# Calendar No. 177

109TH CONGRESS
1ST SESSION

# S. 172

**[Report No. 109–110]**

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.

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IN THE SENATE OF THE UNITED STATES

JANUARY 26, 2005

Mr. DEWINE (for himself, Mr. KENNEDY, Mr. ENZI, Mr. DORGAN, Ms. COLLINS, Mr. HARKIN, Mr. BURR, Mr. BUNNING, Mr. CORZINE, and Mr. VOINOVICH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 27, 2005

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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# A 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.

*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.~~

**~~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 described in that paragraph.''.~~

***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.*

***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.".*

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