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115TH CONGRESS
1ST SESSION

H. R. 2009

To amend the Federal Food, Drug, and Cosmetic Act to provide clarity with respect to the regulation of diagnostic imaging devices intended for use with contrast agents.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2017

Mr. COSTELLO of Pennsylvania (for himself and Mr. PETERS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide clarity with respect to the regulation of diagnostic imaging devices intended for use with contrast agents.

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 ''Fostering Innovation in Medical Imaging Act of 2017''.

SEC. 2. APPROVAL OF APPLICATIONS FOR CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j) is amended by adding at the end the following:

''Diagnostic Imaging Devices Intended for Use With Contrast Agents

''(p)(1) The Secretary may, subject to the succeeding provisions of this subsection, approve an application (or supplement to such an application) submitted under section 515 with respect to an applicable medical imaging device, or, in the case of an applicable medical imaging device for which a notification was submitted under section 510(k) (or a supplement to such a notification), may make a substantial equivalence determination with respect to such applicable medical imaging device, if the indications and conditions of use proposed in such application or notification do not involve the use of a contrast agent—

''(A) in a concentration, rate of administration, or route of administration that is different from those described in the approved labeling of the contrast agent;

''(B) in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, unless the Secretary determines, based on information contained in

the application or notification involved, that the difference does not reduce the safety of the contrast agent when used with the device;

''(C) in a new patient population for which the contrast agent is determined by the Secretary to pose an increased risk; or

''(D) in an imaging modality (such as an ultrasonic, ionizing radiation, or magnetic resonance imagine modality) that is different from those described in the approved labeling of the contrast agent.

''(2) The agency center charged with premarket review of devices shall have primary jurisdiction with respect to the review of an application or notification described in paragraph (1). In conducting such review, such agency center may—

''(A) consult with the agency center charged with the premarket review of drugs and biological products; and

''(B) review information and data provided to the Secretary by the sponsor of a contrast agent in an application submitted under section 505, so long as the sponsor of such contrast agent has provided to the sponsor of the applicable medical imaging de-

vice that is the subject of such review a right of reference or use.

''(3) An application submitted under section 515 or a notification submitted under section 510(k) with respect to an applicable medical imaging device shall be subject to the requirements of such respective section, and shall not be subject to subsection (d) or (e) of section 505 (including the substantial evidence standard specified in such subsections).

''(4) An application submitted under section 515 or a notification submitted under section 510(k) with respect to an applicable medical imaging device intended for use in conjunction with a contrast agent to which clause (ii) or (iii) of section 505(c)(3)(E) applies shall refer to such contrast agent by trade or brand name, rather than to a class of drugs.

''(5) For purposes of this subsection and section 505(y)—

''(A) the term 'applicable medical imaging device' means a device intended to be used in conjunction with a contrast agent (or class of contrast agents) for a use that is not described in the indications and usage section of the approved labeling of such contrast agent (or the approved labeling of any

contrast agent in the same class as such contrast agent); and

''(B) the term 'contrast agent' means a drug that—

''(i) is a radioactive drug (as defined in section 310.3(n) of title 21, Code of Federal Regulations); or

''(ii)(I) is approved under section 505;

''(II) is intended for use in conjunction with a diagnostic imaging device; and

''(III) achieves its intended use by enhancing the contrast between a target tissue, structure, or fluid and the surrounding tissues or structures within the body.''.

SEC. 3. APPLICATIONS FOR APPROVAL OF CONTRAST AGENTS INTENDED FOR USE WITH CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.

Section 505 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 355) is amended by adding at the end the following:

''(y) CONTRAST AGENTS INTENDED FOR USE WITH APPLICABLE MEDICAL IMAGING DEVICES.—

''(1) The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking

approval for the use of the contrast agent for a new contrast indication.

''(2) In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may—

''(A) consult with the center charged with the premarket review of devices; and

''(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 515 or 510(k), so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference or use.

''(3) For purposes of this subsection—

''(A) the term 'new contrast indication' means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 520(p), but that is not described in the indications and usage section of the approved labeling of the contrast agent; and

"(B) the term 'applicable medical imaging device' and 'contrast agent' have the meanings given such terms in section 520(p).".

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