

117TH CONGRESS
2D SESSION

S. 4333

To deem certain products regulated by the Food and Drug Administration
as drugs.

IN THE SENATE OF THE UNITED STATES

MAY 26, 2022

Ms. SMITH (for herself and Mr. MARSHALL) introduced the following bill;
which was read twice and referred to the Committee on Health, Edu-
cation, Labor, and Pensions

A BILL

To deem certain products regulated by the Food and Drug
Administration as drugs.

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 “Consistent Legal Eval-
5 uation And Regulation of Medical Products Act” or the
6 “CLEAR Act”.

7 **SEC. 2. REGULATION OF CERTAIN PRODUCTS AS DRUGS.**

8 (a) IN GENERAL.—Section 503 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 353) is amended by
10 adding at the end the following:

1 “(h) DEEMING CERTAIN PRODUCTS AS DRUGS.—

2 “(1) IN GENERAL.—Any contrast agent, radio-
3 active drug, OTC monograph drug, or ophthalmic
4 drug article shall be deemed to be a drug under sec-
5 tion 201(g) and not a device under section 201(h).

6 “(2) DEFINITIONS.—For purposes of this sub-
7 section—

8 “(A) the term ‘contrast agent’ means an
9 article that is intended for use in conjunction
10 with an applicable medical imaging device,
11 and—

12 “(i) is a diagnostic radiopharma-
13 ceutical, as defined in section 315.2 and
14 601.31 of title 21, Code of Federal Regula-
15 tions (or any successor regulations); or

16 “(ii) is a diagnostic agent that im-
17 proves the visualization of structure or
18 function within the body by increasing the
19 relative difference in signal intensity within
20 the target tissue, structure, or fluid;

21 “(B) the term ‘ophthalmic drug article’
22 means any eye cup, eye dropper, or other non-
23 invasive and non-implanted dispenser intended
24 for ophthalmic use if packaged with the drug
25 with which such article is intended to be used;

1 “(C) the term ‘OTC monograph drug’ has
2 the meaning given such term in section 744L;
3 and

4 “(D) the term ‘radioactive drug’ has the
5 meaning given such term in section 310.3(n) of
6 title 21, Code of Federal Regulations (or any
7 successor regulations), except that such term
8 does not include—

9 “(i) implants or articles similar to an
10 implant;

11 “(ii) articles that apply radiation from
12 outside of the body; or

13 “(iii) the radiation source of an article
14 described in clause (i) or (ii).

15 “(3) NO EFFECT ON DETERMINATIONS RE-
16 GARDING OTHER DRUGS OR DEVICES.—Paragraph
17 (1) shall not be construed as bearing on, or being
18 relevant to, the question of whether any product
19 other than a drug described in such paragraph is a
20 device as defined by section 201(h) or a drug as de-
21 fined by section 201(g).”.

22 (b) APPLICATION.—The amendment made by sub-
23 section (a) shall apply to any application submitted under
24 subsection (b) or (j) of section 505 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 355) and to any appli-

1 cation submitted under subsection (a) or (k) of section
2 351 of the Public Health Service Act (42 U.S.C. 262),
3 whether such submission was prior to, on, or after the date
4 of enactment of this Act, and shall apply to all actions
5 pending on the day of enactment of this Act.

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