

117TH CONGRESS
2D SESSION

S. 4037

To amend the Public Health Service Act to increase the transparency of pharmaceutical research costs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 7, 2022

Ms. STABENOW (for herself and Ms. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to increase the transparency of pharmaceutical research costs, 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 “Pharmaceutical Re-
5 search Transparency Act of 2022”.

1 **SEC. 2. EXPANSION OF REGISTRY AND RESULTS DATA**
2 **BANK TO INCLUDE COSTS OF DRUG CLINICAL**
3 **TRIALS.**

4 (a) IN GENERAL.—Section 402(j) of the Public
5 Health Service Act (42 U.S.C. 282(j)) is amended—

6 (1) by redesignating paragraph (7) as para-
7 graph (8); and

8 (2) by inserting after paragraph (6) the fol-
9 lowing new paragraph:

10 “(7) CREATION OF CLINICAL TRIAL COST DATA
11 REPOSITORY.—

12 “(A) GENERALLY.—The Secretary, acting
13 through the Director of NIH, shall create a
14 publicly available Federal website to serve as a
15 repository of cost data for all applicable drug
16 clinical trials (in this paragraph referred to as
17 the ‘cost data repository’). Such repository shall
18 be searchable by the following criteria:

19 “(i) The responsible party or sponsor
20 of the applicable drug clinical trial, or any
21 entity funding the applicable drug clinical
22 trial.

23 “(ii) The name of the intervention, in-
24 cluding any drug being studied in the ap-
25 plicable drug clinical trial.

1 “(iii) The study phase of the applica-
2 ble drug clinical trial.

3 “(iv) The start date and completion
4 date of the applicable drug clinical trial.

5 “(v) Such other criteria as the Sec-
6 retary deems appropriate.

7 “(B) COST DATA DEFINED.—For purposes
8 of this paragraph, the term ‘cost data’ includes
9 the following information:

10 “(i) The total cost of the applicable
11 drug clinical trial.

12 “(ii) The cost of the trial per patient.

13 “(iii) Expenditures for each of the fol-
14 lowing categories:

15 “(I) Personnel.

16 “(II) Any intervention or treat-
17 ment that is administered in one or
18 more arms of the applicable drug clin-
19 ical trial.

20 “(III) Materials and supplies.

21 “(IV) Health care services pro-
22 vided to subjects.

23 “(V) Site management.

24 “(VI) Laboratory.

25 “(VII) Equipment.

1 “(VIII) The allocable portion of
 2 any facilities costs, administrative
 3 costs, or other costs that are not sole-
 4 ly attributable to the applicable drug
 5 clinical trial.

6 “(IX) Such other categories as
 7 the Secretary may identify by regula-
 8 tion.

9 “(C) POSTING OF CLINICAL TRIAL COST
 10 DATA.—

11 “(i) IN GENERAL.—Except as pro-
 12 vided in clause (iii), each responsible party
 13 of an applicable drug clinical trial shall
 14 post cost data for that trial to the cost
 15 data repository no later than 1 year after
 16 the completion date of the trial.

17 “(ii) FORMAT AND METHODOLOGY OF
 18 POSTING.—A cost data posting under
 19 clause (i) shall—

20 “(I) include individual data
 21 points for the information required
 22 under subparagraphs (B)(i) and
 23 (B)(ii), separated by year;

24 “(II) include individual data
 25 points for each category listed under

1 subparagraph (B)(iii), separated by
2 year;

3 “(III) limit the cost of the inter-
4 vention or treatment under subpara-
5 graph (B)(iii)(II) to manufacturing
6 costs unless the responsible party of
7 the trial was required to purchase the
8 intervention or treatment from an un-
9 affiliated third party;

10 “(IV) include detailed docu-
11 mentation and methodology for the
12 calculation of costs identified under
13 subparagraph (B)(iii)(VIII); and

14 “(V) include a signed certifi-
15 cation that the posted data is com-
16 plete and accurate.

17 “(iii) DELAYED POSTING OF COST
18 DATA AND EXTENSIONS.—

19 “(I) SEEKING INITIAL APPROVAL
20 OF DRUG, OR APPROVAL OF A NEW
21 USE.—If the responsible party for an
22 applicable drug clinical trial submits a
23 certification that paragraph (3)(E)(iv)
24 or paragraph (3)(E)(v) applies to
25 such trial, the responsible party shall

1 post cost data under clause (i) at the
2 time that clinical trial information is
3 required to be submitted under the
4 applicable paragraph.

5 “(II) EXTENSION FOR GOOD
6 CAUSE.—The Director of NIH may
7 provide an extension of the deadline
8 for posting of cost data under clause
9 (i) if the responsible party for the
10 trial submits to the Director a written
11 request that demonstrates good cause
12 for the extension and provides an esti-
13 mate of the date on which the infor-
14 mation will be posted. The Director of
15 NIH may grant more than one such
16 extension for a clinical trial, but
17 under no circumstances shall an ex-
18 tension under this subclause extend
19 beyond the date that is 18 months
20 after the completion date of the trial.

21 “(III) EXTENSION TO ESTABLISH
22 NECESSARY INFRASTRUCTURE.—If
23 necessary to establish the necessary
24 infrastructure to accept, organize, and
25 post cost data submitted under clause

(i), the Director of NIH may extend the deadline for the posting of cost data under clause (i) to not later than 2 years after the date of enactment of the Pharmaceutical Research Transparency Act of 2022.

“(IV) RULE OF CONSTRUCTION.—This clause shall not be construed to have any effect on reporting obligations of the responsible party under provisions other than this paragraph.

“(D) LINKING TO COST DATA REPOSITORY.—

“(i) CREATION OF FIELD.—The Director of NIH shall create a field within the registry and results data bank to include an electronic link to the relevant cost data posting under subparagraph (C)(i).

“(ii) POSTING.—The responsible party for an applicable drug clinical trial shall post in the field created under clause (i) a link to the relevant cost data posting no later than 5 days after initial posting of the cost data under subparagraph (C)(i).

1 “(E) RULEMAKING.—

2 “(i) IN GENERAL.—The Secretary
3 shall promulgate regulations to carry out
4 this paragraph that include—

5 “(I) definitions for each category
6 of information identified in subpara-
7 graph (B);

8 “(II) standards for allocating
9 fixed expenditures across multiple
10 years of an applicable drug clinical
11 trial;

12 “(III) a standard format for the
13 submission and posting of cost data
14 under this paragraph;

15 “(IV) procedures, standards, and
16 requirements for the reporting docu-
17 mentation and methodology required
18 under subparagraph (C)(ii)(IV); and

19 “(V) any other procedures,
20 standards, or requirements necessary
21 to ensure public transparency of cost
22 data as required by this paragraph.

23 “(ii) INITIAL REGULATIONS.—The
24 Secretary shall—

1 “(I) not later than one year after
 2 the date of enactment of the Pharma-
 3 ceutical Research Transparency Act of
 4 2022, propose initial regulations
 5 under clause (i); and

6 “(II) not later than 2 years after
 7 such date of enactment, finalize such
 8 regulations.

9 “(F) APPLICABILITY.—The requirements
 10 of this paragraph apply only to applicable drug
 11 clinical trials with a start date on or after the
 12 date of enactment of the Pharmaceutical Re-
 13 search Transparency Act of 2022.”.

14 (b) CONFORMING CHANGES.—Section 402(j) of the
 15 Public Health Service Act (42 U.S.C. 282(j)), as amended
 16 by subsection (a), is further amended—

17 (1) in paragraph (1)(A)(iv), by striking “para-
 18 graph (2) or under paragraph (3)” and inserting
 19 “paragraph (2), (3), or (7)”;

20 (2) in paragraph (4)—

21 (A) in subparagraph (A), by striking
 22 “paragraph (2) or paragraph (3)” and inserting
 23 “paragraph (2), (3), or (7)”; and

24 (B) in subparagraph (B)(i), by striking
 25 “paragraphs (2) and (3)” each place it appears

1 and inserting “paragraphs (2), (3), and (7)”;

2 and

3 (3) in paragraph (5)—

4 (A) in subparagraph (A), by striking

5 “paragraphs (2) and (3)” each place it appears

6 and inserting “paragraphs (2), (3), and (7)”;

7 and

8 (B) in subparagraph (E)(i), by striking

9 “paragraphs (2) or (3)” and inserting “para-

10 graph (2), (3), or (7)”.

11 **SEC. 3. DISCLOSURE OF RESEARCH AND DEVELOPMENT**

12 **EXPENDITURES BY DRUG MANUFACTURERS.**

13 Section 13 of the Securities Exchange Act of 1934

14 (15 U.S.C. 78m) is amended by adding at the end the

15 following:

16 “(s) DISCLOSURE OF RESEARCH AND DEVELOPMENT

17 EXPENDITURES BY DRUG MANUFACTURERS.—

18 “(1) DEFINITIONS.—In this subsection:

19 “(A) DRUG.—The term ‘drug’ means any

20 product for which one or more components have

21 been the subject of any of the following applica-

22 tions filed with the Food and Drug Administra-

23 tion:

24 “(i) A new drug application (or sup-

25 plemental new drug application) filed

1 under subsection (b) or (j) of section 505
2 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 355).

4 “(ii) A biologic product application (or
5 supplemental application) filed under sub-
6 section (a) or (k) of section 351 of the
7 Public Health Service Act (42 U.S.C.
8 262).

9 “(B) DRUG MANUFACTURER ISSUER.—The
10 term ‘drug manufacturer issuer’ means an
11 issuer that—

12 “(i) is required to file an annual re-
13 port with the Commission under subsection
14 (a); and

15 “(ii) engages in the development,
16 manufacture, or marketing of any drug.

17 “(2) DISCLOSURE.—

18 “(A) IN GENERAL.—Subject to the other
19 provisions of this paragraph, the Commission
20 shall issue rules that require each drug manu-
21 facturer issuer’s annual report under subsection
22 (a) to include information regarding the drug
23 manufacturer issuer’s research and development
24 expenditures with respect to—

25 “(i) a drug; and

1 “(ii) any preliminary research or de-
 2 velopment of a drug product or drug sub-
 3 stance, as those terms are defined in sec-
 4 tion 314.3 of title 21, Code of Federal
 5 Regulations (or any successor regulation)
 6 for which the drug manufacturer issuer
 7 has not submitted an application described
 8 in clause (i) or (ii) of paragraph (1)(A).

9 “(B) INITIAL RULES.—The Commission
 10 shall—

11 “(i) not later than 1 year after the
 12 date of enactment of the Pharmaceutical
 13 Research Transparency Act of 2022, pro-
 14 pose initial rules under subparagraph (A);
 15 and

16 “(ii) not later than 2 years after the
 17 date of enactment described in clause (i),
 18 finalize the rules required under subpara-
 19 graph (A).

20 “(C) REQUIRED INFORMATION.—The in-
 21 formation required under subparagraph (A)
 22 shall include total expenditures, which shall be
 23 disaggregated to each stage of drug research
 24 and development, including—

25 “(i) basic research;

1 “(ii) pre-clinical research;

2 “(iii) phase I of a clinical investiga-
3 tion of a new drug, as described in section
4 312.21(a) of title 21, Code of Federal Reg-
5 ulations, or any successor regulation;

6 “(iv) phase II of a clinical investiga-
7 tion of a new drug, as described in section
8 312.21(b) of title 21, Code of Federal Reg-
9 ulations, or any successor regulation;

10 “(v) phase III of a clinical investiga-
11 tion of a new drug, as described in section
12 312.21(c) of title 21, Code of Federal Reg-
13 ulations, or any successor regulation; and

14 “(vi) post-market studies or clinical
15 trials required under section 505(o) of the
16 Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 355(o)).

18 “(D) LIMITATIONS CALCULATION.—The
19 calculation of expenditure information disclosed
20 under subparagraph (A) shall not include the
21 following information, although such informa-
22 tion may be disclosed separately:

23 “(i) Costs incurred in connection with
24 licensing agreements or acquiring intellec-
25 tual property.

1 “(ii) The cost of mergers or acquisi-
2 tions.

3 “(iii) Any intangible costs, including
4 estimates, adjustments, and assumptions
5 related to the risk of failure, or the risk as-
6 sociated with seeking regulatory approval
7 by the Food and Drug Administration or
8 another agency.

9 “(iv) The estimated cost of capital.

10 “(3) CONSULTATION IN RULEMAKING.—In
11 issuing rules under this subsection, the Commis-
12 sion—

13 “(A) shall consult with the Commissioner
14 of Food and Drugs and the Director of the Na-
15 tional Institutes of Health; and

16 “(B) may consult with the head of any
17 other Federal agency or entity that the Com-
18 mission determines is relevant.”.

19 **SEC. 4. SEVERABILITY.**

20 If any provision of this Act, an amendment made by
21 this Act, or the application of any such provision or
22 amendment to any person or circumstance is held to be
23 unconstitutional, the remainder of the provisions of this
24 Act, the amendments made by this Act, and the applica-

- 1 tion of such provisions and amendments to any person or
- 2 circumstance shall not be affected thereby.

