

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.

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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

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## 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

1 (i), the Director of NIH may extend  
2 the deadline for the posting of cost  
3 data under clause (i) to not later than  
4 2 years after the date of enactment of  
5 the Pharmaceutical Research Trans-  
6 parency Act of 2022.

7 “(IV) RULE OF CONSTRU-  
8 TION.—This clause shall not be con-  
9 strued to have any effect on reporting  
10 obligations of the responsible party  
11 under provisions other than this para-  
12 graph.

13 “(D) LINKING TO COST DATA REPOSI-  
14 TORY.—

15 “(i) CREATION OF FIELD.—The Di-  
16 rector of NIH shall create a field within  
17 the registry and results data bank to in-  
18 clude an electronic link to the relevant cost  
19 data posting under subparagraph (C)(i).

20 “(ii) POSTING.—The responsible party  
21 for an applicable drug clinical trial shall  
22 post in the field created under clause (i) a  
23 link to the relevant cost data posting no  
24 later than 5 days after initial posting of  
25 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)”;

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.

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