

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

The amendment (No. 1646) was agreed to, as follows:

(Purpose: To specify that no Federal funds are to be used to establish, construct, or operate the National Women's History Museum)

At the end, add the following:

SEC. 6. FEDERAL PARTICIPATION.

The United States shall pay no expense incurred in the establishment, construction, or operation of the National Women's History Museum, which shall be operated and maintained by the Museum Sponsor after completion of construction.

The bill (S. 501), as amended, was read the third time and passed.

(The bill will be printed in a future edition of the RECORD.)

REGULATION OF CONTACT LENSES AS MEDICAL DEVICES

Mr. FRIST. I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 177, S. 172.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

A bill (S. 172) to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes.

There being no objection, the Senate proceeded to consider the bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes, which had been reported from the Committee on Health, Education, Labor, and Pensions, with an amendment.

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

S. 172

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

SECTION 1. FINDINGS.

[Congress finds as follows:

“(1) All contact lenses have significant effects on the eye and pose serious potential health risks if improperly manufactured or used without appropriate involvement of a qualified eye care professional.

“(2) Most contact lenses currently marketed in the United States, including certain plano and decorative contact lenses, have been approved as medical devices pursuant to premarket approval applications or cleared pursuant to premarket notifications by the Food and Drug Administration (“FDA”).

“(3) FDA has asserted medical device jurisdiction over most corrective and noncorrective contact lenses as medical devices currently marketed in the United States, including certain plano and decorative contact lenses, so as to require approval pursuant to premarket approval applications or clearance pursuant to premarket notifications.

“(4) All contact lenses can present risks if used without the supervision of a qualified eye care professional. Eye injuries in children and other consumers have been reported for contact lenses that are regulated by FDA as medical devices primarily when used without professional involvement, and noncorrective contact lenses sold without approval or clearance as medical devices have caused eye injuries in children.

SECTION 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL DEVICES.

[Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

“(Regulation of Contact Lens as Devices

“(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

“(2) Paragraph 1 shall not be construed as having any legal effect on any article that is not described in that paragraph.”.]

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Congress finds as follows:

(1) All contact lenses have significant effects on the eye and pose serious potential health risks if improperly manufactured or used without appropriate involvement of a qualified eye care professional.

(2) Most contact lenses currently marketed in the United States, including certain plano and decorative contact lenses, have been approved as medical devices pursuant to premarket approval applications or cleared pursuant to premarket notifications by the Food and Drug Administration (“FDA”).

(3) FDA has asserted medical device jurisdiction over most corrective and noncorrective contact lenses as medical devices currently marketed in the United States, including certain plano and decorative contact lenses, so as to require approval pursuant to premarket approval applications or clearance pursuant to premarket notifications.

(4) All contact lenses can present risks if used without the supervision of a qualified eye care professional. Eye injuries in children and other consumers have been reported for contact lenses that are regulated by FDA as medical devices primarily when used without professional involvement, and noncorrective contact lenses sold without approval or clearance as medical devices have caused eye injuries in children.

SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

“(Regulation of Contact Lens as Devices

“(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

“(2) Paragraph (1) shall not be construed as having any legal effect on any article that is not subject to such paragraph.”.

Mr. FRIST. I ask unanimous consent that the DeWine amendment be agreed to, the committee-reported amendment, as amended, 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 amendment (No. 1647) was agreed to, as follows:

(Purpose: To provide a complete substitute)

In lieu of the matter to be inserted, insert the following:

SECTION 1. REGULATION OF CERTAIN ARTICLES AS MEDICAL DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following subsection:

“(Regulation of Contact Lens as Devices

“(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

“(2) Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 201(h) or a drug as defined by section 201(g).”.

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

The bill (S. 172), as amended, was passed.

APPOINTMENT

The PRESIDING OFFICER. The Chair, on behalf of the President pro tempore, and upon the recommendation of the majority leader, pursuant to 22 U.S.C. 2761, as amended, appoints the following individuals as delegates of the Senate Delegation to the British-American Interparliamentary Group conference during the 109th Congress: the Honorable JUDD GREGG of New Hampshire; and the Honorable PAT ROBERTS of Kansas.

AUTHORITY FOR COMMITTEES TO REPORT

Mr. FRIST. I ask unanimous consent that notwithstanding the Senate's adjournment, committees be authorized to report legislative and executive matters on Wednesday, August 31, from 10 a.m. to 12 noon.

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

AUTHORITY TO MAKE APPOINTMENTS

Mr. FRIST. I ask unanimous consent that notwithstanding the upcoming recess or adjournment of the Senate, the President of the Senate, the President pro tempore, and the majority and minority leaders be authorized to make appointments to commissions, committees, boards, conferences or interparliamentary conferences authorized by law, by concurrent action of the two Houses or by order of the Senate.

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

ORDERS FOR TUESDAY, SEPTEMBER 6, 2005

Mr. FRIST. I ask unanimous consent that when the Senate completes its business today, it stand in adjournment under the provisions of H. Con. Res. 225 until 12 noon on Tuesday, September 6.

I further ask that following the prayer and the pledge, the morning hour be deemed expired, the Journal of proceedings be approved to date, the time for the two leaders be reserved, and there then be a period for morning business until 12:30, with Senators permitted to speak for up to 5 minutes each; provided further that the Senate stand in recess from 12:30 to 2:15 for weekly policy luncheons.

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

UNANIMOUS CONSENT AGREEMENT—MOTION TO PROCEED TO S. 147

Mr. FRIST. I ask unanimous consent that at 2:15, the Senate resume the motion to proceed to S. 147, the Native Hawaiians bill.