''(2) PAYMENTS FOR YEARS SERVED.—

''(A) IN GENERAL.—For each year of obligated service that an individual contracts to serve under subsection (a) the Secretary may pay up to $35,000 on behalf of the individual for loans described in paragraph (1). In making a determination of the amount to pay for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—

''(i) affects the ability of the Secretary to maximize the number of agreements that may be provided under this section from the amounts appropriated for such agreements;

''(ii) provides an incentive to serve in areas with the greatest shortages of pharmacists; and

''(iii) provides an incentive with respect to the pharmacist involved remaining in the area and continuing to provide pharmacy services after the completion of the period of obligated service under agreement.

''(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made not later than the end of the fiscal year in which the individual completes such year of service.

''(3) TAX LIABILITY.—For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual—

''(A) the Secretary shall, in addition to such payments, make payments to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved; and

''(B) may make such additional payments as the Secretary determines to be appropriate with respect to such purpose.

''(4) PAYMENT SCHEDULE.—The Secretary may enter into an agreement with the holder of any loan for which payments are made under this section to establish a schedule for the making of such payments.

''(c) PREFERENCES.—In entering into agreements under subsection (a), the Secretary shall give preference to qualified applicants with the greatest financial need.

''(d) REPORTS.—

''(1) ANNUAL REPORT.—Not later than 18 months after the date of enactment of the Pharmacy Education Aid Act, and annually thereafter, the Secretary shall prepare and submit to Congress a report describing the program carried out under this section, including statements regarding—

''(A) the number of applicants and contract recipients;

''(B) the amount of loan repayments made;

''(C) which educational institution the recipients attended;

''(D) the number and practice locations of the loan repayment recipients at health care facilities with a critical shortage of pharmacists;

''(E) the default rate and actions required;

''(F) the amount of outstanding default funds of the loan repayment program;

''(G) to the extent that it can be determined, the reason for the default;

''(H) the demographics of the individuals participating in the loan repayment program; and

''(I) an evaluation of the overall costs and benefits of the program.

''(2) 5-YEAR REPORT.—Not later than 5 years after the date of enactment of the Pharmacy Education Aid Act, the Secretary shall prepare and submit to Congress a report on how the program carried out under this section interacts with other Federal loan repayment programs for pharmacists and determining the relative effectiveness of such programs in increasing pharmacists practicing in underserved areas.

''(e) APPLICATION OF CERTAIN PROVISIONS.—

''(1) IN GENERAL.—The provisions of section 338C, 338G, and 338I shall apply to the program established under this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program under subpart III of part D of title III, including the applicability of provisions regarding reimbursements for increased tax liability and bankruptcy.

''(2) BREACH OF AGREEMENT.—An individual who enters into an agreement under subsection (a) shall be liable to the Federal Government for the amount of the award under such agreement (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual fails to provide health services in accordance with the program under this section for the period of time applicable under the program.

''(3) WAIVER OR SUSPENSION OF LIABILITY.—In the case of an individual or health facility making an agreement for purposes of subsection (a), the Secretary shall provide for the waiver or suspension of liability under paragraph (2) if compliance by the individual or the health facility, as the case may be, with the agreement involved is impossible, or would involve extreme hardship to the individual or facility, and if enforcement of the agreements with respect to the individual or facility would be unconscionable.

''(4) DATE CERTAIN FOR RECOVERY.—Subject to paragraph (3), any amount that the Federal Government is entitled to recover under paragraph (2) shall be paid to the United States not later than the expiration of the 3-year period beginning on the date the United States becomes so entitled.

''(5) AVAILABILITY.—Amounts recovered under paragraph (2) with respect to a program under this section shall be available for the purposes of such program, and shall remain available for such purposes until expended.

''(f) DEFINITION.—In this section, the term 'health care facility' means a facility with a critical shortage of pharmacists as determined by the Secretary.

''(g) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of payments under agreements entered into under subsection (a), there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2004 through 2008.

''SEC. 782. PHARMACY FACULTY LOAN REPAYMENT PROGRAM.

''(a) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program under which the Secretary will enter into contracts with individuals described in subsection (b) and such individuals will agree to serve as faculty members of schools of pharmacy in consideration of the Federal Government agreeing to pay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such individuals.

''(b) ELIGIBLE INDIVIDUALS.—An individual is described in this subsection if such individual—

''(1) has a baccalaureate degree in pharmacy or a Doctor of Pharmacy degree from an accredited program; or

''(2) is enrolled as a full-time student—

''(A) in an accredited pharmacy program; and

''(B) in the final year of a course of a study or program, offered by such institution and approved by the Secretary, leading to a baccalaureate degree in pharmacy or a Doctor of Pharmacy degree from such a school.

''(c) REQUIREMENTS REGARDING FACULTY POSITIONS.—The Secretary may not enter into a contract under subsection (a) unless—

''(1) the individual involved has entered into a contract with a school of pharmacy to serve as a member of the faculty of the school for not less than 2 years; and

''(2) the contract referred to in paragraph (1) provides that—

''(A) the school will, for each year for which the individual will serve as a member of the faculty under contract with the school, make payments of the principal and interest due on the educational loans of the individual for such year in an amount equal to the amount of such payments made by the Secretary for the year;

''(B) the payments made by the school pursuant to subparagraph (A) on behalf of the individual will be in addition to the compensation that the individual would otherwise receive for serving as a member of such faculty; and

''(C) the school, in making a determination of the amount of compensation to be provided by the school to the individual for serving as a member of the faculty, will make the determination without regard to the amount of payments made (or to be made) to the individual by the Federal Government under subsection (a).

''(d) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of sections 338C, 338G, and 338I shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, including the applicability of provisions regarding reimbursements for increased tax liability and regarding bankruptcy.

''(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2004 through 2008.

''SEC. 783. DEFINITIONS.

''In this subpart:

''(1) SCHOOL OF PHARMACY.—The term 'school of pharmacy' means a college or school of pharmacy (as defined in section 799B) that, in providing clinical experience for students, requires that the students serve in a clinical rotation in which pharmacist services (as defined in section 331(a)(3)(E)) are provided at or for—

''(A) a medical facility that serves a substantial number of individuals who reside in or are members of a medically underserved community (as so defined);

''(B) an entity described in any of subparagraphs (A) through (L) of section 340B(a)(4) (relating to the definition of covered entity);

''(C) a health care facility of the Department of Veterans Affairs or of any of the Armed Forces of the United States;

''(D) a health care facility of the Bureau of Prisons;

''(E) a health care facility operated by, or with funds received from, the Indian Health Service; or

''(F) a disproportionate share hospital under section 1923 of the Social Security Act.

''(2) PHARMACIST SERVICES.—The term 'pharmacist services' includes drug therapy management services furnished by a pharmacist, individually or on behalf of a pharmacy provider, and such services and supplies furnished incident to the pharmacist's drug therapy management services, that the pharmacist is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided for by State law).''.

Mr. MCCONNELL. I ask unanimous consent the committee substitute amendment be agreed to; the bill, as amended, be read the third time and passed; the motion to reconsider be laid upon the table, and any statements be printed in the RECORD.

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

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

The bill (S. 648), as amended, was read the third time and passed.

MEDICAL DEVICES TECHNICAL CORRECTIONS ACT

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 412, S. 1881.

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

The assistant legislative clerk read as follows:

A bill (S. 1881) to amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes.

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

[Strike the part shown in black brackets and insert the part shown in italic.]

S. 1881

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 ''Medical Devices Technical Corrections Act''.

[SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC LAW 107–250.

[(a) TITLE I; FEES RELATING TO MEDICAL DEVICES.—Part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as added by section 102 of Public Law 107–250 (116 Stat. 1589), is amended—

[(1) in section 737—

[(A) in paragraph (4)(B), by striking ''and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness'' and inserting ''and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness'';

[(B) in paragraph (4)(D), by striking ''manufacturing,'';

[(C) in paragraph (5)(J), by striking ''a premarket application'' and all that follows and inserting ''a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act.''; and

[(D) in paragraph (8), by striking ''The term 'affiliate' means a business entity that has a relationship with a second business entity'' and inserting ''The term 'affiliate' means a business entity that has a relationship with a second business entity (whether domestic or international)''; and

[(2) in section 738—

[(A) in subsection (a)(1)—

[(i) in subparagraph (A)—

[(I) in the matter preceding clause (i) by striking ''subsection (d),'' and inserting ''subsections (d) and (e),'';

[(II) in clause (iv), by striking ''clause (i),'' and all that follows and inserting ''clause (i).''; and

[(III) in clause (vii), by striking ''clause (i),'' and all that follows and inserting ''clause (i), subject to any adjustment under subsection (e)(2)(C)(ii).''; and

[(ii) in subparagraph (D), in each of clauses (i) and (ii), by striking ''application'' and inserting ''application, report,'';

[(B) in subsection (d)(2)(B), beginning in the second sentence, by striking ''firms. which show'' and inserting ''firms, which show'';

[(C) in subsection (e)—

[(i) in paragraph (1), by striking ''Where'' and inserting ''For fiscal year 2004 and each subsequent fiscal year, where''; and

[(ii) in paragraph (2)—

[(I) in subparagraph (B), beginning in the second sentence, by striking ''firms. which show'' and inserting ''firms, which show''; and

[(II) in subparagraph (C)(i), by striking ''Where'' and inserting ''For fiscal year 2004 and each subsequent fiscal year, where'';

[(D) in subsection (f), by striking ''for filing''; and

[(E) in subsection (h)(2)—

[(i) by striking subparagraph (A)(ii) and inserting the following:

[''(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs for fiscal year 2002 when multiplied by the adjustment factor (the determination of the costs of the resources allocated for the process for the review of device applications for fiscal year 2003 through 2007, for purposes of this subparagraph, shall not include costs paid from fees collected under this section).''; and

[(ii) in subparagraph (B)—

[(I) in clause (ii), by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively;

[(II) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

[(III) by striking ''The Secretary'' and inserting the following:

[''(i) IN GENERAL.—The Secretary''; and

[(IV) by adding at the end the following:

[''(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.''.

[(b) TITLE II; AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES.—

[(1) INSPECTIONS BY ACCREDITED PERSONS.—Section 704(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)), as added by section 201 of Public Law 107–250 (116 Stat. 1602), is amended—

[(A) in paragraph (1), in the first sentence, by striking ''conducting inspections'' and all that follows and inserting ''conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 510(h) or are inspections of such establishments required to register under section 510(i).'';

[(B) in paragraph (6)(A)—

[(i) in clause (i), by striking ''of the establishment pursuant to subsection (h) or (i) of section 510'' and inserting ''described in paragraph (1)'';

[(ii) in clause (ii)—

[(I) in the matter preceding subclause (I)—

[(aa) by striking ''each inspection'' and inserting ''inspections''; and

[(bb) by inserting ''during a 2-year period'' after ''person''; and

[(II) in subclause (I), by striking ''such a person'' and inserting ''an accredited person'';

[(iii) in clause (iii)—

[(I) in the matter preceding subclause (I), by striking ''and the following additional conditions are met:'' and inserting ''and 1 or both of the following additional conditions are met:'';

[(II) in subclause (I), by striking ''under subclause (II) of this clause'' and inserting ''under clause (ii)(II)''; and

[(III) in subclause (II), by inserting ''or by a person accredited under paragraph (2)'' after ''by the Secretary'';

[(iv) in clause (iv)(I)—

[(I) in the first sentence—

[(aa) by striking ''the two immediately preceding inspections of the establishment'' and inserting ''inspections of the establishment during the previous 4 years''; and

[(bb) by inserting ''section'' after ''pursuant to''; and

[(II) in the third sentence—

[(aa) by striking ''the petition states a commercial reason for the waiver;''; and

[(bb) by inserting ''not'' after ''the Secretary has not determined that the public health would''; and

[(v) in clause (iv)(II)—

[(I) by inserting ''of a device establishment required to register'' after ''to be conducted''; and

[(II) by inserting ''section'' after ''pursuant to'';

[(C) in paragraph (6)(B)(iii)—

[(i) in the first sentence, by striking '', and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502''; and

[(ii) in the second sentence—

[(I) by striking ''inspections'' and inserting ''inspectional findings''; and

[(II) by striking '', together with all other compliance data the Secretary deems necessary'';

[(D) in paragraph (6)(C)(ii), by striking ''in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable'';

[(E) in paragraph (10)(B)(iii), by striking ''a reporting'' and inserting ''a report''; and

[(F) in paragraph (12)—

[(i) by striking subparagraph (A) and inserting the following:

[''(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);''; and

[(ii) in subparagraph (E), by striking ''obtained by the Secretary'' and all that follows and inserting ''obtained by the Secretary pursuant to inspections conducted by Federal employees;''.

[(2) OTHER CORRECTIONS.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as amended by section 206 of Public Law 107–250 (116 Stat. 1613), is amended, in the last sentence—

[(A) by inserting ''or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments'' after ''in health care facilities'';

[(B) by inserting a comma after ''means'';

[(C) by striking ''requirements of law and, that'' and inserting ''requirements of law, and that'';

[(D) by striking ''the manufacturer affords health care facilities the opportunity'' and inserting ''the manufacturer affords such users the opportunity''; and

[(E) by striking ''the health care facility''.

[(c) TITLE III; ADDITIONAL AMENDMENTS.—Section 510(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(o)), as added by section 302(b) of Public Law 107–250 (116 Stat. 1616), is amended—

[(1) in paragraph (1)(B), by striking '', adulterated'' and inserting ''or adulterated''; and

[(2) in paragraph (2)—

[(A) in subparagraph (B), by striking '', adulterated'' and inserting ''or adulterated''; and

[(B) in subparagraph (E), by striking ''semicritical'' and inserting ''semi-critical''.

[(d) MISCELLANEOUS CORRECTIONS.—

[(1) CERTAIN AMENDMENTS TO SECTION 515.—

[(A) IN GENERAL.—

[(i) TECHNICAL CORRECTION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)), as amended by sections 209 and 302(c)(2)(A) of Public Law 107–250 (116

Stat. 1613, 1618), is amended by redesignating paragraph (3) (as added by section 209 of such Public Law) as paragraph (4).

[(ii) MODULAR REVIEW.—Section 515(c)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(4)(B)) is amended by striking ''unless an issue of safety'' and inserting ''unless a significant issue of safety''.

[(B) CONFORMING AMENDMENT.—Section 210 of Public Law 107–250 (116 Stat. 1614) is amended by striking '', as amended'' and all that follows through ''by adding'' and inserting ''is amended in paragraph (3), as redesignated by section 302(c)(2)(A) of this Act, by adding''.

[(2) CERTAIN AMENDMENTS TO SECTION 738.—

[(A) IN GENERAL.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)), as amended by subsection (a), is amended—

[(i) in the matter preceding paragraph (1)—

[(I) by striking ''(a) TYPES OF FEES.—Beginning on'' and inserting the following:

[''(a) TYPES OF FEES.—

[''(1) IN GENERAL.—Beginning on''; and

[(II) by striking ''this section as follows:'' and inserting ''this section.''; and

[(ii) by striking ''(1) PREMARKET APPLICATION,'' and inserting the following: ''(2) PREMARKET APPLICATION,''.

[(B) CONFORMING AMENDMENTS.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j), as amended by subparagraph (A), is amended—

[(i) in subsection (d)(1), in the last sentence, by striking ''subsection (a)(1)(A)'' and inserting ''subsection (a)(2)(A)'';

(ii) in subsection (e)(1), by striking ''subsection (a)(1)(A)(vii)'' and inserting ''subsection (a)(2)(A)(vii)'';

[(iii) in subsection (e)(2)(C)—

[(I) in each of clauses (i) and (ii), by striking ''subsection (a)(1)(A)(vii)'' and inserting ''subsection (a)(2)(A)(vii)''; and

[(II) in clause (ii), by striking ''subsection (a)(1)(A)(i)'' and inserting ''subsection (a)(2)(A)(i)''; and

[(iv) in subsection (j), by striking ''subsection (a)(1)(D),'' and inserting ''subsection (a)(2)(D),''.

[(C) ADDITIONAL CONFORMING AMENDMENT.—Section 102(b)(1) of Public Law 107–250 (116 Stat. 1600) is amended, in the matter preceding subparagraph (A), by striking ''section 738(a)(1)(A)(ii)'' and inserting ''section 738(a)(2)(A)(ii)''.

[(3) PUBLIC LAW 107–250.—Public Law 107–250 is amended—

[(A) in section 102(a) (116 Stat. 1589), by striking ''(21 U.S.C. 379F et seq.)'' and inserting ''(21 U.S.C. 379f et seq.)'';

[(B) in section 102(b) (116 Stat. 1600)—

[(i) by striking paragraph (2);

[(ii) in paragraph (1), by redesignating subparagraphs (A) and (B) as paragraphs (1) and (2), respectively; and

[(iii) by striking:

[''(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—

[''(1) IN GENERAL.—A person submitting a premarket report'' and inserting:

[''(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—A person submitting a premarket report'';

[(C) in section 212(b)(2) (116 Stat. 1614), by striking '', such as phase IV trials,''; and

[(D) in section 301(b) (116 Stat. 1616), by striking ''18 months'' and inserting ''36 months''.

[SEC. 3. HUMANITARIAN DEVICE EXEMPTION AND PEDIATRIC PRODUCTS.

[(a) AMENDMENT TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 520(m)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(3)) is amended to read as follows:

[''(3) Excluding devices intended for the treatment or diagnosis of diseases or conditions that affect pediatric patients, no person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. The exclusion from the prohibition under the previous sentence for devices intended for the treatment or diagnosis of diseases or conditions that affect pediatric patients, shall not apply in the case of a request for an exemption under paragraph (2) made on or after October 1, 2007. In this paragraph, the term 'pediatric patient' means a patient who is 14 years of age or younger at the time of diagnosis or treatment.''.

[(b) REPORT.—Not later than October 1, 2006, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) in ensuring the development of devices designed to treat or diagnose diseases or conditions that affect fewer than 4,000 pediatric patients in the United States. Such report shall include the number and importance of devices for pediatric patients that are receiving exemptions under section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)).]

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Devices Technical Corrections Act''.

SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC LAW 107–250.

(a) TITLE I; FEES RELATING TO MEDICAL DEVICES.—Part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as added by section 102 of Public Law 107–250 (116 Stat. 1589), is amended—

(1) in section 737—

(A) in paragraph (4)(B), by striking ''and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness'' and inserting ''and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness'';

(B) in paragraph (4)(D), by striking ''manufacturing,'';

(C) in paragraph (5)(J), by striking ''a premarket application'' and all that follows and inserting ''a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act.''; and

(D) in paragraph (8), by striking ''The term 'affiliate' means a business entity that has a relationship with a second business entity'' and inserting ''The term 'affiliate' means a business entity that has a relationship with a second business entity (whether domestic or international)''; and

(2) in section 738—

(A) in subsection (a)(1)—

(i) in subparagraph (A)—

(I) in the matter preceding clause (i) by striking ''subsection (d),'' and inserting ''subsections (d) and (e),'';

(II) in clause (iv), by striking ''clause (i),'' and all that follows and inserting ''clause (i).''; and

(III) in clause (vii), by striking ''clause (i),'' and all that follows and inserting ''clause (i), subject to any adjustment under subsection (e)(2)(C)(ii).''; and

(ii) in subparagraph (D), in each of clauses (i) and (ii), by striking ''application'' and inserting ''application, report,'';

(B) in subsection (d)(2)(B), beginning in the second sentence, by striking ''firms. which show'' and inserting ''firms, which show'';

(C) in subsection (e)—

(i) in paragraph (1), by striking ''Where'' and inserting ''For fiscal year 2004 and each subsequent fiscal year, where''; and

(ii) in paragraph (2)—

(I) in subparagraph (B), beginning in the second sentence, by striking ''firms. which show'' and inserting ''firms, which show''; and

(II) in subparagraph (C)(i), by striking ''Where'' and inserting ''For fiscal year 2004 and each subsequent fiscal year, where'';

(D) in subsection (f), by striking ''for filing''; and

(E) in subsection (h)(2)(B)—

(i) in clause (ii), by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively;

(ii) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(iii) by striking ''The Secretary'' and inserting the following:

''(i) IN GENERAL.—The Secretary''; and

(iv) by adding at the end the following:

''(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.''.

(b) TITLE II; AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES.—

(1) INSPECTIONS BY ACCREDITED PERSONS.—Section 704(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)), as added by section 201 of Public Law 107–250 (116 Stat. 1602), is amended—

(A) in paragraph (1), in the first sentence, by striking ''conducting inspections'' and all that follows and inserting ''conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 510(h) or are inspections of such establishments required to register under section 510(i).'';

(B) in paragraph (6)(A)—

(i) in clause (i), by striking ''of the establishment pursuant to subsection (h) or (i) of section 510'' and inserting ''described in paragraph (1)'';

(ii) in clause (ii)—

(I) in the matter preceding subclause (I)—

(aa) by striking ''each inspection'' and inserting ''inspections''; and

(bb) by inserting ''during a 2-year period'' after ''person''; and

(II) in subclause (I), by striking ''such a person'' and inserting ''an accredited person'';

(iii) in clause (iii)—

(I) in the matter preceding subclause (I), by striking ''and the following additional conditions are met:'' and inserting ''and 1 or both of the following additional conditions are met:'';

(II) in subclause (I), by striking ''under subclause (II) of this clause'' and inserting ''under clause (ii)(II)''; and

(III) in subclause (II), by inserting ''or by a person accredited under paragraph (2)'' after ''by the Secretary'';

(iv) in clause (iv)(I)—

(I) in the first sentence—

(aa) by striking ''the two immediately preceding inspections of the establishment'' and inserting ''inspections of the establishment during the previous 4 years''; and

(bb) by inserting ''section'' after ''pursuant to'';

(II) in the third sentence—

(aa) by striking ''the petition states a commercial reason for the waiver;''; and

(bb) by inserting ''not'' after ''the Secretary has not determined that the public health would''; and

(III) in the fourth sentence, by striking ''granted until'' and inserting ''granted or deemed to be granted until''; and

(v) in clause (iv)(II)—

(I) by inserting ''of a device establishment required to register'' after ''to be conducted''; and

(II) by inserting ''section'' after ''pursuant to'';

(C) in paragraph (6)(B)(iii)—

(i) in the first sentence, by striking '', and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502''; and

(ii) in the second sentence—

(I) by striking ''inspections'' and inserting ''inspectional findings''; and

(II) by inserting ''relevant'' after ''together with all other'';

(D) in paragraph (6)(C)(ii), by striking ''in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable'';

(E) in paragraph (10)(B)(iii), by striking ''a reporting'' and inserting ''a report''; and

(F) in paragraph (12)—

(i) by striking subparagraph (A) and inserting the following:

''(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);''; and

(ii) in subparagraph (E), by striking ''obtained by the Secretary'' and all that follows and inserting ''obtained by the Secretary pursuant to inspections conducted by Federal employees;''.

(2) OTHER CORRECTIONS.—

(A) PROHIBITED ACTS.—Section 301(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(gg)), as amended by section 201(d) of Public Law 107–250 (116 Stat. 1609), is amended to read as follows:

''(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.''.

(B) ELECTRONIC LABELING.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as amended by section 206 of Public Law 107–250 (116 Stat. 1613), is amended, in the last sentence—

(i) by inserting ''or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments'' after ''in health care facilities'';

(ii) by inserting a comma after ''means'';

(iii) by striking ''requirements of law and, that'' and inserting ''requirements of law, and that'';

(iv) by striking ''the manufacturer affords health care facilities the opportunity'' and inserting ''the manufacturer affords such users the opportunity''; and

(v) by striking ''the health care facility''.

(c) TITLE III; ADDITIONAL AMENDMENTS.—

(1) EFFECTIVE DATE.—Section 301(b) of Public Law 107–250 (116 Stat. 1616), is amended by striking ''18 months'' and inserting ''36 months''.

(2) PREMARKET NOTIFICATION.—Section 510(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(o)), as added by section 302(b) of Public Law 107–250 (116 Stat. 1616), is amended—

(A) in paragraph (1)(B), by striking '', adulterated'' and inserting ''or adulterated''; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking '', adulterated'' and inserting ''or adulterated''; and

(ii) in subparagraph (E), by striking ''semicritical'' and inserting ''semi-critical''.

(d) MISCELLANEOUS CORRECTIONS.—

(1) CERTAIN AMENDMENTS TO SECTION 515.—

(A) IN GENERAL.—

(i) TECHNICAL CORRECTION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)), as amended by sections 209 and 302(c)(2)(A) of Public Law 107–250 (116 Stat. 1613, 1618), is amended by redesignating paragraph (3) (as added by section 209 of such Public Law) as paragraph (4).

(ii) MODULAR REVIEW.—Section 515(c)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(4)(B)) is amended by striking ''unless an issue of safety'' and inserting ''unless a significant issue of safety''.

(B) CONFORMING AMENDMENT.—Section 210 of Public Law 107–250 (116 Stat. 1614) is amended by striking '', as amended'' and all that follows through ''by adding'' and inserting ''is amended in paragraph (3), as redesignated by section 302(c)(2)(A) of this Act, by adding''.

(2) CERTAIN AMENDMENTS TO SECTION 738.—

(A) IN GENERAL.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)), as amended by subsection (a), is amended—

(i) in the matter preceding paragraph (1)—

(I) by striking ''(a) TYPES OF FEES.—Beginning on'' and inserting the following:

''(a) TYPES OF FEES.—

''(1) IN GENERAL.—Beginning on''; and

(II) by striking ''this section as follows:'' and inserting ''this section.''; and

(ii) by striking ''(1) PREMARKET APPLICATION,'' and inserting the following: ''(2) PREMARKET APPLICATION,''.

(B) CONFORMING AMENDMENTS.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j), as amended by subparagraph (A), is amended—

(i) in subsection (d)(1), in the last sentence, by striking ''subsection (a)(1)(A)'' and inserting ''subsection (a)(2)(A)'';

(ii) in subsection (e)(1), by striking ''subsection (a)(1)(A)(vii)'' and inserting ''subsection (a)(2)(A)(vii)'';

(iii) in subsection (e)(2)(C)—

(I) in each of clauses (i) and (ii), by striking ''subsection (a)(1)(A)(vii)'' and inserting ''subsection (a)(2)(A)(vii)''; and

(II) in clause (ii), by striking ''subsection (a)(1)(A)(i)'' and inserting ''subsection (a)(2)(A)(i)''; and

(iv) in subsection (j), by striking ''subsection (a)(1)(D),'' and inserting ''subsection (a)(2)(D),''.

(C) ADDITIONAL CONFORMING AMENDMENT.—Section 102(b)(1) of Public Law 107–250 (116 Stat. 1600) is amended, in the matter preceding subparagraph (A), by striking ''section 738(a)(1)(A)(ii)'' and inserting ''section 738(a)(2)(A)(ii)''.

(3) PUBLIC LAW 107–250.—Public Law 107–250 is amended—

(A) in section 102(a) (116 Stat. 1589), by striking ''(21 U.S.C. 379F et seq.)'' and inserting ''(21 U.S.C. 379f et seq.)'';

(B) in section 102(b) (116 Stat. 1600)—

(i) by striking paragraph (2);

(ii) in paragraph (1), by redesignating subparagraphs (A) and (B) as paragraphs (1) and (2), respectively; and

(iii) by striking:

''(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—

''(1) IN GENERAL.—A person submitting a premarket report'' and inserting:

''(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—A person submitting a premarket report''; and

(C) in section 212(b)(2) (116 Stat. 1614), by striking '', such as phase IV trials,''.

SEC. 3. REPORT ON BARRIERS TO AVAILABILITY OF DEVICES INTENDED FOR CHILDREN.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the barriers to the availability of devices intended for the treatment or diagnosis of diseases and conditions that affect children. The report shall include any recommendations of the Secretary of Health and Human Services for changes to existing statutory authority, regulations, or agency policy or practice to encourage the invention and development of such devices.

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the committee substitute amendment be agreed to, the bill, as amended, be read a third time and passed, 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 committee amendment in the nature of a substitute was agreed to.

The bill (S. 1881), as amended, was read the third time and passed.

COMMEMORATING THE 25TH ANNIVERSARY OF VIETNAM VETERANS OF AMERICA

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Judiciary Committee be discharged from further consideration of S. Res. 120 and that the Senate proceed to its immediate consideration.

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

The assistant legislative clerk read as follows:

A resolution (S. Res. 120) commemorating the 25th anniversary of Vietnam Veterans of America.

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

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motion to reconsider be laid upon the table, with no intervening action or debate, and that any statements relating to the measure be printed in the RECORD.

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

The resolution (S. Res. 120) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 120

Whereas the year 2003 marks the 25th anniversary of the founding of Vietnam Veterans of America;

Whereas the history of Vietnam Veterans of America is a story of the United States' gradual recognition of the tremendous sacrifices of its Vietnam-era veterans and their families;

Whereas Vietnam Veterans of America is dedicated to advocating on behalf of its members;

Whereas Vietnam Veterans of America raises public and member awareness of critical issues affecting Vietnam-era veterans and their families;

Whereas the local grassroots efforts of Vietnam Veterans of America chapters, such as Chapter One in Rutland, Vermont, which was founded 23 years ago in April of 1980, have greatly contributed to the quality of the lives of veterans in our Nation's communities;

Whereas Vietnam Veterans of America promotes its principles through volunteerism, professional advocacy, and claims work; and

Whereas the future of Vietnam Veterans of America will rely not only on its past accomplishments, but also on the future accomplishments of its members, and these will ensure that Vietnam Veterans of America remains a leader among veterans advocacy organizations: Now, therefore, be it