

114TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

To provide for the regulation of over-the-counter hearing aids.

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IN THE SENATE OF THE UNITED STATES

Ms. WARREN (for herself and Mr. GRASSLEY) introduced the following bill;  
which was read twice and referred to the Committee on

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**A BILL**

To provide for the regulation of over-the-counter hearing  
aids.

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. SHORT TITLE.**

4 This Act may be cited as the “Over-the-Counter  
5 Hearing Aid Act of 2016”.

6 **SEC. 2. REGULATION OF OVER-THE-COUNTER HEARING**  
7 **AIDS.**

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

1           “(o) REGULATION OF OVER-THE-COUNTER HEARING  
2 AIDS.—

3           “(1) DEFINITION.—In this subsection, the term  
4 ‘over-the-counter hearing aid’ means a device—

5                   “(A) that uses the same fundamental sci-  
6 entific technology as air conduction hearing  
7 aids (as defined in section 874.3300 of title 21,  
8 Code of Federal Regulations) (or any successor  
9 regulation) or wireless air conduction hearing  
10 aids (as defined in section 874.3305 of title 21,  
11 Code of Federal Regulations) (or any successor  
12 regulation);

13                   “(B) that is intended to be used by adults  
14 to compensate for mild to moderate hearing im-  
15 pairment;

16                   “(C) that includes tools to allow the user  
17 to control the over-the-counter hearing aid and  
18 customize it to the user’s hearing needs;

19                   “(D) that may—

20                           “(i) use wireless technology; or

21                           “(ii) include tests for self-assessment  
22 of hearing loss; and

23                   “(E) that is available over-the-counter,  
24 without the supervision, prescription, or other  
25 order, involvement, or intervention of a licensed

1 person, to consumers through in-person trans-  
2 actions, by mail, or online.

3 “(2) REGULATION.—An over-the-counter hear-  
4 ing aid shall be subject to the regulations promul-  
5 gated in accordance with section 2(b) of the Over-  
6 the-Counter Hearing Aid Act of 2016 and shall be  
7 exempt from sections 801.420 and 801.421 of title  
8 21, Code of Federal Regulations (or any successor  
9 regulations).”.

10 (b) REGULATIONS TO ESTABLISH CATEGORY.—

11 (1) IN GENERAL.—The Secretary of Health and  
12 Human Services (referred to in this section as the  
13 “Secretary”), not later than 3 years after the date  
14 of enactment of this Act, shall promulgate proposed  
15 regulations to establish a category of over-the-  
16 counter hearing aids, as defined in subsection (o) of  
17 section 520 of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 360j) as amended by sub-  
19 section (a), and, not later than 180 days after the  
20 date on which the proposed regulations are issued,  
21 shall issue such final regulations.

22 (2) REQUIREMENTS.—In promulgating the reg-  
23 ulations under paragraph (1), the Secretary shall—

24 (A) include requirements that provide rea-  
25 sonable assurances of the safety and efficacy of

1 over-the-counter hearing aids, such as appro-  
2 priate consumer labeling; and

3 (B) describe the requirements under which  
4 the sale of over-the-counter hearing aids is per-  
5 mitted, without the supervision, prescription, or  
6 other order, involvement, or intervention of a li-  
7 censed person, to consumers through in-person  
8 transactions, by mail, or online.

9 (3) **PREMARKET NOTIFICATION.**—The Sec-  
10 retary shall make findings under section 510(m) of  
11 the Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 360(m)) to determine whether over-the-  
13 counter hearing aids (as defined in section 520(o) of  
14 the Federal Food, Drug, and Cosmetic Act (21  
15 U.S.C. 360j(o)), as amended by subsection (a)) re-  
16 quire a report under section 510(k) to provide rea-  
17 sonable assurance of safety and effectiveness.

18 (4) **EFFECT ON STATE LAW.**—No State or local  
19 government shall establish or continue in effect any  
20 law, regulation, order, or other requirement related  
21 to the manufacturing, marketing, sale, customer  
22 support, or distribution of over-the-counter hearing  
23 aids (as defined in section 520(o) of the Federal  
24 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)),  
25 as amended by subsection (a)) through in-person

1 transactions, by mail, or online, that is different  
2 from, in addition to, or otherwise not identical to,  
3 the regulations promulgated under this subsection.

4 (c) GUIDANCE.—

5 (1) WITHDRAWAL OF GUIDANCE.—

6 (A) WITHDRAWAL.—Effective as of the  
7 date of enactment of this Act, the Secretary  
8 shall not use the draft guidance of the Depart-  
9 ment of Health and Human Services entitled,  
10 “Regulatory Requirements for Hearing Aid De-  
11 vices and Personal Sound Amplification Prod-  
12 ucts”, issued on November 7, 2013, as the  
13 basis for any premarket review under the Fed-  
14 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
15 301 et seq.) or for any related compliance or  
16 enforcement decisions or actions.

17 (B) INTERIM GUIDANCE.—Until such time  
18 as new final guidance is issued under paragraph  
19 (2) to replace the guidance described in sub-  
20 paragraph (A), the draft guidance entitled  
21 “Guidance for Industry and FDA Staff: Regu-  
22 latory Requirements for Hearing Aid Devices  
23 and Personal Sound Amplification Products,”  
24 issued on February 25, 2009, shall be in effect.

1           (2) NEW GUIDANCE ISSUED.—Not later than  
2           the date on which final regulations are issued under  
3           subsection (b), the Secretary shall update the draft  
4           guidance described in paragraph (1)(A). Such up-  
5           dated guidance shall clarify which products, on the  
6           basis of claims or other marketing, advertising, or  
7           labeling material, meet the definition of a device, as  
8           defined in section 201 of the Federal Food, Drug,  
9           and Cosmetic Act (21 U.S.C. 321) and which prod-  
10          ucts meet the definition of a personal sound amplifi-  
11          cation product, as set forth in such guidance.