE.

[The purposes of this Act are—

(1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies owning patents on branded drugs and companies who could manufacture generic or bioequivalent versions of such branded drugs; and

(2) by providing timely notice, to—

(A) enhance the effectiveness and efficiency of the enforcement of the antitrust laws of the United States; and

(B) deter pharmaceutical companies from engaging in anticompetitive actions or actions that tend to unfairly restrain trade.

#### SEC. 4. DEFINITIONS.

[In this Act:

(1) AGREEMENT.—The term "agreement" means an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(2) ANTITRUST LAWS.—The term "antitrust laws" has the same meaning as in section 1 of the Clayton Act (15 U.S.C. 12), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(3) ANDA.—The term "ANDA" means an Abbreviated New Drug Application, as defined under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(4) BRAND NAME DRUG COMPANY.—The term "brand name drug company" means a person engaged in the manufacture or marketing of a drug approved under section 505(b) of the Federal Food, Drug and Cosmetic Act.

(5) COMMISSION.—The term "Commission" means the Federal Trade Commission.

(6) FDA.—The term "FDA" means the United States Food and Drug Administration.

(7) GENERIC DRUG.—The term "generic drug" is a product that the Food and Drug Administration has approved under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(8) GENERIC DRUG APPLICANT.—The term "generic drug applicant" means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(9) NDA.—The term "NDA" means a New Drug Application, as defined under section 505(b) et seq. of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(b) et seq.)

#### SEC. 5. NOTIFICATION OF AGREEMENTS AFFECTING THE SALE OR MARKETING OF GENERIC DRUGS.

[A brand name drug manufacturer and a generic drug manufacturer that enter into an agreement regarding the sale or manufacture of a generic drug equivalent of a brand name drug that is manufactured by that brand name manufacturer and which agreement could have the effect of limiting—

(1) the research, development, manufacture, marketing or selling of a generic drug

product that could be approved for sale by the FDA pursuant to the ANDA; or

(2) the research, development, manufacture, marketing or selling of a generic drug product that could be approved by the FDA; [both shall file with the Commission and the Attorney General the text of the agreement, an explanation of the purpose and scope of the agreement and an explanation of whether the agreement could delay, restrain, limit, or in any way interfere with the production, manufacture or sale of the generic version of the drug in question.

#### SEC. 6. FILING DEADLINES.

[Any notice, agreement, or other material required to be filed under section 5 shall be filed with the Attorney General and the FTC not later than 10 business days after the date the agreements are executed.

#### SEC. 7. ENFORCEMENT.

(a) CIVIL FINE.—Any person, or any officer, director, or partner thereof, who fails to comply with any provision of this Act shall be liable for a civil penalty of not more than \$20,000 for each day during which such person is in violation of this Act. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any person, or any officer, director, partner, agent, or employee thereof, fails to comply with the notification requirement under section 5 of this Act, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Commission or the Assistant Attorney General.

#### SEC. 8. RULEMAKING.

[The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, consistent with the purposes of this Act—

(1) may require that the notice described in section 5 of this Act be in such form and contain such documentary material and information relevant to the agreement as is necessary and appropriate to enable the Commission and the Assistant Attorney General to determine whether such agreement may violate the antitrust laws;

(2) may define the terms used in this Act;

(3) may exempt classes of persons or agreements from the requirements of this Act; and

(4) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this Act.

#### SEC. 9. EFFECTIVE DATES.

[This Act shall take effect 90 days after the date of enactment of this Act.]

#### SECTION. 1. SHORT TITLE.

*This Act may be cited as the "Drug Competition Act of 2001".*

#### SEC. 2. FINDINGS.

*Congress finds that—*

(1) prescription drug prices are increasing at an alarming rate and are a major worry of many senior citizens and American families;

(2) there is a potential for companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs to enter into financial deals that could tend to restrain trade and greatly reduce competition and increase prescription drug expenditures for American citizens; and

(3) enhancing competition among these companies can significantly reduce prescription drug expenditures for Americans.

#### SEC. 3. PURPOSES.

*The purposes of this Act are—*

(1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with

patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs; and

(2) by providing timely notice, to enhance the effectiveness and efficiency of the enforcement of the antitrust and competition laws of the United States.

#### SEC. 4. DEFINITIONS.

In this Act:

(1) **ANDA.**—The term “ANDA” means an Abbreviated New Drug Application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(aa)).

(2) **ASSISTANT ATTORNEY GENERAL.**—The term “Assistant Attorney General” means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) **BRAND NAME DRUG.**—The term “brand name drug” means a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)).

(4) **BRAND NAME DRUG COMPANY.**—The term “brand name drug company” means the party that received Food and Drug Administration approval to market a brand name drug pursuant to an NDA, where that drug is the subject of an ANDA, or a party owning or controlling enforcement of any patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations of the Food and Drug Administration for that drug, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(5) **COMMISSION.**—The term “Commission” means the Federal Trade Commission.

(6) **GENERIC DRUG.**—The term “generic drug” means a product that the Food and Drug Administration has approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(7) **GENERIC DRUG APPLICANT.**—The term “generic drug applicant” means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(8) **NDA.**—The term “NDA” means a New Drug Application, as defined under section 505(b) et seq. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b) et seq.).

#### SEC. 5. NOTIFICATION OF AGREEMENTS.

(a) **IN GENERAL.**—

(1) **REQUIREMENT.**—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(vii)(IV)) and a brand name drug company that enter into an agreement described in paragraph (2), prior to the generic drug that is the subject of the application entering the market, shall each file the agreement as required by subsection (b).

(2) **DEFINITION.**—An agreement described in this paragraph is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the subject of the generic drug applicant's ANDA;

(B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant's ANDA; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) **FILING.**—

(1) **AGREEMENT.**—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that the generic drug applicant and the brand-name drug company shall not be required to file an agreement that solely concerns—

- (A) purchase orders for raw material supplies;
- (B) equipment and facility contracts; or
- (C) employment or consulting contracts.

(2) **OTHER AGREEMENTS.**—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any other agreements not described in subsection (a)(2) between the generic drug applicant and the brand name drug company which are contingent upon, provide a contingent condition for, or are otherwise related to an agreement which must be filed under this Act.

(3) **DESCRIPTION.**—In the event that any agreement required to be filed by paragraph (1) or (2) has not been reduced to text, both the generic drug applicant and the brand name drug company shall file written descriptions of the non-textual agreement or agreements that must be filed sufficient to reveal all of the terms of the agreement or agreements.

#### SEC. 6. FILING DEADLINES.

Any filing required under section 5 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

#### SEC. 7. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this Act shall be exempt from disclosure under section 552 of title 5, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.

#### SEC. 8. ENFORCEMENT.

(a) **CIVIL PENALTY.**—Any brand name drug company or generic drug applicant which fails to comply with any provision of this Act shall be liable for a civil penalty of not more than \$11,000, for each day during which such entity is in violation of this Act. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) **COMPLIANCE AND EQUITABLE RELIEF.**—If any brand name drug company or generic drug applicant fails to comply with any provision of this Act, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission. Equitable relief under this subsection may include an order by the district court which renders unenforceable, by the brand name drug company or generic drug applicant failing to file, any agreement that was not filed as required by this Act for the period of time during which the agreement was not filed by the company or applicant as required by this Act.

#### SEC. 9. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5 United States Code, consistent with the purposes of this Act—

- (1) may define the terms used in this Act;
- (2) may exempt classes of persons or agreements from the requirements of this Act; and
- (3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this Act.

#### SEC. 10. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this Act shall not bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant at any time under any other provision of law, nor shall any filing under this Act constitute or create a presump-

tion of any violation of any antitrust or competition laws.

#### SEC. 11. EFFECTIVE DATE.

This Act shall—

(1) take effect 30 days after the date of enactment of this Act; and

(2) shall apply to agreements described in section 5 that are entered into 30 days after the date of enactment of this Act.

Mr. LEAHY. Mr. President, I am pleased that the Senate has, at long last, taken up the Drug Competition Act of 1002, S. 754. Prescription drug prices are rapidly increasing, and are a source of considerable concern to many Americans, especially senior citizens and families. Generic drug prices can be as much as 80 percent lower than the comparable brand name version.

While the Drug Competition Act is a small bill in terms of length, it is a large one in terms of impact. It will ensure that law enforcement agencies can take quick and decisive action against companies that are driven more by greed than by good sense. It gives the Federal Trade Commission and the Justice Department access to information about secret deals between drug companies that keep generic drugs off the market. This is a practice that hurts American families, particularly senior citizens, by denying them access to low-cost generic drugs, and further inflating medical costs.

This has been a genuine bipartisan effort, and I must thank all my colleagues, including Senator HATCH who has a long-standing interest in these issues, subcommittee Chairman KOHL who has worked with me from the start on this effort, and particularly Senator GRASSLEY, who has worked hard to reach consensus on this bill that will help protect consumers.

The issue of drug companies paying generic companies not to compete was exposed in recent years by the FTC, and by articles in major newspapers, including an editorial in the July 26, 2000, the New York Times, titled “Driving Up Drug Prices.” This editorial concluded that the problem “needs help from Congress to close loopholes in federal law.” And while the FTC has sued pharmaceutical companies that have made such secret and anticompetitive deals, as the then-Director of the Bureau of Competition Molly Boast testified before the Judiciary Committee in May 2001, the antitrust enforcement agencies are only finding out about such deals by luck, or by accident. Most recently, the FTC has issued a comprehensive study of the generic pharmaceutical industry which explicitly supported passage of S. 754.

Under current law, the first generic manufacturer that gets permission to sell a generic drug before the patent on the brand-name drug expires, enjoys protection from competition for 180 days—a headstart on other generic companies. That was a good idea—but the unfortunate loophole exploited by a few is that secret deals can be made that allow the manufacturer of the generic drug to claim the 180-day grace

period—to block other generic drugs from entering the market—while, at the same time, getting paid by the brand-name manufacturer to not sell the generic drug.

The bill closes this loophole for those who want to cheat the public, but keeps the system the same for companies engaged in true competition. The deals would be reviewed only by those agencies—the agreements would not be available to the public. I think it is important for Congress not to overact and throw out the good with the bad. Most generic companies want to take advantage of this 180-day provision and deliver quality generic drugs at much lower costs for consumers. We should not eliminate the incentive for them. Instead, we should let the FTC and Justice look at every deal that could lead to abuse, so that only the deals that are consistent with the intent of that law will be allowed to stand. This bill accomplishes precisely that goal, and helps ensure effective and timely access to generic pharmaceuticals that can lower the cost of prescription drugs for seniors, for families, and for all of us.

Mr. REID. Mr. President, I ask unanimous consent that the Hatch-Leahy amendment which is at the desk be agreed to; that the committee amendment, as amended, be agreed to; that the bill, as amended, be read the third time, passed, and the motion to reconsider be laid upon the table, with no intervening action or debate; and that any statements relating to the bill be printed in the RECORD.

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

The amendment (No. 4965) was agreed to, as follows:

#### AMENDMENT NO. 4965

On page 11, line 17, strike “or”.

On page 11, line 18, strike the period and insert “; or”.

On page 11, after line 18, insert the following: (D) packaging and labeling contracts.

On page 13, line 17, strike all beginning with “Equitable” through line 23.

The committee amendment in the nature of a substitute, as amended, was agreed to.

The bill (S. 754), as amended, was read the third time and passed, as follows:

#### S. 754

*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 “Drug Competition Act of 2002”.

#### SEC. 2. FINDINGS.

Congress finds that—

(1) prescription drug prices are increasing at an alarming rate and are a major worry of many senior citizens and American families;

(2) there is a potential for companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs to enter into financial deals that could tend to restrain trade and greatly reduce competition and increase prescription drug expenditures for American citizens; and

(3) enhancing competition among these companies can significantly reduce prescription drug expenditures for Americans.

#### SEC. 3. PURPOSES.

The purposes of this Act are—

(1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs; and

(2) by providing timely notice, to enhance the effectiveness and efficiency of the enforcement of the antitrust and competition laws of the United States.

#### SEC. 4. DEFINITIONS.

In this Act:

(1) **ANDA.**—The term “ANDA” means an Abbreviated New Drug Application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(aa)).

(2) **ASSISTANT ATTORNEY GENERAL.**—The term “Assistant Attorney General” means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) **BRAND NAME DRUG.**—The term “brand name drug” means a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)).

(4) **BRAND NAME DRUG COMPANY.**—The term “brand name drug company” means the party that received Food and Drug Administration approval to market a brand name drug pursuant to an NDA, where that drug is the subject of an ANDA, or a party owning or controlling enforcement of any patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations of the Food and Drug Administration for that drug, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(5) **COMMISSION.**—The term “Commission” means the Federal Trade Commission.

(6) **GENERIC DRUG.**—The term “generic drug” means a product that the Food and Drug Administration has approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(7) **GENERIC DRUG APPLICANT.**—The term “generic drug applicant” means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(8) **NDA.**—The term “NDA” means a New Drug Application, as defined under section 505(b) et seq. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b) et seq.).

#### SEC. 5. NOTIFICATION OF AGREEMENTS.

(a) **IN GENERAL.**—

(1) **REQUIREMENT.**—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(vii)(IV)) and a brand name drug company that enter into an agreement described in paragraph (2), prior to the generic drug that is the subject of the application entering the market, shall each file the agreement as required by subsection (b).

(2) **DEFINITION.**—An agreement described in this paragraph is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the subject of the generic drug applicant’s ANDA;

(B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant’s ANDA; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) **FILING.**—

(1) **AGREEMENT.**—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that the generic drug applicant and the brand-name drug company shall not be required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) **OTHER AGREEMENTS.**—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any other agreements not described in subsection (a)(2) between the generic drug applicant and the brand name drug company which are contingent upon, provide a contingent condition for, or are otherwise related to an agreement which must be filed under this Act.

(3) **DESCRIPTION.**—In the event that any agreement required to be filed by paragraph (1) or (2) has not been reduced to text, both the generic drug applicant and the brand name drug company shall file written descriptions of the non-textual agreement or agreements that must be filed sufficient to reveal all of the terms of the agreement or agreements.

#### SEC. 6. FILING DEADLINES.

Any filing required under section 5 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

#### SEC. 7. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this Act shall be exempt from disclosure under section 552 of title 5, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.

#### SEC. 8. ENFORCEMENT.

(a) **CIVIL PENALTY.**—Any brand name drug company or generic drug applicant which fails to comply with any provision of this Act shall be liable for a civil penalty of not more than \$11,000, for each day during which such entity is in violation of this Act. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) **COMPLIANCE AND EQUITABLE RELIEF.**—If any brand name drug company or generic drug applicant fails to comply with any provision of this Act, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission.

#### SEC. 9. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5 United States Code, consistent with the purposes of this Act—

(1) may define the terms used in this Act;

(2) may exempt classes of persons or agreements from the requirements of this Act; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this Act.

#### SEC. 10. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this Act shall not bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant at any time under any other provision of law, nor shall any filing under this Act constitute or create a presumption of any violation of any antitrust or competition laws.

#### SEC. 11. EFFECTIVE DATE.

This Act shall—  
(1) take effect 30 days after the date of enactment of this Act; and  
(2) shall apply to agreements described in section 5 that are entered into 30 days after the date of enactment of this Act.

### CONSUMER PRODUCT SAFETY ACT AMENDMENT

Mr. REID. Mr. President, I ask unanimous consent that the Commerce Committee be discharged from further consideration of H.R. 727 and that the Senate proceed to its consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 727) to amend the Consumer Product Safety Act to provide that low-speed electric bicycles are consumer products subject to such Act.

There being no objection, the Senate proceeded to consider the bill.

Mr. REID. Mr. President, I ask unanimous consent that the bill be read three times, passed, and the motion to reconsider be laid upon the table, with no intervening action or debate; and that any statements relating to the bill be in the RECORD.

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

The bill (H.R. 727) was read the third time and passed.

### CHILD SAFETY ENHANCEMENT ACT OF 2002

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 5504.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 5504) to provide for the improvement of the safety of child restraints in passenger motor vehicles, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. REID. Mr. President, I ask unanimous consent that the bill be read a third time, passed, and the motion to reconsider be laid upon the table; and that any statements relating to the bill be printed in the RECORD.

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

The bill (H.R. 5504) was read the third time and passed.

### FEDERAL AVIATION ADMINISTRATION RESEARCH, ENGINEERING AND DEVELOPMENT ACT OF 2002

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 697, S. 2951, a bill to authorize appropriations for the Federal Aviation Administration.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 2951) to authorize appropriations for the Federal Aviation Administration, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. REID. I understand Senators ROCKEFELLER, HOLLINGS, MCCAIN, and HUTCHISON of Texas have an amendment at the desk, and I ask that the amendment be considered and agreed to; the bill, as amended, be read three times, passed, and the motion to reconsider be laid upon the table; that any statements relating thereto be printed in the RECORD, with no intervening action or debate.

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

The amendment (No. 4966) was agreed to, as follows:

#### AMENDMENT NO. 4966

(Purpose: To include the House of Representatives Committee on Science as a recipient of each of all the required reports, and to make other minor changes)

On page 3, beginning in line 21, strike "Transportation and" and insert "Transportation,".

On page 3, line 23, strike "Infrastructure," and insert "Infrastructure, and the House of Representatives Committee on Science,".

On page 4, strike lines 18 through 23, and insert the following:

The Federal Aviation Administration Administrator shall continue the program to consider awards to nonprofit concrete and asphalt pavement research foundations to improve the design, construction, rehabilitation, and repair of concrete and asphalt airfield pavements to aid in the development of safer, more cost-effective, and more durable airfield pavements.

On page 5, beginning in line 22, strike "Transportation and" and insert "Transportation,".

On page 5, line 24, strike "Infrastructure," and insert "Infrastructure, and the House of Representatives Committee on Science,".

On page 8, strike lines 9 through 13, and insert the following:

(b) REPORT.—A report containing the results of the assessment shall be provided to the Senate Committee on Commerce, Science, and Transportation, the House of Representatives Committee on Transportation and Infrastructure, and the House of Representatives Committee on Science not later than 1 year after the date of enactment of this Act.

The bill (S. 2951), as amended, was read the third time and passed, as follows:

S. 2951

*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 "Federal Aviation Administration Research, Engineering, and Development Act of 2002".

#### SEC. 2. AUTHORIZATION OF APPROPRIATIONS.

(a) AMOUNTS AUTHORIZED.—Section 48102(a) of title 49, United States Code, is amended—

(1) by striking "and" at the end of paragraph (7);

(2) by striking the period at the end of paragraph (8) and inserting a semicolon; and  
(3) by adding at the end the following:

"(9) for fiscal year 2003, \$261,000,000, including—

"(A) \$211,000,000 to improve aviation safety;

"(B) \$18,000,000 to improve the efficiency of the air traffic control system;

"(C) \$16,000,000 to reduce the environmental impact of aviation; and

"(D) \$16,000,000 to improve the efficiency of mission support;

"(10) for fiscal year 2004, \$274,000,000, including—

"(A) \$221,000,000 to improve aviation safety;

"(B) \$19,000,000 to improve the efficiency of the air traffic control system;

"(C) \$17,000,000 to reduce the environmental impact of aviation; and

"(D) \$17,000,000 to improve the efficiency of mission support; and

"(11) for fiscal year 2005, \$287,000,000, including—

"(A) \$231,000,000 to improve aviation safety;

"(B) \$20,000,000 to improve the efficiency of the air traffic control system;

"(C) \$18,000,000 to reduce the environmental impact of aviation; and

"(D) \$18,000,000 to improve the efficiency of mission support."

#### SEC. 3. COORDINATION OF NATIONAL AVIATION SAFETY AND SECURITY RESEARCH PROGRAMS.

(a) DEVELOPMENT OF PLAN.—Not later than June 30, 2003, the National Aeronautics and Space Administration Administrator, the Federal Aviation Administration Administrator, and the Under Secretary of Transportation for Security shall prepare and transmit an updated integrated civil aviation research and development plan to the Senate Committee on Commerce, Science, and Transportation, the House of Representatives Committee on Transportation and Infrastructure, and the House of Representatives Committee on Science.

(b) CONTENTS.—The updated integrated civil aviation research and development plan shall include—

(1) identification of the respective aviation research and development requirements, roles, and responsibilities of the National Aeronautics and Space Administration, the Federal Aviation Administration, and the Transportation Security Administration; and

(2) review of steps they could take to facilitate the transfer and adoption of new technologies in an operational environment, including consideration of increasing the exchange of research staff, providing greater details on funding at the project level in joint plans, and providing for greater use of technology readiness in program plans and budgets to help frame the maturity of new technologies and determine when they can be implemented.

#### SEC. 4. RESEARCH PROGRAM TO IMPROVE AIR- FIELD PAVEMENTS.

The Federal Aviation Administration Administrator shall continue the program to consider awards to nonprofit concrete and asphalt pavement research foundations to improve the design, construction, rehabilitation, and repair of concrete and asphalt airfield pavements to aid in the development of safer, more cost-effective, and more durable airfield pavements. The Administrator may use grants or cooperative agreements in carrying out this section. Nothing in this section requires the Administrator to prioritize