SEC. 1. REGULATION OF CERTAIN PRODUCTS AS DRUGS.

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 with an injectable route of administration, or which is a radioactive drug, or OTC monograph drug 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 a drug 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 'OTC monograph drug ' has the meaning given such term in section 744L; and

"(C) 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).".