

117TH CONGRESS
2D SESSION

H. R. 9297

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

NOVEMBER 15, 2022

Mr. GUTHRIE (for himself, Ms. ESHOO, Mr. GRIFFITH, Mr. PETERS, Mr. BURGESS, and Ms. MATSUI) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the exchange of certain product information, 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”.

6 **SEC. 2. FACILITATING EXCHANGE OF PRODUCT INFORMA-**
7 **TION PRIOR TO APPROVAL.**

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

1 (1) in paragraph (a)—

2 (A) by striking “drugs for coverage” and
3 inserting “drugs or devices for coverage”; and

4 (B) by striking “drug” each place it ap-
5 pears and inserting “drug or device”, respec-
6 tively;

7 (2) in paragraphs (a)(1) and (a)(2)(B), by
8 striking “under section 505 or under section 351 of
9 the Public Health Service Act” and inserting “under
10 section 505, 510(k), 513(f)(2), or 515 of this Act or
11 section 351 of the Public Health Service Act”;

12 (3) in paragraph (a)(1)—

13 (A) by striking “under section 505 or
14 under section 351(a) of the Public Health Serv-
15 ice Act” and inserting “under section 505,
16 510(k), 513(f)(2), or 515 of this Act or section
17 351 of the Public Health Service Act”; and

18 (B) by striking “in section 505(a) or in
19 subsections (a) and (k) of section 351 of the
20 Public Health Service Act” and inserting “in
21 section 505, 510(k), 513(f)(2), or 515 of this
22 Act or section 351 of the Public Health Service
23 Act”; and

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

1 “(gg)(1) Unless its labeling bears adequate directions
2 for use in accordance with paragraph (f), except that (in
3 addition to drugs or devices that conform with exemptions
4 pursuant to such paragraph) no drug or device shall be
5 deemed to be misbranded under such paragraph through
6 the provision of product information to a payor, formulary
7 committee, or other similar entity with knowledge and ex-
8 pertise in the area of health care economic analysis car-
9 rying out its responsibilities for the selection of drugs or
10 devices for coverage or reimbursement if the product infor-
11 mation relates to an investigational drug or device or in-
12 vestigational use of a drug or device that is approved,
13 cleared, granted marketing authorization, or licensed
14 under section 505, 510(k), 513(f)(2), or 515 of this Act
15 or section 351 of the Public Health Service Act (as appli-
16 cable), provided—

17 “(A) the product information includes—

18 “(i) a clear statement that the investiga-
19 tional drug or device or investigational use of a
20 drug or device has not been approved, cleared,
21 granted marketing authorization, or licensed
22 under section 505, 510(k), 513(f)(2), or 515 of
23 this Act or section 351 of the Public Health
24 Service Act (as applicable) and that the safety

1 and effectiveness of the drug or device or use
2 has not been established;

3 “(ii) information related to the stage of de-
4 velopment of the drug or device involved, such
5 as—

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

9 “(II) how the study or studies relate
10 to the overall plan for the development of
11 the drug or device; and

12 “(III) whether an application, pre-
13 market notification, or request for classi-
14 fication for the investigational drug or de-
15 vice or investigational use has been sub-
16 mitted to the Secretary and when such a
17 submission is planned;

18 “(iii) in the case of information that in-
19 cludes factual presentations of results from
20 studies, which shall not be selectively presented,
21 a description of—

22 “(I) all material aspects of study de-
23 sign, methodology, and results; and

1 “(II) all material limitations related
2 to the study design, methodology, and re-
3 sults;

4 “(iv) where applicable, a prominent state-
5 ment disclosing the indication or indications for
6 which the Secretary has approved, granted mar-
7 keting authorization, cleared, or licensed the
8 product pursuant to section 505, 510(k),
9 513(f)(2), or 515 of this Act or section 351 of
10 the Public Health Service Act, and a copy of
11 the most current required labeling; and

12 “(v) updated information, if previously
13 communicated information becomes materially
14 outdated as a result of significant changes or as
15 a result of new information regarding the prod-
16 uct or its review status; and

17 “(B) the product information does not in-
18 clude—

19 “(i) information that represents that an
20 unapproved product—

21 “(I) has been approved, cleared,
22 granted marketing authorization, or li-
23 censed under section 505, 510(k),
24 513(f)(2), or 515 of this Act or section

1 351 of the Public Health Service Act (as
2 applicable); or

3 “(II) has otherwise been determined
4 to be safe or effective for the purpose or
5 purposes for which the drug or device is
6 being studied; or

7 “(ii) information that represents that an
8 unapproved use of a drug or device that has
9 been so approved, granted marketing authoriza-
10 tion, cleared, or licensed—

11 “(I) is so approved, granted mar-
12 keting authorization, cleared, or licensed;
13 or

14 “(II) that the product is safe or effec-
15 tive for the use or uses for which the drug
16 or device is being studied.

17 “(2) For purposes of this paragraph, the term ‘prod-
18 uct information’ includes—

19 “(A) information describing the drug or device
20 (such as drug class, device description, and fea-
21 tures);

22 “(B) information about the indication or indica-
23 tions being investigated;

24 “(C) the anticipated timeline for a possible ap-
25 proval, clearance, marketing authorization, or licen-

1 sure pursuant to section 505, 510(k), 513, or 515
2 of this Act or section 351 of the Public Health Serv-
3 ice Act;

4 “(D) drug or device pricing information;

5 “(E) patient utilization projections;

6 “(F) product-related programs or services; and

7 “(G) factual presentations of results from stud-
8 ies that do not characterize or make conclusions re-
9 garding safety or efficacy.”.

10 (b) GAO STUDY AND REPORT.—Beginning on the
11 date that is 5 years and 6 months after the date of enact-
12 ment of this Act, the Comptroller General of the United
13 States shall conduct a study on the provision and use of
14 information pursuant to section 502(gg) of the Federal
15 Food, Drug, and Cosmetic Act, as added by this sub-
16 section (a), between manufacturers of drugs and devices
17 (as defined in section 201 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 321)) and entities described in
19 such section 502(gg). Such study shall include an analysis
20 of the following:

21 (1) The types of information communicated be-
22 tween such manufacturers and payors.

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

1 (3)(A) Whether such manufacturers file an ap-
2 plication for approval, marketing authorization,
3 clearance, or licensing of a new drug or device or the
4 new use of a drug or device that is the subject of
5 communication between such manufacturers and
6 payors under section 502(gg) of the Federal Food,
7 Drug, and Cosmetic Act, as added by subsection (a).

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

11 (C) The timeframe between the initial commu-
12 nications permitted under section 502(gg) of the
13 Federal Food, Drug, and Cosmetic Act, as added by
14 subsection (a), regarding an investigational drug or
15 device or investigational use, and the initial mar-
16 keting of such drug or device.

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