

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:

1 **TITLE VIII—FOSTERING INNOVA-**
2 **TION IN MEDICAL IMAGING**

3 **SEC. 801. APPROVAL OF APPLICATIONS FOR CERTAIN DI-**
4 **AGNOSTIC MEDICAL IMAGING DEVICES.**

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

8 “(q) DIAGNOSTIC IMAGING DEVICES INTENDED FOR
9 USE WITH CONTRAST AGENTS.—

10 “(1) The Secretary may, subject to the suc-
11 ceeding provisions of this subsection, approve an ap-
12 plication (or a supplement to such an application)
13 submitted under section 515 with respect to an ap-
14 plicable medical imaging device, or, in the case of an
15 applicable medical imaging device for which a notifi-
16 cation is submitted under section 510(k), may make

1 a substantial equivalence determination with respect
2 to an applicable medical imaging device, or may
3 grant a request submitted under section 513(f)(2)
4 for an applicable medical imaging device, if the indi-
5 cations and conditions of use proposed in such appli-
6 cation, notification, or request involve the use of a
7 contrast agent that is not—

8 “(A) in a concentration, rate of adminis-
9 tration, or route of administration that is dif-
10 ferent from those described in the approved la-
11 beling of the contrast agent, except that the
12 Secretary may approve such application, make
13 such substantial equivalence determination, or
14 grant such request if the Secretary determines
15 that such differences in concentration, rate of
16 administration, or route of administration exist
17 but do not adversely affect the safety and effec-
18 tiveness of the contrast agent when used with
19 the device;

20 “(B) in a region, organ, or system of the
21 body that is different from those described in
22 the approved labeling of the contrast agent, ex-
23 cept that the Secretary may approve such appli-
24 cation, make such substantial equivalence deter-
25 mination, or grant such request if the Secretary

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

5 “(C) in a patient population that is dif-
6 ferent from those described in the approved la-
7 beling of the contrast agent, except that the
8 Secretary may approve such application, make
9 such substantial equivalence determination, or
10 grant such request if the Secretary determines
11 such differences in patient population exist but
12 do not adversely affect the safety and effective-
13 ness of the contrast agent when used with the
14 device; or

15 “(D) in an imaging modality (such as an
16 ultrasound, an x-ray, diagnostic radiopharma-
17 ceutical-based technologies, fluorescent imaging
18 technology, or magnetic resonance) that is dif-
19 ferent from those described in the approved la-
20 beling of the contrast agent.

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

1 “(A) consult with the agency center
2 charged with the premarket review of drugs or
3 biological products; and

4 “(B) review information and data provided
5 to the Secretary by the sponsor of a contrast
6 agent in an application submitted under section
7 505 of this Act or section 351 of the Public
8 Health Service Act, so long as the sponsor of
9 such contrast agent has provided to the sponsor
10 of the applicable medical imaging device that is
11 the subject of such review a right of reference
12 and the application is submitted in accordance
13 with this subsection.

14 “(3) An application submitted under section
15 515, a notification submitted under section 510(k),
16 or a request submitted under section 513(f)(2), as
17 described in paragraph (1), with respect to an appli-
18 cable medical imaging device shall be subject to the
19 requirements of such respective section. Such appli-
20 cation, notification, or request shall only be subject
21 to the requirements of this Act applicable to devices.

22 “(4) For purposes of this subsection and sec-
23 tion 505(y)—

24 “(A) the term ‘applicable medical imaging
25 device’ means a device intended to be used in

1 conjunction with a contrast agent (or class of
2 contrast agents) for an imaging use that is not
3 described in the approved labeling of such con-
4 trast agent (or the approved labeling of any
5 contrast agent in the same class as such con-
6 trast agent); and

7 “(B) the term ‘contrast agent’ means a
8 drug that is approved under section 505 or li-
9 censed under section 351 of the Public Health
10 Service Act, is intended for use in conjunction
11 with an applicable medical imaging device,
12 and—

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

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

1 **SEC. 802. APPLICATIONS FOR APPROVAL OF CONTRAST**
2 **AGENTS INTENDED FOR USE WITH CERTAIN**
3 **DIAGNOSTIC MEDICAL IMAGING DEVICES.**

4 Section 505 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 355) is amended by adding at the end the
6 following:

7 “(y) CONTRAST AGENTS INTENDED FOR USE WITH
8 APPLICABLE MEDICAL IMAGING DEVICES.—

9 “(1) The sponsor of a contrast agent for which
10 an application has been approved under this section
11 may submit a supplement to the application seeking
12 approval for the use of the contrast agent for a new
13 indication and conditions of use following the au-
14 thorization of a premarket submission for an appli-
15 cable medical imaging device for that use with the
16 contrast agent pursuant to section 520(q)(1).

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

20 “(A) consult with the center charged with
21 the premarket review of devices; and

22 “(B) review information and data sub-
23 mitted to the Secretary by the sponsor of an
24 applicable medical imaging device pursuant to
25 section 515, 510(k), or 513(f)(2) so long as the
26 sponsor of such applicable medical imaging de-

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

3 “(3) For purposes of this subsection—

4 “(A) the term ‘new indication’ means a use
5 of a contrast agent that is described in the ap-
6 proved labeling of an applicable medical imag-
7 ing device described in section 520(q), but that
8 is not described in the approved labeling of the
9 contrast agent; and

10 “(B) the term ‘applicable medical imaging
11 device’ and ‘contrast agent’ have the meanings
12 given such terms in section 520(q).”.

