II

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, Education, Labor, and Pensions

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Consistent Legal Evaluation And Regulation of Medical Products Act'' or the ''CLEAR Act''.

SEC. 2. REGULATION OF CERTAIN PRODUCTS AS DRUGS.

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

''(h) DEEMING CERTAIN PRODUCTS AS DRUGS.—

''(1) IN GENERAL.—Any contrast agent, radioactive drug, OTC monograph drug, or ophthalmic drug article shall be deemed to be a drug under section 201(g) and not a device under section 201(h).

''(2) DEFINITIONS.—For purposes of this subsection—

''(A) the term 'contrast agent' means an article that is intended for use in conjunction with an applicable medical imaging device, and—

''(i) is a diagnostic radiopharmaceutical, as defined in section 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations); or

''(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid;

''(B) the term 'ophthalmic drug article' means any eye cup, eye dropper, or other non-invasive and non-implanted dispenser intended for ophthalmic use if packaged with the drug with which such article is intended to be used;

''(C) the term 'OTC monograph drug' has the meaning given such term in section 744L; and

''(D) the term 'radioactive drug' has the meaning given such term in section 310.3(n) of title 21, Code of Federal Regulations (or any successor regulations), except that such term does not include—

''(i) implants or articles similar to an implant;

''(ii) articles that apply radiation from outside of the body; or

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

''(3) NO EFFECT ON DETERMINATIONS REGARDING OTHER DRUGS OR DEVICES.—Paragraph (1) shall not be construed as bearing on, or being relevant to, the question of whether any product other than a drug described in such paragraph is a device as defined by section 201(h) or a drug as defined by section 201(g).''.

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

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

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