**AMENDMENT**

**OFFERED BY MR. PETERS**

Redesignate title VIII of the bill as title IX, and redesignate sections 801 and 802 as sections 901 and 902, respectively.

After title VII, insert the following new title:

# TITLE VIII—FOSTERING INNOVATION IN MEDICAL IMAGING

### SEC. 801. APPROVAL OF APPLICATIONS FOR CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j), as amended by section 613, is further amended by adding at the end the following:

"(q) DIAGNOSTIC IMAGING DEVICES INTENDED FOR USE WITH CONTRAST AGENTS.—

"(1) The Secretary may, subject to the succeeding provisions of this subsection, approve an application (or a 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 is submitted under section 510(k), may make

a substantial equivalence determination with respect to an applicable medical imaging device, or may grant a request submitted under section 513(f)(2) for an applicable medical imaging device, if the indications and conditions of use proposed in such application, notification, or request involve the use of a contrast agent that is not—

"(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, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in concentration, rate of administration, or route of administration exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

"(B) in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary

determines that such differences in region, organ, or system of the body exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

"(C) in a patient population that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines such differences in patient population exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device; or

"(D) in an imaging modality (such as an ultrasound, an x-ray, diagnostic radiopharmaceutical-based technologies, fluorescent imaging technology, or magnetic resonance) 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, notification, or request 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 or 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 of this Act or section 351 of the Public Health Service Act, so long as the sponsor of such contrast agent has provided to the sponsor of the applicable medical imaging device that is the subject of such review a right of reference and the application is submitted in accordance with this subsection.

"(3) An application submitted under section 515, a notification submitted under section 510(k), or a request submitted under section 513(f)(2), as described in paragraph (1), with respect to an applicable medical imaging device shall be subject to the requirements of such respective section. Such application, notification, or request shall only be subject to the requirements of this Act applicable to devices.

"(4) 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 an imaging use that is not described in 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 is approved under section 505 or licensed under section 351 of the Public Health Service Act, 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.".

**SEC. 802. 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 (21 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 indication and conditions of use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 520(q)(1).

"(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, 510(k), or 513(f)(2) so long as the sponsor of such applicable medical imaging de-

vice has provided to the sponsor of the contrast agent a right of reference.

"(3) For purposes of this subsection—

"(A) the term 'new 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(q), but that is not described in 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(q).".

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