Brett Guthrie

(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the exchange of certain product information, 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 amend the Federal Food, Drug, and Cosmetic Act to facilitate the exchange of certain product information, 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 PRODUCT INFORMATION PRIOR TO APPROVAL.

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

(1) in paragraph (a)—

(A) by striking "drugs for coverage" and inserting "drugs or devices for coverage"; and

(B) by striking "drug" each place it appears and inserting "drug or device", respectively;

(2) in paragraphs (a)(1) and (a)(2)(B), by striking "under section 505 or under section 351 of the Public Health Service Act" and inserting "under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act";

(3) in paragraph (a)(1)—

(A) by striking "under section 505 or under section 351(a) of the Public Health Service Act" and inserting "under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act"; and

(B) by striking "in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act" and inserting "in section 505, 510(k), 513(f)(2), or 515 of this

Act or section 351 of the Public Health Service Act"; and

(4) by adding at the end the following:

"(gg)(1) Unless its labeling bears adequate directions for use in accordance with paragraph (f), except that (in addition to drugs or devices that conform with exemptions pursuant to such paragraph) no drug or device shall be deemed to be misbranded under such paragraph through the provision of product information to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement if the product information relates to an investigational drug or device or investigational use of a drug or device that is approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable), provided—

"(A) the product information includes—

"(i) a clear statement that the investigational drug or device or investigational use of a drug or device has not been approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), 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 been established;

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

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

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

"(III) whether an application, premarket notification, or request for classification 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 information that includes factual presentations of results from studies, which shall not be selectively presented, a description of—

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

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

"(iv) where applicable, a prominent statement disclosing the indication or indications for which the Secretary has approved, granted marketing authorization, cleared, or licensed the product pursuant to section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act, and a copy of the most current required labeling; and

"(v) updated information, if previously communicated information becomes materially outdated as a result of significant changes or as a result of new information regarding the product or its review status; and

"(B) the product information does not include—

"(i) information that represents that an unapproved product—

"(I) has been approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section

351 of the Public Health Service Act (as applicable); or

"(II) has otherwise been determined to be safe or effective for the purpose or purposes for which the drug or device is being studied; or

"(ii) information that represents that an unapproved use of a drug or device that has been so approved, granted marketing authorization, cleared, or licensed—

"(I) is so approved, granted marketing authorization, cleared, or licensed; or

"(II) that the product is safe or effective for the use or uses for which the drug or device is being studied.

"(2) For purposes of this paragraph, the term 'product information' includes—

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

"(B) information about the indication or indications being investigated;

"(C) the anticipated timeline for a possible approval, clearance, marketing authorization, or licen-

sure pursuant to section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act;

"(D) drug or device pricing information;

"(E) patient utilization projections;

"(F) product-related programs or services; and

"(G) factual presentations of results from studies that do not characterize or make conclusions regarding safety or efficacy.".

(b) 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 shall conduct a study on the provision and use of information pursuant to section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by this subsection (a), between manufacturers of drugs and devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) and entities described in such section 502(gg). Such study shall include an analysis of the following:

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

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

(3)(A) Whether such manufacturers file an application 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 under section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(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 permitted under section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), regarding an investigational drug or device or investigational use, and the initial marketing of such drug or device.