I

115TH CONGRESS
1ST SESSION

H. R. 2026

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.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2017

Mr. GUTHRIE introduced the following bill; which was referred to the Committee on Energy and Commerce

---

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.

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 ''Pharmaceutical Information Exchange Act''.

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) Health care economic information or scientific information provided 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 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 paragraph, or a violation of section 505 of this Act or section 351 of the Public Health Service Act, or otherwise prohibited pre-approval promotion of a drug, if it is based on competent and reliable scientific evidence and relates to an investigational new drug or an investigational use of an approved drug. In order for information relating to an investigational use of an approved drug to be provided pursuant to this subparagraph, there must have been submitted to the Secretary a supplemental application for approval of such use, or the study or studies needed to support the

submission of a supplemental application for such use must have been completed with the intention that a supplemental application will be submitted to the Secretary for approval of the use. For purposes of this subparagraph, scientific information includes clinical and pre-clinical data and results relating to an unapproved drug therapy, or drug indication, or other condition of use being investigated or developed.''; and

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

(A) by striking ''(A)''; and

(B) by striking clause (B).

○