

109TH CONGRESS
1ST SESSION

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.

IN THE SENATE OF THE UNITED STATES

JANUARY 26, 2005

Mr. DEWINE (for himself and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. FINDINGS.**

4 Congress finds as follows:

5 (1) All contact lenses have significant effects on
6 the eye and pose serious potential health risks if im-
7 properly manufactured or used without appropriate
8 involvement of a qualified eye care professional.

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

7 (3) FDA has asserted medical device jurisdic-
8 tion over most corrective and noncorrective contact
9 lenses as medical devices currently marketed in the
10 United States, including certain plano and decora-
11 tive contact lenses, so as to require approval pursu-
12 ant to premarket approval applications or clearance
13 pursuant to premarket notifications.

14 (4) All contact lenses can present risks if used
15 without the supervision of a qualified eye care pro-
16 fessional. Eye injuries in children and other con-
17 sumers have been reported for contact lenses that
18 are regulated by FDA as medical devices primarily
19 when used without professional involvement, and
20 noncorrective contact lenses sold without approval or
21 clearance as medical devices have caused eye injuries
22 in children.

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

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

6 “Regulation of Contact Lens as Devices

7 “(n)(1) All contact lenses shall be deemed to be de-
8 vices under section 201(h).

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

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