The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from California (Mr. OSE) that the House suspend the rules and pass the bill, H.R. 1385, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mr. OSE. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

MEDICAL DEVICES TECHNICAL CORRECTIONS ACT

Mr. GREENWOOD. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3493) 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, as amended.

The Clerk read as follows:

H.R. 3493

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)(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 (5)(B), in the first sentence, by inserting after ''standards of accreditation,'' the following: ''or where the Secretary has information indicating that the relationship between the establishment and the accredited person may create a conflict of interest,'';

(C) 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 ''identified under subclause (II) of this clause'' and inserting ''identified under clause (ii)(II) as a person authorized to conduct inspections of device establishments''; 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'';

(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''; and

(vi) by adding at the end the following clause:

''(v) The eligibility of the establishment for inspections by accredited persons has not been suspended under subparagraph (B)(iv)(II).'';

(D) 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'';

(ii) in the second sentence—

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

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

(iii)(I) by inserting ''(I)'' after ''(iii)'';

(II) by adding at the end the following subclause:

''(II) In making a decision under this paragraph, the Secretary may consider any information relevant to the establishment's compliance with any provision of this Act. Nothing in the preceding sentence shall be construed to expand the Secretary's inspectional authority under subsection (a).'';

(E) in paragraph (6)(B)(iv)—

(i) by inserting ''(I)'' after ''(iv)''; and

(ii) by adding at the end the following subclause:

''(II) If, during the two-year period following clearance under subparagraph (A) with respect to a device establishment, the Secretary obtains information indicating significant deviations from compliance with this Act or implementing regulations, the Secretary may, after notice and an opportunity for a written response, notify the establishment that the eligibility of the establishment for inspections by accredited person has been suspended.'';

(F) 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'';

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

(H) 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.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Pennsylvania (Mr. GREENWOOD) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Pennsylvania (Mr. GREENWOOD).

GENERAL LEAVE

Mr. GREENWOOD. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and insert extraneous material on H.R. 3493.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

Mr. GREENWOOD. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, H.R. 3493 is a bill that I introduced with the gentlewoman from California (Ms. ESHOO), which seeks to make technical and clarifying amendments to the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). That bill, which was signed into law by President Bush on October 26, 2002, made sweeping changes to the laws that govern medical device approvals to establish new programs and streamline processes to accelerate the availability of medical devices to patients. For example, MDUFMA established a user fee program that will provide substantial new resources to speed up the approval of the medical devices. It streamlined the approval of combination products such as drug-coated stents which are one of the most exciting new areas of technology. It expanded the role of third parties and outside experts to augment the FDA resources to help FDA meet its beneficial manufacturing inspection requirements; and MDUFMA also extended the use of third-party review programs for 1 year so that it expires in conjunction with other device provisions.

The legislation before us today amends the Medical Device User Fee Modernization Act to ensure that it is being implemented properly. While some of the amendments are truly technical, others clarify the intentions of Congress. For example, this legislation ensures that the user fee reductions that apply to small businesses apply for 2004 and years in the future. In addition, the legislation clarifies that as part of the third-party inspection program, companies must submit reports of inspectional findings consistent with current FDA practices.

□ 1445

H.R. 3493 clarifies which data need to be submitted for a firm to be eligible for third-party inspection.

Medical devices are some of our health care system's most remarkable innovations. The provisions in this technical and clarifying amendments bill will allow the FDA to continue to reduce review times, increase the efficiency of its operations and allow these wonderful technologies to be delivered to patients more quickly.

I want to thank the gentleman from Louisiana (Mr. TAUZIN), the gentleman from Florida (Mr. BILIRAKIS), the gentleman from Michigan (Mr. DINGELL) and the gentleman from Ohio (Mr. BROWN) as well as the gentleman from California (Mr. WAXMAN) and each of their staffs for this legislation. This has been another outstanding example of teamwork and bipartisanship on the part of the Committee on Energy and Commerce.

Mr. Speaker, I urge a ''yes'' vote on this bill.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

I am pleased to support this legislation which is intended to, and will,

help ensure that FDA's medical device user fee and third-party review programs operate as intended. The goal of these programs is to promote timely access to medical devices without compromising FDA's ability to properly evaluate both the safety and the effectiveness of those devices. Successful bipartisan negotiations produced the authorizing legislation for these programs, and it is the same with this follow-up measure today.

I commend the gentlewoman from California (Ms. ESHOO) and the gentleman from Pennsylvania (Mr. GREENWOOD) as well as the gentleman from Louisiana (Mr. TAUZIN), the gentleman from Michigan (Mr. DINGELL) and the gentleman from Florida (Mr. BILIRAKIS), the subcommittee Chair, for their leadership on this successful committee effort. Unfortunately, the need for noncontroversial technical corrections is not the only obstacle preventing the medical device user fee program from fulfilling its potential. It is important for colleagues on both sides of the aisle to be aware that continuation of the user fee program, and it is this program that enables patients to receive cutting-edge medical devices on a timely basis, the continuation of the user fee program does in fact hinge on the appropriations process.

User fees do no incremental good if they supplant, rather than supplement, Federal spending. As in the successful prescription drug user fee program, the continuation of user fees depends on sufficient annual appropriations. Last year's appropriation for medical device reviews was insufficient to sustain the medical device user fee program in an optimal way. If this year's appropriation does not address that shortfall, the user fee program will likely fold.

Hard work went into establishing this program. The existence of the program enables patients more timely access to medical devices at no additional cost to American taxpayers. We need to make sure the program does not indeed fold.

I hope the President's budget includes sufficient funding for the user fee program, and I hope we follow through by allocating sufficient dollars to keep this program alive.

Mr. Speaker, I reserve the balance of my time.

Mr. GREENWOOD. Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield 5 minutes to the gentlewoman from California (Ms. ESHOO), one of the architects of this bill.

Ms. ESHOO. Mr. Speaker, I thank our distinguished ranking member and my colleague, the gentleman from Pennsylvania (Mr. GREENWOOD) who, together we introduced this legislation, H.R. 3493. I appreciate always his cooperation and that of his staff. This is not the first effort where we have worked together and been successful. We are proud of that and proud of the work that has come out of our committee.

This bill makes important technical corrections. While it may seem a little dull and dry, the technical corrections really enhance the Medical Device User Fee and Modernization Act which was a very important piece of legislation which allowed major new programs that really streamline the Food and Drug Administration's medical device approval process to be actually implemented. This bipartisan bill is about making sure that patients are, one, able to safely benefit from new medical technologies and, secondly, as quickly as possible. As medical technologies become more advanced, it takes more attention and resources to ensure that these products are safe and effective.

Last year, the House overwhelmingly passed the Medical Device User Fee and Modernization Act which helps the FDA get lifesaving products to patients faster, as well as resources to the agency to assure this. Specifically under that law, and I think it is important to underscore what was in that law and why we are bolstering it, the importance of bolstering it today, the medical device industry agreed to pay fees to the FDA for every product it proposes to market. These fees will help the FDA hire additional staff, much needed, I might add, and to purchase needed equipment so that they can review the products on a timely basis.

Secondly, the resources were increased for additional inspections of manufacturing plants and facilities, a very, very important part of that legislation, as well as the creation of an Office of Combination Products to shepherd advanced products, such as devices with drug coating, through the approval process. This new administrative flexibility allows the FDA to devote its resources to the devices that patients need most.

Finally, the bill created a way to regulate what are known as reprocessed devices. Some people may have tuned into nationally televised programs where the national discovery was made that reprocessed devices were being used in hospitals unbeknownst to doctors and unbeknownst to patients. I did not like that when I heard it, and we addressed it in the bill.

The bill requires that reprocessed products undergo additional scrutiny by the FDA and that they be held to the highest standards that the FDA can apply. It also required that doctors, who are often unaware that they are using a reprocessed device, be informed about the reused device so that they can, in turn, inform their patients about the reused device.

This Technical Corrections Act is an important bill because it is ultimately, Mr. Speaker, about patients, and it will implement the Medical Device User Fee and Modernization Act as Congress fully intended.

One of the best parts of doing something like this is to work with the very able people that helped make it possible, so I want to thank the gentleman from Louisiana (Mr. TAUZIN), chairman of our full committee; the gentleman from Florida (Mr. BILIRAKIS), our distinguished subcommittee chairman; the gentleman from Michigan (Mr. DINGELL), ranking member of our full committee; the gentleman from California (Mr. WAXMAN) and certainly my colleague, who is the ranking member of the Subcommittee on Health.

I also want to thank several staff people: Pat Ronan of Chairman TAUZIN's staff; Alan Eisenberg of the office of the gentleman from Pennsylvania (Mr. GREENWOOD); John Ford of the office of the gentleman from Michigan (Mr. DINGELL); and Anne Witt of the office of the gentleman from California (Mr. WAXMAN). Without all of these good people, we would not be here today doing this. So we have come a long way, and I think we have created something that will serve our country very well.

I urge all of my colleagues to vote for this, to make it unanimous. We will then accomplish yet something else very good and important for the American people.

Mr. BROWN of Ohio. Mr. Speaker, I yield back the balance of my time.

Mr. GREENWOOD. Mr. Speaker, I yield myself the balance of my time.

I also would like to thank my very able staff member, Mr. Alan Eisenberg, for his tireless work on this and so many other issues.

Ms. JACKSON-LEE of Texas, Mr. Speaker, I rise today as a supporter of H.R. 3493 which amends Federal Food, Drug, and Cosmetic Act. This legislation is necessary to clarify certain provisions relating to the Medical Device User Fee and Modernization Act of 2002. I am pleased to see that this bill enjoys broad bipartisan support in this body after it was passed by unanimous consent in the Senate. It is imperative that we continually update and rework the regulations that govern the use of our Nation's medical devices.

I would also like to recognize my distinguished colleague Representative SHERROD BROWN and affirm his view on the necessity of providing additional appropriations funding for the Medical Device User Program. In the last series of appropriations this vital program was under funded and was left with a potentially dangerous mandate. While H.R. 3493 is a timely bill, we must make sure to provide the necessary resources for all medical device programs in order to make this legislation truly effective.

Mr. ENGEL. Mr. Speaker, I rise today in support of the Medical Devices Technical Corrections Act. This bipartisan legislation makes technical corrections to the Medical Device User Fee and Modernization Act of 2002, which I was proud to cosponsor.

The Medical Device User Fee and Modernization Act has several key components that will result in a better, more efficient process in which the Food and Drug Administration works with medical device companies to review applications, inspect device plants, and ensure that reprocessed devices are used in a safe and identifiable fashion. The user fees included in the legislation are intended to provide FDA with additional resources to review new or updated device applications more quickly, but also more effectively. Every day,

medical devices save or improve the lives of patients around the world and this legislation will mean that patients will have access to new and improved devices in a much timelier fashion.

Mr. Speaker, the manner in which the Energy and Commerce Committee worked to enact the original bill and the legislation before us today should be a model for future legislative efforts. Because of the truly bipartisan process, the Medical Device User Fee and Modernization Act enjoys widespread support which will work to ensure its success. I commend the medical device community and my colleagues for their efforts to improve the delivery of health care to millions of Americans.

Mr. GREENWOOD. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from Pennsylvania (Mr. GREENWOOD) that the House suspend the rules and pass the bill, H.R. 3493, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mr. GREENWOOD. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

AUTHORIZING THE SPEAKER TO DECLARE A RECESS ON WEDNESDAY, FEBRUARY 4, 2004, FOR THE PURPOSE OF RECEIVING IN JOINT MEETING HIS EXCELLENCY JOSE MARIA AZNAR, PRESIDENT OF THE GOVERNMENT OF SPAIN

Mr. GREENWOOD. Mr. Speaker, I ask unanimous consent that it may be in order at any time on Wednesday, February 4, 2004, for the Speaker to declare a recess, subject to the call of the Chair, for the purpose of receiving in joint meeting His Excellency Jose Maria Aznar, President of the Government of Spain.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 2 o'clock and 54 minutes p.m.), the House stood in recess subject to the call of the Chair.

□ 1831

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mrs. BIGGERT) at 6 o'clock and 31 minutes p.m.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF S. 610, NASA WORKFORCE FLEXIBILITY ACT OF 2003

Mr. LINCOLN DIAZ-BALART of Florida from the Committee on Rules, submitted a privileged report (Rept. No. 108–406) on the resolution (H. Res. 502) providing for consideration of the Senate bill (S. 610) to amend the provisions of title 5, United States Code, to provide for workforce flexibilities and certain Federal personnel provisions relating to the National Aeronautics and Space Administration, and for other purposes, which was referred to the House Calendar and ordered to be printed.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF S. 1920, BANKRUPTCY ABUSE PREVENTION AND CONSUMER PROTECTION ACT OF 2004

Mr. LINCOLN DIAZ-BALART of Florida, from the Committee on Rules, submitted a privileged report (Rept. No. 108–407) on the resolution (H. Res. 503) providing for consideration of the Senate bill (S. 1920) to extend for 6 months the period for which chapter 12 of title 11 of the United States Code is reenacted, which was referred to the House Calendar and ordered to be printed.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will resume on motions to suspend the rules previously postponed.

Votes will be taken in the following order:

H.R. 1385, by the yeas and nays; and

H.R. 3493, by the yeas and nays.

The first electronic vote will be conducted as a 15-minute vote; the second will be conducted as a 5-minute vote.

BREAST CANCER STAMP EXTENSION

The SPEAKER pro tempore. The pending business is the question of suspending the rules and passing the bill, H.R. 1385, as amended.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from California (Mr. OSE) that the House suspend the rules and pass the bill, H.R. 1385, as amended, on which the yeas and nays are ordered.

The vote was taken by electronic device, and there were—yeas 331, nays 1, not voting 100, as follows:

[Roll No. 6]

YEAS—331

Aderholt
Akin
Allen
Andrews
Baca
Baird
Baker
Baldwin
Barrett (SC)
Bartlett (MD)
Barton (TX)
Bass
Beauprez
Becerra
Bell
Bereuter
Berkley
Berman
Berry
Biggert
Bilirakis
Bishop (GA)
Bishop (NY)
Bishop (UT)
Blackburn
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonner
Boswell
Boyd
Bradley (NH)
Brady (TX)
Brown (OH)
Brown (SC)
Brown-Waite, Ginny
Burgess
Burns
Burton (IN)
Cannon
Cantor
Capito
Capps
Cardin
Cardoza
Carson (IN)
Case
Castle
Chabot
Chocola
Clay
Coble
Cole
Collins
Conyers
Cooper
Cox
Cramer
Crane
Crenshaw
Crowley
Cubin
Davis (AL)
Davis (CA)
Davis (FL)
Davis (IL)
Davis (TN)
Davis, Tom
Deal (GA)
DeLauro
DeLay
Deutsch
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Dooley (CA)
Doyle
Dreier
Dunn
Edwards
Ehlers
Emanuel
Emerson
Engel
Eshoo
Etheridge
Evans
Everett
Farr
Feeney
Ferguson
Filner
Flake
Foley
Fossella
Frank (MA)
Franks (AZ)
Frelinghuysen
Garrett (NJ)
Gerlach
Gibbons
Gilchrest
Gillmor
Gingrey
Gonzalez
Goode
Goodlatte
Gordon
Goss
Granger
Graves
Green (TX)
Green (WI)
Greenwood
Grijalva
Gutierrez
Hall
Harman
Harris
Hart
Hastings (WA)
Hayes
Hayworth
Hefley
Hensarling
Herger
Hill
Hinchey
Hinojosa
Hoeffel
Hoekstra
Holden
Holt
Hooley (OR)
Hostettler
Houghton
Hoyer
Hulshof
Inslee
Isakson
Issa
Istook
Jackson (IL)
Jackson-Lee (TX)
Jefferson
John
Johnson (CT)
Johnson, E. B.
Johnson, Sam
Jones (OH)
Kanjorski
Kaptur
Keller
Kelly
Kennedy (MN)
Kennedy (RI)
Kildee
Kilpatrick
Kind
King (IA)
King (NY)
Kirk
Kline
Knollenberg
Kolbe
LaHood
Lampson
Langevin
Larsen (WA)
Larson (CT)
Latham
Lee
Levin
Lewis (GA)
Lewis (KY)
Linder
LoBiondo
Lofgren
Lowey
Lucas (KY)
Lucas (OK)
Lynch
Majette
Maloney
Manzullo
Markey
Marshall
Matheson
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCotter
McCrery
McDermott
McGovern
McHugh
McInnis
McKeon
McNulty
Meehan
Meek (FL)
Menendez
Mica
Michaud
Millender-McDonald
Miller (FL)
Miller, Gary
Moore
Moran (KS)
Moran (VA)
Murphy
Musgrave
Myrick
Napolitano
Neal (MA)
Nethercutt
Neugebauer
Ney
Norwood
Nunes
Nussle
Oberstar
Obey
Olver
Osborne
Ose
Otter
Oxley
Pallone
Pascrell
Pastor
Pearce
Pelosi
Pence
Peterson (MN)
Peterson (PA)
Petri
Pickering
Pitts
Platts
Pomeroy
Porter
Portman
Pryce (OH)
Putnam
Quinn
Radanovich
Rahall
Ramstad
Rangel
Regula
Rehberg
Renzi
Reynolds
Rogers (AL)
Rogers (MI)
Ros-Lehtinen
Ross
Ruppersberger
Ryan (WI)
Ryun (KS)
Sanchez, Loretta
Sanders
Saxton
Schakowsky
Schiff
Schrock
Scott (VA)
Sensenbrenner
Sessions
Shadegg
Shaw
Shays
Sherman
Sherwood
Shimkus
Shuster
Simmons
Simpson
Skelton
Smith (MI)
Smith (NJ)