

108TH CONGRESS
1ST SESSION

H. R. 2218

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of noncorrective contact lens as medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 22, 2003

Mr. BOOZMAN (for himself, Mr. WAXMAN, Mr. NORWOOD, Mr. SNYDER, Mr. FLETCHER, Mr. WELDON of Florida, Mr. BURGESS, and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of noncorrective contact lens 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 The Congress finds as follows:

5 (1) Both corrective and noncorrective contact
6 lenses have significant effects on the eye and pose
7 serious potential health risks if improperly manufac-

1 tured or used without the supervision of a qualified
2 eyecare practitioner.

3 (2) Noncorrective lenses sold outside the protec-
4 tions of medical device regulation have caused eye
5 injuries in children.

6 (3) Both corrective and noncorrective lenses
7 have been approved as medical devices by the Food
8 and Drug Administration (“FDA”).

9 (4) FDA has until recently publicly claimed ju-
10 risdiction over both corrective and noncorrective con-
11 tact lenses as medical devices.

12 **SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL**
13 **DEVICES.**

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

17 “Regulation of Contact Lens as Devices

18 “(n)(1) Both corrective and noncorrective contact
19 lenses and similar articles shall be considered devices
20 under section 201(h).

21 “(2) With respect to an article that is not described
22 in paragraph (1), such paragraph may not be construed
23 as having any legal effect on any determination by the

- 1 Secretary of whether the article is a food, a drug, a device,
- 2 or a cosmetic.”.

