



(Original Signature of Member)

117TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

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.

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IN THE HOUSE OF REPRESENTATIVES

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

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**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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pre-approval Informa-  
5 tion Exchange Act of 2022”.

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

3 Section 502(a) of the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 352(a)) is amended—

5 (1) by redesignating subparagraph (2) as sub-  
6 paragraph (3);

7 (2) by inserting after subparagraph (1) the fol-  
8 lowing:

9 “(2)(A) Health care economic information, scientific  
10 information, or product support information provided to  
11 a covered payor responsible for the selection of drugs or  
12 devices for coverage, reimbursement, or other population-  
13 based health care management, shall not be considered  
14 false or misleading or any other form of misbranding  
15 under this section or a violation of section 505, 510(k),  
16 513, or 515 of this Act or section 351 of the Public Health  
17 Service Act, or otherwise prohibited pre-approval pro-  
18 motion of a drug or device, if it—

19 “(i)(I) in the case of health care economic in-  
20 formation, is based on competent and reliable sci-  
21 entific evidence; or

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

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

1       proved, cleared, or licensed under section 505,  
2       510(k), 513, or 515 of this Act or section 351 of the  
3       Public Health Service Act (as applicable).

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

9               “(i) the information must include—

10                       “(I) a clear statement that the investiga-  
11                       tional drug or device or investigational use of a  
12                       drug or device has not been approved, cleared,  
13                       or licensed under section 505, 510(k), 513, or  
14                       515 of this Act or section 351 of the Public  
15                       Health Service Act (as applicable) and that the  
16                       safety and effectiveness of the drug or device or  
17                       use has not yet been established;

18                       “(II) information related to the stage of  
19                       development of the drug or device involved,  
20                       such as—

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21                               “(aa) the status of any study or stud-  
22                               ies in which the investigational drug or de-  
23                               vice or investigational use is being inves-  
24                               tigated;

1                   “(bb) how the study or studies relate  
2                   to the overall plan for the development of  
3                   the drug or device;

4                   “(cc) whether a marketing application  
5                   or notification for the investigational drug  
6                   or device or investigational use has been  
7                   submitted to the Secretary and when such  
8                   a submission is planned;

9                   “(III) in the case of communications that  
10                  include factual presentations of results from  
11                  studies, a description of—

12                  “(aa) material aspects of study de-  
13                  sign, methodology, and results; and

14                  “(bb) material limitations related to  
15                  the study design, methodology, and results;  
16                  and

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

24                  “(C) For purposes of this subparagraph—

1           “(i) the term ‘covered payor’ means a payor,  
2           formulary committee, drug information center, tech-  
3           nology assessment committee, pharmacy benefit  
4           manager, and other multidisciplinary entity that, on  
5           behalf of health care organizations, reviews scientific  
6           or technology assessments, or other similar entity  
7           with knowledge and expertise to evaluate health care  
8           economic analysis or scientific information on a pop-  
9           ulation basis;

10           “(ii) the term ‘product support information’ in-  
11           cludes—

12                   “(I) information describing the drug or de-  
13                   vice (such as drug class, device description, and  
14                   features);

15                   “(II) information about the indication or  
16                   indications sought;

17                   “(III) the anticipated timeline for a pos-  
18                   sible approval, clearance, or licensure pursuant  
19                   to section 505, 510(k), 513, or 515 of this Act  
20                   or section 351 of the Public Health Service Act;

21                   “(IV) drug or device pricing information;

22                   “(V) patient utilization projections; and

23                   “(VI) product-related programs or services.

24           “(iii) the term ‘scientific information’ includes  
25           clinical and pre-clinical data and results relating to

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

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

5 (A) by striking “(A)”;

6 (B) by striking clause (B); and

7 (C) by striking “drug” each place it ap-  
8 pears and inserting “drug or device”; and

9 (4) by adding at the end the following:

10 “(4) Nothing in this section shall be construed to  
11 limit the ability of manufacturers or sponsors of drugs or  
12 devices to engage in communications or activities not spec-  
13 ified in subparagraph (2) or (3) that are otherwise permis-  
14 sible.”.

15 **SEC. 3. GAO STUDY AND REPORT.**

16 Beginning on the date that is 5 years and 6 months  
17 after the date of enactment of this Act, the Comptroller  
18 General of the United States (in this subsection referred  
19 to as the “Comptroller General”) shall conduct a study  
20 on the provision and use of information pursuant to sec-  
21 tion 502(a)(2) of the Federal Food, Drug, and Cosmetic  
22 Act, as added by section 2 of this Act, between manufac-  
23 turers of, and covered entities (as defined in such section  
24 502(a)(2)) for, drugs and devices (as defined in section  
25 201 of the Federal Food, Drug, and Cosmetic Act (21

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

3 (1) The type of information communicated be-  
4 tween such manufacturers and payors.

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

7 (3)(A) Whether such manufacturers file a sub-  
8 mission for approval, marketing authorization, clear-  
9 ance, or licensing of a new drug or device or the new  
10 use of a drug or device that is the subject of commu-  
11 nication between such manufacturers and payors be-  
12 fore the new use is approved, granted marketing au-  
13 thorization, cleared, or licensed.

14 (B) How frequently the Food and Drug Admin-  
15 istration approves, grants marketing authorization,  
16 clears, or licenses the new drug or device or new use.

17 (C) The timeframe between the initial commu-  
18 nications under section 502(a) of the Federal Food,  
19 Drug, and Cosmetic Act, as amended by this Act,  
20 regarding an investigational drug or device or inves-  
21 tigational use, and the initial marketing of such  
22 drug or device or investigational use.