AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 1691 OFFERED BY MR. SMITH OF MISSOURI

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ensuring Patient Access to Critical Breakthrough Products Act of 2024''.

SEC. 2. ENSURING PROMPT COVERAGE OF BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM.

(a) ENSURING COVERAGE THROUGH A TRANSITIONAL COVERAGE PERIOD.—

(1) IN GENERAL.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

(A) in subparagraph (O), by striking ''and'' at the end;

(B) in subparagraph (P), by adding ''and'' at the end; and

(C) by inserting after subparagraph (P) the following new subparagraph:

''(Q) in the case of a breakthrough device (as defined in section 1861(nnn)) furnished during the transitional coverage period (as so defined) with respect to such device, which is not furnished in accordance with the Food and Drug Administration-approved labeling for such device or that the Secretary determines, based on a review of clinical data, presents an undue risk of harm that outweighs the potential clinical benefits for individuals entitled to benefits under part A or enrolled under part B;''.

(2) DEFINITIONS.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''(nnn) BREAKTHROUGH DEVICE.—

''(1) IN GENERAL.—The term 'breakthrough device' means a device so designated by the Secretary under section 1899C.

''(2) TRANSITIONAL COVERAGE PERIOD.—The term 'transitional coverage period' means, with respect to a breakthrough device, the 4-year period that begins on the date that such device is so designated by the Secretary under section 1899C.''.

(3) BREAKTHROUGH DEVICE DETERMINATIONS.—Part E of title XVIII of the Social Security

Act (42 U.S.C. 1395x et seq.) is amended by adding at the end the following new section:

"SEC. 1899C. DESIGNATION OF BREAKTHROUGH DEVICES.

''(a) IN GENERAL.—Beginning 18 months after the date of the enactment of this section, upon application of a manufacturer of a device (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) that is cleared, classified, or approved under section 510(k), 513(f)(2), or 515 of such Act on or after the date of the enactment of this section, the Secretary shall designate such device as a breakthrough device if the Secretary determines that such device meets the criteria specified in subsection (b).

''(b) CRITERIA.—For purposes of subsection (a), the criteria specified in this subsection are, with respect to a device, the following:

''(1) The device is provided with priority review pursuant to section 515B of the Federal Food, Drug, and Cosmetic Act.

''(2) In the case such device is cleared under section 510(k) of such Act, such device is so cleared based on clinical trial information from an applicable device clinical trial (as such terms are defined in section 402(j) of such Act) that enrolled individuals en-

titled to benefits under part A or enrolled under part B.

''(3) The device is not a clinical diagnostic laboratory test.

''(c) DETERMINATION PROCESS.—

''(1) IN GENERAL.—The Secretary shall make a determination with respect to a device that is the subject of an application described in subsection (a) not later than 6 months after such application is submitted to the Secretary.

''(2) EXPLANATION REQUIRED IN CASE OF DETERMINATION THAT DEVICE DOES NOT MEET CRITERIA FOR DESIGNATION.—In the case that the Secretary determines that a device that is the subject of an application described in subsection (a) does not meet the criteria specified in subsection (b), the Secretary shall notify the manufacturer of such device of such determination and include in such notification an explanation identifying the specific criterion or criteria that such device failed to meet.

''(d) REPORTS.—The Secretary shall submit to Congress on an annual basis a report specifying—

''(1) the number of applications received under this section during such year;

''(2) the number of devices designated as breakthrough devices under this section during such year; and

''(3) the number of applications for a designation for a device under this section with respect to which the Secretary determined that such device did not meet the criteria specified in subsection (b) during such year.''.

(b) ENSURING ISSUANCE OF NATIONAL COVERAGE DETERMINATION DURING TRANSITION PERIOD.—Section 1862(l)(2) of the Social Security Act (42 U.S.C. 1395y(l)(2)) is amended by adding at the end the following new flush sentence:

''In the case of a request for a national coverage determination with respect to a breakthrough device (as defined in section 1861(nnn)), the Secretary shall ensure that a final decision is made on such request prior to the end of the transitional coverage period (as so defined) for such device if such request was submitted to the Secretary before the date that is 9 months (or 12 months, in the case such request is a request to which subparagraph (B) applies) before the last day of such period.''.

(c) FUNDING.—In addition to amounts otherwise available, there are appropriated to the Centers for Medi-

care & Medicaid Services Program Management Account, out of any monies in the Treasury not otherwise appropriated, $10,000,000 for each of fiscal years 2025 through 2030, to remain available until expended, to carry out the amendments made by this section.