Brett Guthrie

(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. 7008

To improve patient access to emerging medication therapies by clarifying the scope of permitted health care economic and scientific information communications between biopharmaceutical manufacturers and population health decision makers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GUTHRIE introduced the following bill; which was referred to the Committee on _____

A BILL

To improve patient access to emerging medication therapies by clarifying the scope of permitted health care economic and scientific information communications between biopharmaceutical manufacturers and population health decision makers, and for other purposes.

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 "Pre-approval Information Exchange Act of 2022".

SEC. 2. FACILITATING EXCHANGE OF INFORMATION PRIOR TO APPROVAL.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) is amended—

(1) by redesignating subparagraph (2) as subparagraph (3);

(2) by inserting after subparagraph (1) the following:

"(2)(A) Health care economic information, scientific information, or product support information provided to a covered payor responsible for the selection of drugs or devices for coverage, reimbursement, or other population-based health care management, shall not be considered false or misleading or any other form of misbranding under this section or a violation of section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act, or otherwise prohibited pre-approval promotion of a drug or device, if it—

"(i)(I) in the case of health care economic information, is based on competent and reliable scientific evidence; or

"(II) in the case of scientific information other than health care economic information, is truthful and nonmisleading; and

"(ii) relates to an investigational drug or device or investigational use of a drug or device that is ap-

proved, cleared, or licensed under section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act (as applicable).

"(B) In order to provide information pursuant to this subparagraph relating to an investigational drug or device, or an investigational use of an drug or device that has been approved, granted marketing authorization, cleared, or licensed—

"(i) the information must include—

"(I) a clear statement that the investigational drug or device or investigational use of a drug or device has not been approved, cleared, or licensed under section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act (as applicable) and that the safety and effectiveness of the drug or device or use has not yet been established;

"(II) information related to the stage of development of the drug or device involved, such as—

"(aa) the status of any study or studies in which the investigational drug or device or investigational use is being investigated;

"(bb) how the study or studies relate to the overall plan for the development of the drug or device;

"(cc) whether a marketing application or notification for the investigational drug or device or investigational use has been submitted to the Secretary and when such a submission is planned;

"(III) in the case of communications that include factual presentations of results from studies, a description of—

"(aa) material aspects of study design, methodology, and results; and

"(bb) material limitations related to the study design, methodology, and results; and

"(IV) where applicable, a conspicuous and prominent statement describing any material differences between the information provided and the labeling approved, granted marketing authorization, cleared, or licensed pursuant to section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act.

"(C) For purposes of this subparagraph—

"(i) the term 'covered payor' means a payor, formulary committee, drug information center, technology assessment committee, pharmacy benefit manager, and other multidisciplinary entity that, on behalf of health care organizations, reviews scientific or technology assessments, or other similar entity with knowledge and expertise to evaluate health care economic analysis or scientific information on a population basis;

"(ii) the term 'product support information' includes—

"(I) information describing the drug or device (such as drug class, device description, and features);

"(II) information about the indication or indications sought;

"(III) the anticipated timeline for a possible approval, clearance, or licensure pursuant to section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act;

"(IV) drug or device pricing information;

"(V) patient utilization projections; and

"(VI) product-related programs or services.

"(iii) the term 'scientific information' includes clinical and pre-clinical data and results relating to

a drug or device or use that has not been approved, granted marketing authorization, cleared, or licensed and is being investigated or developed.";

(3) in subparagraph (3), as redesignated—

(A) by striking "(A)";

(B) by striking clause (B); and

(C) by striking "drug" each place it appears and inserting "drug or device"; and

(4) by adding at the end the following:

"(4) Nothing in this section shall be construed to limit the ability of manufacturers or sponsors of drugs or devices to engage in communications or activities not specified in subparagraph (2) or (3) that are otherwise permissible.".

SEC. 3. GAO STUDY AND REPORT.

Beginning on the date that is 5 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States (in this subsection referred to as the "Comptroller General") shall conduct a study on the provision and use of information pursuant to section 502(a)(2) of the Federal Food, Drug, and Cosmetic Act, as added by section 2 of this Act, between manufacturers of, and covered entities (as defined in such section 502(a)(2)) for, drugs and devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 321)). Such study shall include an analysis of the following:

(1) The type of information communicated between such manufacturers and payors.

(2) The manner of communication between such manufacturers and payors.

(3)(A) Whether such manufacturers file a submission for approval, marketing authorization, clearance, or licensing of a new drug or device or the new use of a drug or device that is the subject of communication between such manufacturers and payors before the new use is approved, granted marketing authorization, cleared, or licensed.

(B) How frequently the Food and Drug Administration approves, grants marketing authorization, clears, or licenses the new drug or device or new use.

(C) The timeframe between the initial communications under section 502(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, regarding an investigational drug or device or investigational use, and the initial marketing of such drug or device or investigational use.