

119TH CONGRESS
1ST SESSION

S. 3188

To establish a Biopharmaceutical Center of Excellence, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 18, 2025

Mr. COONS (for himself and Mr. BUDD) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

A BILL

To establish a Biopharmaceutical Center of Excellence, 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 “Biomanufacturing Ex-
5 cellence Act of 2025”.

6 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

7 (a) FINDINGS.—Congress finds the following:

8 (1) Biotechnology is the designing and engi-
9 neering of biological systems. Biotechnology allows

1 scientists to grow everything from medicines to crops
2 to materials, enabling “biology by design”.

3 (2) Biotechnology holds the potential for the
4 United States to transform its military capabilities,
5 strengthen food security and agricultural resilience,
6 and cure life-threatening diseases, but it holds that
7 same potential for other countries. The countries
8 that master biotechnology first will gain the ability
9 to shape how those technologies are used for decades
10 to come.

11 (3) Biotechnology unlocks the capabilities of
12 producing medicines via biological systems, known as
13 biopharmaceutical manufacturing. Biopharma-
14 ceutical manufacturing will enable better and less
15 invasive treatments that extend and improve lives.

16 (4) By investing in biomanufacturing, the
17 United States Government would reduce dependency
18 on foreign supply chains.

19 (5) For United States manufacturers, the big-
20 gest roadblock to commercialization is proving that
21 their products and processes can scale and produce
22 a return on investment. Biomanufacturing requires
23 flexible and affordable infrastructure for develop-
24 ment, to ensure that innovative products can rapidly
25 move from the lab to commercial-scale production.

1 (b) SENSE OF CONGRESS.—It is the sense of Con-
 2 gress that—

3 (1) to realize the potential of biotechnology, the
 4 United States Government should establish a bio-
 5 pharmaceutical manufacturing center of excellence;

6 (2) the center should facilitate and accelerate
 7 manufacturing innovation, support good manufac-
 8 turing practices, and provide for collaboration
 9 among public, private, and nonprofit institutions;
 10 and

11 (3) the center should also facilitate training for
 12 workers to operate biotechnology tools and equip-
 13 ment and to bolster talent throughout the bio-
 14 technology sector.

15 **SEC. 3. ESTABLISHMENT OF NATIONAL BIOPHARMA-**
 16 **CEUTICAL CENTER OF EXCELLENCE.**

17 The National Institute of Standards and Technology
 18 Act (15 U.S.C. 271 et seq.) is amended—

19 (1) by redesignating section 36 as section 37;
 20 and

21 (2) by inserting after section 35 the following:

22 **“SEC. 36. NATIONAL BIOPHARMACEUTICAL CENTER OF EX-**
 23 **CELLENCE.**

24 **“(a) ESTABLISHMENT OF CENTER OF EXCEL-**
 25 **LENCE.—**

1 “(1) IN GENERAL.—The Director shall award a
2 grant to or enter into an other transaction agree-
3 ment with, on a competitive basis, an eligible entity
4 to establish and operate a center of excellence to be
5 known as the National Biopharmaceutical Manufac-
6 turing Center of Excellence (in this section referred
7 to as the ‘Center of Excellence’).

8 “(2) OBJECTIVES.—The objectives of the Cen-
9 ter of Excellence include—

10 “(A) advancing the science of biopharma-
11 ceutical manufacturing, especially with respect
12 to products of particular importance to the na-
13 tional security, health security, or economic se-
14 curity of the United States, including by—

15 “(i) developing and demonstrating
16 flexible biopharmaceutical manufacturing
17 technologies and systems;

18 “(ii) improving upstream and down-
19 stream processes for multiple biopharma-
20 ceutical manufacturing platforms or prod-
21 uct modalities;

22 “(iii) improving biopharmaceutical
23 manufacturing equipment and capabilities;
24 and

1 “(iv) reducing supply bottlenecks and
2 strengthening supply chain self-sufficiency
3 through demonstration of innovative tech-
4 nologies;

5 “(B) supporting good manufacturing prac-
6 tices, quality by design, and standardization of
7 chemistry, manufacturing, and controls to en-
8 sure effective and efficient manufacturing and
9 to improve the regulation of innovative methods
10 of manufacturing;

11 “(C) advancing workforce training and de-
12 velopment by working with educational and
13 community partners to bolster biotechnology
14 talent;

15 “(D) developing the science of and deploy-
16 ing the infrastructure for innovative biopharma-
17 ceutical manufacturing by engaging with—

18 “(i) institutions of higher education;

19 “(ii) small, medium, and large phar-
20 maceutical manufacturers;

21 “(iii) Federal, State, and local govern-
22 ment agencies and institutes;

23 “(iv) non-profit organizations;

24 “(v) professional organizations; and

1 “(vi) any other entity the Director
2 considers relevant;

3 “(E) sharing with the head of any Execu-
4 tive agency that oversees the planning, manage-
5 ment, or coordination of Federal activities relat-
6 ing to biotechnology research generated by the
7 Center of Excellence, including data regarding
8 best practices for biopharmaceutical manufac-
9 turing; and

10 “(F) any other objective the Director con-
11 siders relevant.

12 “(3) FUNDING.—The Director shall award the
13 Center of Excellence funding for any of the fol-
14 lowing:

15 “(A) To facilitate the construction of facili-
16 ties necessary to accomplish the objectives de-
17 scribed in paragraph (2).

18 “(B) To conduct collaborative research on
19 new technology for scaling biopharmaceutical
20 manufacturing in the United States for com-
21 mercial production.

22 “(C) To facilitate workforce training pro-
23 grams for biopharmaceutical manufacturing.

1 “(D) To fund relevant research and pro-
2 grams for the development of biopharmaceutical
3 manufacturing.

4 “(b) APPLICATION; AWARD.—

5 “(1) IN GENERAL.—Not later than 180 days
6 after the date of the enactment of this section, the
7 Director shall solicit applications from eligible enti-
8 ties specified in paragraph (2) and award to or enter
9 into with one such entity a grant or other trans-
10 action agreement to establish the Center of Excel-
11 lence.

12 “(2) ELIGIBILITY.—An entity is eligible to sub-
13 mit an application pursuant to paragraph (1) if—

14 “(A) the entity is—

15 “(i) a public-private partnership;

16 “(ii) an institution of higher edu-
17 cation; or

18 “(iii) a consortia of entities specified
19 in clauses (i) or (ii); and

20 “(B) the entity is not a Federal entity.

21 “(3) CONTENT OF APPLICATION.—An applica-
22 tion submitted by an entity pursuant to paragraph
23 (1) shall include—

24 “(A) examples from the entity of previous
25 research, development, implementation, and

1 demonstration of innovative practices of bio-
2 pharmaceutical manufacturing;

3 “(B) a description of the manner by which
4 the entity plans to advance the science of bio-
5 pharmaceutical manufacturing, especially with
6 respect to products of particular importance to
7 the national security, health security, or eco-
8 nomic security of the United States;

9 “(C) a description of the manner by which
10 the entity plans to incorporate good manufac-
11 turing practices, quality by design, and stand-
12 ardization of chemistry, manufacturing, and
13 controls, and similar guidance to ensure effec-
14 tive and efficient manufacturing and to make
15 innovative methods of manufacturing more un-
16 derstandable to Executive agencies that are
17 tasked with regulating such methods;

18 “(D) examples of trainings facilitated by
19 the entity that prepare workers for the bio-
20 technology sector;

21 “(E) a description of any existing partner-
22 ships with educational or community partners
23 that help facilitate workforce training for the
24 biotechnology sector;

1 “(F) a description of any experience par-
2 ticipating in or leading biopharmaceutical man-
3 ufacturing partnerships, including those with
4 institutions of higher education, pharmaceutical
5 manufacturers, non-profit organizations, and
6 governmental agencies—

7 “(i) to organize and conduct research
8 and development aimed at—

9 “(I) creating and standardizing
10 new and more effective technology;

11 “(II) developing best practices
12 and sharing knowledge about such
13 technology;

14 “(III) creating intellectual prop-
15 erty; and

16 “(IV) maintaining technological
17 leadership in the United States;

18 “(ii) to support the deployment of in-
19 novative practices and infrastructure of
20 biopharmaceutical manufacturing in the
21 United States; and

22 “(iii) to support developing a skilled
23 workforce ready to use innovations in the
24 biopharmaceutical manufacturing sector;
25 and

1 “(G) a description of how the entity in-
2 tends to utilize any funds authorized under this
3 section to build or expand facilities and infra-
4 structure to achieve any of the objectives de-
5 scribed in subsection (a)(2).

6 “(4) SELECTION CRITERIA.—In selecting an ap-
7 plicant for a grant or other transaction agreement
8 under paragraph (1), the Director shall consider the
9 following:

10 “(A) The potential of the applicant to es-
11 tablish a Center of Excellence that would
12 achieve the objectives set forth in subsection
13 (a)(2).

14 “(B) The past performance of the appli-
15 cant in biopharmaceutical manufacturing work-
16 force development and the potential of the ap-
17 plicant to support workforce development activi-
18 ties in various regions throughout the United
19 States.

20 “(C) The extent to which the applicant
21 proposes to leverage the activities of other bio-
22 pharmaceutical manufacturing innovation, de-
23 velopment, and scaling initiatives.

24 “(D) Whether the proposed location for
25 the Center of Excellence is proximate to other

1 biomanufacturing infrastructure, training facili-
2 ties, or industrial clusters.

3 “(E) The time the applicant estimates is
4 needed for the Center of Excellence to be fully
5 operational and to start delivering impact.

6 “(F) The amount of co-investment com-
7 mitted by Federal, State, private, and other
8 sources to establish the Center of Excellence.

9 “(G) Any additional criteria that the Di-
10 rector considers relevant.

11 “(c) ANNUAL REPORTS.—

12 “(1) INITIAL REPORT.—Not later than one year
13 after the date on which the Director awards to or
14 enters into with an eligible entity a grant or other
15 transaction agreement to establish the Center of Ex-
16 cellence under subsection (b)(1), the Director shall
17 submit to Congress a report describing the progress
18 on establishing the Center of Excellence, including—

19 “(A) the construction of facilities;

20 “(B) any activities, partnerships, and col-
21 laborations by the Center of Excellence; and

22 “(C) any other information regarding the
23 formation of the Center of Excellence that the
24 Director considers relevant.

1 “(2) PROGRESS REPORT.—Not later than one
2 year after the date on which operations at the Cen-
3 ter of Excellence officially begin, the Director shall
4 submit to Congress a report describing—

5 “(A) the activities, partnerships, collabora-
6 tions, and findings of the Center of Excellence;
7 and

8 “(B) any other information regarding the
9 Center of Excellence that the Director considers
10 relevant.

11 “(3) FINAL REPORT.—Not later than 5 years
12 after the date on which operations at the Center of
13 Excellence officially begin, the Director shall submit
14 to Congress a report describing—

15 “(A) the activities, partnerships, collabora-
16 tions, and findings of the Center of Excellence;
17 and

18 “(B) any other information regarding the
19 Center of Excellence that the Director considers
20 relevant.

21 “(4) PUBLICATION.—The Director shall make
22 the reports required by paragraphs (1), (2), and (3)
23 available to the public in an easily accessible elec-
24 tronic format on a website of the Federal Govern-
25 ment that includes information on biotechnology.

1 “(d) INTELLECTUAL PROPERTY.—The Director shall
 2 ensure that, prior to commencing operations, the Center
 3 of Excellence, in consultation with similar existing institu-
 4 tions, such as Manufacturing USA institutes (as defined
 5 in section 34(d)), establishes intellectual property guide-
 6 lines for research conducted within or in collaboration with
 7 the Center of Excellence.

8 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
 9 is authorized to be appropriated to the Director to carry
 10 out this section \$120,000,000 for fiscal year 2026.

11 “(f) DEFINITIONS.—In this section:

12 “(1) BIOMANUFACTURING.—The term ‘bio-
 13 manufacturing’ means the application of bio-
 14 technology to manufacturing.

15 “(2) BIOPHARMACEUTICAL.—The term ‘bio-
 16 pharmaceutical’ means a pharmaceutical drug prod-
 17 uct manufactured using, extracted from, or syn-
 18 thesized from living cells or biological organisms.

19 “(3) BIOTECHNOLOGY.—The term ‘bio-
 20 technology’ means the application of science or engi-
 21 neering, directly or indirectly, to—

22 “(A) a living organism;

23 “(B) a part or product of a living orga-
 24 nism; or

1 “(C) a modified form of subparagraph (A)
2 or (B).

3 “(4) EXECUTIVE AGENCY.—The term ‘Execu-
4 tive agency’—

5 “(A) has the meaning given that term in
6 section 105 of title 5, United States Code; and

7 “(B) includes the Executive Office of the
8 President and the Office of the Vice President.

9 “(5) INSTITUTION OF HIGHER EDUCATION.—
10 The term ‘institution of higher education’ has the
11 meaning given that term in section 101 of the High-
12 er Education Act of 1965 (20 U.S.C. 1001).”.

○