

*Mark B. Enzi*

AMENDMENT NO. 297 Calendar No. \_\_\_\_\_

Purpose: To amend the Public Health Service Act to establish a pathway for the licensure of biosimilar biological products, to promote innovation in the life sciences.

**IN THE SENATE OF THE UNITED STATES—111th Cong., 1st Sess.**

**S.** \_\_\_\_\_

To make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Enzi, Mr. Hatch

Viz: and Ms. Hagan

1

2 On page 596, after line 17, insert the following:

3 **SEC. 601. SHORT TITLE.**

4 This subtitle may be cited as the "Biologics Price

5 Competition and Innovation Act of 2009".

1 **SEC. 602. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGI-**  
2 **CAL PRODUCTS.**

3 (a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-  
4 SIMILAR OR INTERCHANGEABLE.—Section 351 of the  
5 Public Health Service Act (42 U.S.C. 262) is amended—

6 (1) in subsection (a)(1)(A), by inserting “under  
7 this subsection or subsection (k)” after “biologics li-  
8 cense”; and

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

10 “(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-  
11 SIMILAR OR INTERCHANGEABLE.—

12 “(1) IN GENERAL.—Any person may submit an  
13 application for licensure of a biological product  
14 under this subsection.

15 “(2) CONTENT.—

16 “(A) IN GENERAL.—

17 “(i) REQUIRED INFORMATION.—An  
18 application submitted under this subsection  
19 shall include information demonstrating  
20 that—

21 “(I) the biological product is bio-  
22 similar to a reference product based  
23 upon data derived from—

24 “(aa) analytical studies that  
25 demonstrate that the biological  
26 product is highly similar to the

1 reference product notwith-  
2 standing minor differences in  
3 clinically inactive components;

4 “(bb) animal studies (includ-  
5 ing the assessment of toxicity);  
6 and

7 “(cc) a clinical study or  
8 studies (including the assessment  
9 of immunogenicity and phar-  
10 macokinetics or  
11 pharmacodynamics) that are suf-  
12 ficient to demonstrate safety, pu-  
13 rity, and potency in 1 or more  
14 appropriate conditions of use for  
15 which the reference product is li-  
16 censed and intended to be used  
17 and for which licensure is sought  
18 for the biological product;

19 “(II) the biological product and  
20 reference product utilize the same  
21 mechanism or mechanisms of action  
22 for the condition or conditions of use  
23 prescribed, recommended, or sug-  
24 gested in the proposed labeling, but  
25 only to the extent the mechanism or

1 mechanisms of action are known for  
2 the reference product;

3 “(III) the condition or conditions  
4 of use prescribed, recommended, or  
5 suggested in the labeling proposed for  
6 the biological product have been pre-  
7 viously approved for the reference  
8 product;

9 “(IV) the route of administra-  
10 tion, the dosage form, and the  
11 strength of the biological product are  
12 the same as those of the reference  
13 product; and

14 “(V) the facility in which the bio-  
15 logical product is manufactured, proc-  
16 essed, packed, or held meets stand-  
17 ards designed to assure that the bio-  
18 logical product continues to be safe,  
19 pure, and potent.

20 “(ii) DETERMINATION BY SEC-  
21 RETARY.—The Secretary may determine,  
22 in the Secretary’s discretion, that an ele-  
23 ment described in clause (i)(I) is unneces-  
24 sary in an application submitted under this  
25 subsection.

1                   “(iii) ADDITIONAL INFORMATION.—

2                   An application submitted under this sub-  
3                   section—

4                   “(I) shall include publicly-avail-  
5                   able information regarding the Sec-  
6                   retary’s previous determination that  
7                   the reference product is safe, pure,  
8                   and potent; and

9                   “(II) may include any additional  
10                  information in support of the applica-  
11                  tion, including publicly-available infor-  
12                  mation with respect to the reference  
13                  product or another biological product.

14                  “(B) INTERCHANGEABILITY.—An applica-  
15                  tion (or a supplement to an application) sub-  
16                  mitted under this subsection may include infor-  
17                  mation demonstrating that the biological prod-  
18                  uct meets the standards described in paragraph  
19                  (4).

20                  “(3) EVALUATION BY SECRETARY.—Upon re-  
21                  view of an application (or a supplement to an appli-  
22                  cation) submitted under this subsection, the Sec-  
23                  retary shall license the biological product under this  
24                  subsection if—

1           “(A) the Secretary determines that the in-  
2           formation submitted in the application (or the  
3           supplement) is sufficient to show that the bio-  
4           logical product—

5                   “(i) is biosimilar to the reference  
6                   product; or

7                   “(ii) meets the standards described in  
8                   paragraph (4), and therefore is inter-  
9                   changeable with the reference product; and

10           “(B) the applicant (or other appropriate  
11           person) consents to the inspection of the facility  
12           that is the subject of the application, in accord-  
13           ance with subsection (c).

14           “(4) SAFETY STANDARDS FOR DETERMINING  
15           INTERCHANGEABILITY.—Upon review of an applica-  
16           tion submitted under this subsection or any supple-  
17           ment to such application, the Secretary shall deter-  
18           mine the biological product to be interchangeable  
19           with the reference product if the Secretary deter-  
20           mines that the information submitted in the applica-  
21           tion (or a supplement to such application) is suffi-  
22           cient to show that—

23                   “(A) the biological product—

24                           “(i) is biosimilar to the reference  
25                           product; and

1                   “(ii) can be expected to produce the  
2                   same clinical result as the reference prod-  
3                   uct in any given patient; and

4                   “(B) for a biological product that is ad-  
5                   ministered more than once to an individual, the  
6                   risk in terms of safety or diminished efficacy of  
7                   alternating or switching between use of the bio-  
8                   logical product and the reference product is not  
9                   greater than the risk of using the reference  
10                  product without such alternation or switch.

11                  “(5) GENERAL RULES.—

12                  “(A) ONE REFERENCE PRODUCT PER AP-  
13                  PLICATION.—A biological product, in an appli-  
14                  cation submitted under this subsection, may not  
15                  be evaluated against more than 1 reference  
16                  product.

17                  “(B) REVIEW.—An application submitted  
18                  under this subsection shall be reviewed by the  
19                  division within the Food and Drug Administra-  
20                  tion that is responsible for the review and ap-  
21                  proval of the application under which the ref-  
22                  erence product is licensed.

23                  “(C) RISK EVALUATION AND MITIGATION  
24                  STRATEGIES.—The authority of the Secretary  
25                  with respect to risk evaluation and mitigation

1 strategies under the Federal Food, Drug, and  
2 Cosmetic Act shall apply to biological products  
3 licensed under this subsection in the same man-  
4 ner as such authority applies to biological prod-  
5 ucts licensed under subsection (a).

6 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-  
7 ABLE BIOLOGICAL PRODUCT.—Upon review of an  
8 application submitted under this subsection relying  
9 on the same reference product for which a prior bio-  
10 logical product has received a determination of inter-  
11 changeability for any condition of use, the Secretary  
12 shall not make a determination under paragraph (4)  
13 that the second or subsequent biological product is  
14 interchangeable for any condition of use until the  
15 earlier of—

16 “(A) 1 year after the first commercial  
17 marketing of the first interchangeable bio-  
18 similar biological product to be approved as  
19 interchangeable for that reference product;

20 “(B) 18 months after—

21 “(i) a final court decision on all pat-  
22 ents in suit in an action instituted under  
23 subsection (1)(6) against the applicant that  
24 submitted the application for the first ap-



1           proved interchangeable biosimilar biological  
2           product; or

3                   “(ii) the dismissal with or without  
4           prejudice of an action instituted under sub-  
5           section (l)(6) against the applicant that  
6           submitted the application for the first ap-  
7           proved interchangeable biosimilar biological  
8           product; or

9                   “(C)(i) 42 months after approval of the  
10          first interchangeable biosimilar biological prod-  
11          uct if the applicant that submitted such appli-  
12          cation has been sued under subsection (l)(6)  
13          and such litigation is still ongoing within such  
14          42-month period; or

15                   “(ii) 18 months after approval of the first  
16          interchangeable biosimilar biological product if  
17          the applicant that submitted such application  
18          has not been sued under subsection (l)(6).

19          For purposes of this paragraph, the term ‘final court  
20          decision’ means a final decision of a court from  
21          which no appeal (other than a petition to the United  
22          States Supreme Court for a writ of certiorari) has  
23          been or can be taken.

24                   “(7) EXCLUSIVITY FOR REFERENCE PROD-  
25          UCT.—



1 dosing schedule, dosage form, delivery  
2 system, delivery device, or strength; or

3 “(II) a modification to the struc-  
4 ture of the biological product that  
5 does not result in a change in safety,  
6 purity, or potency.

7 “(8) GUIDANCE DOCUMENTS.—

8 “(A) IN GENERAL.—The Secretary may,  
9 after opportunity for public comment, issue  
10 guidance in accordance, except as provided in  
11 subparagraph (B)(i), with section 701(h) of the  
12 Federal Food, Drug, and Cosmetic Act with re-  
13 spect to the licensure of a biological product  
14 under this subsection. Any such guidance may  
15 be general or specific.

16 “(B) PUBLIC COMMENT.—

17 “(i) IN GENERAL.—The Secretary  
18 shall provide the public an opportunity to  
19 comment on any proposed guidance issued  
20 under subparagraph (A) before issuing  
21 final guidance.

22 “(ii) INPUT REGARDING MOST VALU-  
23 ABLE GUIDANCE.—The Secretary shall es-  
24 tablish a process through which the public

1           may provide the Secretary with input re-  
2           garding priorities for issuing guidance.

3           “(C) NO REQUIREMENT FOR APPLICATION  
4           CONSIDERATION.—The issuance (or non-  
5           issuance) of guidance under subparagraph (A)  
6           shall not preclude the review of, or action on,  
7           an application submitted under this subsection.

8           “(D) REQUIREMENT FOR PRODUCT CLASS-  
9           SPECIFIC GUIDANCE.—If the Secretary issues  
10          product class-specific guidance under subpara-  
11          graph (A), such guidance shall include a de-  
12          scription of—

13                 “(i) the criteria that the Secretary will  
14                 use to determine whether a biological prod-  
15                 uct is highly similar to a reference product  
16                 in such product class; and

17                 “(ii) the criteria, if available, that the  
18                 Secretary will use to determine whether a  
19                 biological product meets the standards de-  
20                 scribed in paragraph (4).

21          “(E) CERTAIN PRODUCT CLASSES.—

22                 “(i) GUIDANCE.—The Secretary may  
23                 indicate in a guidance document that the  
24                 science and experience, as of the date of  
25                 such guidance, with respect to a product or

1 product class (not including any recom-  
2 binant protein) does not allow approval of  
3 an application for a license as provided  
4 under this subsection for such product or  
5 product class.

6 “(ii) MODIFICATION OR REVERSAL.—  
7 The Secretary may issue a subsequent  
8 guidance document under subparagraph  
9 (A) to modify or reverse a guidance docu-  
10 ment under clause (i).

11 “(iii) NO EFFECT ON ABILITY TO  
12 DENY LICENSE.—Clause (i) shall not be  
13 construed to require the Secretary to ap-  
14 prove a product with respect to which the  
15 Secretary has not indicated in a guidance  
16 document that the science and experience,  
17 as described in clause (i), does not allow  
18 approval of such an application.

19 “(l) PATENTS.—

20 “(1) CONFIDENTIAL ACCESS TO SUBSECTION  
21 (k) APPLICATION.—

22 “(A) APPLICATION OF PARAGRAPH.—Un-  
23 less otherwise agreed to by a person that sub-  
24 mits an application under subsection (k) (re-  
25 ferred to in this subsection as the ‘subsection

1 (k) applicant') and the sponsor of the applica-  
2 tion for the reference product (referred to in  
3 this subsection as the 'reference product spon-  
4 sor'), the provisions of this paragraph shall  
5 apply to the exchange of information described  
6 in this subsection.

7 "(B) IN GENERAL.—

8 "(i) PROVISION OF CONFIDENTIAL IN-  
9 FORMATION.—When a subsection (k) ap-  
10 plicant submits an application under sub-  
11 section (k), such applicant shall provide to  
12 the persons described in clause (ii), subject  
13 to the terms of this paragraph, confidential  
14 access to the information required to be  
15 produced pursuant to paragraph (2) and  
16 any other information that the subsection  
17 (k) applicant determines, in its sole discre-  
18 tion, to be appropriate (referred to in this  
19 subsection as the 'confidential informa-  
20 tion').

21 "(ii) RECIPIENTS OF INFORMATION.—  
22 The persons described in this clause are  
23 the following:

24 "(I) OUTSIDE COUNSEL.—One or  
25 more attorneys designated by the ref-

1           erence product sponsor who are em-  
2           ployees of an entity other than the  
3           reference product sponsor (referred to  
4           in this paragraph as the ‘outside  
5           counsel’), provided that such attor-  
6           neys do not engage, formally or infor-  
7           mally, in patent prosecution relevant  
8           or related to the reference product.

9           “(II) IN-HOUSE COUNSEL.—One  
10          attorney that represents the reference  
11          product sponsor who is an employee  
12          of the reference product sponsor, pro-  
13          vided that such attorney does not en-  
14          gage, formally or informally, in patent  
15          prosecution relevant or related to the  
16          reference product.

17          “(iii) PATENT OWNER ACCESS.—A  
18          representative of the owner of a patent ex-  
19          clusively licensed to a reference product  
20          sponsor with respect to the reference prod-  
21          uct and who has retained a right to assert  
22          the patent or participate in litigation con-  
23          cerning the patent may be provided the  
24          confidential information, provided that the  
25          representative informs the reference prod-

1            uct sponsor and the subsection (k) appli-  
2            cant of his or her agreement to be subject  
3            to the confidentiality provisions set forth in  
4            this paragraph, including those under  
5            clause (ii).

6            “(C) LIMITATION ON DISCLOSURE.—No  
7            person that receives confidential information  
8            pursuant to subparagraph (B) shall disclose  
9            any confidential information to any other per-  
10           son or entity, including the reference product  
11           sponsor employees, outside scientific consult-  
12           ants, or other outside counsel retained by the  
13           reference product sponsor, without the prior  
14           written consent of the subsection (k) applicant,  
15           which shall not be unreasonably withheld.

16           “(D) USE OF CONFIDENTIAL INFORMA-  
17           TION.—Confidential information shall be used  
18           for the sole and exclusive purpose of deter-  
19           mining, with respect to each patent assigned to  
20           or exclusively licensed by the reference product  
21           sponsor, whether a claim of patent infringement  
22           could reasonably be asserted if the subsection  
23           (k) applicant engaged in the manufacture, use,  
24           offering for sale, sale, or importation into the  
25           United States of the biological product that is



1           the subject of the application under subsection  
2           (k).

3           “(E) OWNERSHIP OF CONFIDENTIAL IN-  
4           FORMATION.—The confidential information dis-  
5           closed under this paragraph is, and shall re-  
6           main, the property of the subsection (k) appli-  
7           cant. By providing the confidential information  
8           pursuant to this paragraph, the subsection (k)  
9           applicant does not provide the reference product  
10          sponsor or the outside counsel any interest in or  
11          license to use the confidential information, for  
12          purposes other than those specified in subpara-  
13          graph (D).

14          “(F) EFFECT OF INFRINGEMENT AC-  
15          TION.—In the event that the reference product  
16          sponsor files a patent infringement suit, the use  
17          of confidential information shall continue to be  
18          governed by the terms of this paragraph until  
19          such time as a court enters a protective order  
20          regarding the information. Upon entry of such  
21          order, the subsection (k) applicant may redesign-  
22          nate confidential information in accordance  
23          with the terms of that order. No confidential in-  
24          formation shall be included in any publicly-  
25          available complaint or other pleading. In the

1 event that the reference product sponsor does  
2 not file an infringement action by the date spec-  
3 ified in paragraph (6), the reference product  
4 sponsor shall return or destroy all confidential  
5 information received under this paragraph, pro-  
6 vided that if the reference product sponsor opts  
7 to destroy such information, it will confirm de-  
8 struction in writing to the subsection (k) appli-  
9 cant.

10 “(G) RULE OF CONSTRUCTION.—Nothing  
11 in this paragraph shall be construed—

12 “(i) as an admission by the subsection  
13 (k) applicant regarding the validity, en-  
14 forceability, or infringement of any patent;  
15 or

16 “(ii) as an agreement or admission by  
17 the subsection (k) applicant with respect to  
18 the competency, relevance, or materiality  
19 of any confidential information.

20 “(H) EFFECT OF VIOLATION.—The disclo-  
21 sure of any confidential information in violation  
22 of this paragraph shall be deemed to cause the  
23 subsection (k) applicant to suffer irreparable  
24 harm for which there is no adequate legal rem-  
25 edy and the court shall consider immediate in-

1           junctive relief to be an appropriate and nec-  
2           essary remedy for any violation or threatened  
3           violation of this paragraph.

4           “(2) SUBSECTION (k) APPLICATION INFORMA-  
5           TION.—Not later than 20 days after the Secretary  
6           notifies the subsection (k) applicant that the applica-  
7           tion has been accepted for review, the subsection (k)  
8           applicant—

9                   “(A) shall provide to the reference product  
10           sponsor a copy of the application submitted to  
11           the Secretary under subsection (k), and such  
12           other information that describes the process or  
13           processes used to manufacture the biological  
14           product that is the subject of such application;  
15           and

16                   “(B) may provide to the reference product  
17           sponsor additional information requested by or  
18           on behalf of the reference product sponsor.

19           “(3) LIST AND DESCRIPTION OF PATENTS.—

20                   “(A) LIST BY REFERENCE PRODUCT SPON-  
21           SOR.—Not later than 60 days after the receipt  
22           of the application and information under para-  
23           graph (2), the reference product sponsor shall  
24           provide to the subsection (k) applicant—

1                   “(i) a list of patents for which the ref-  
2                   erence product sponsor believes a claim of  
3                   patent infringement could reasonably be  
4                   asserted by the reference product sponsor,  
5                   or by a patent owner that has granted an  
6                   exclusive license to the reference product  
7                   sponsor with respect to the reference prod-  
8                   uct, if a person not licensed by the ref-  
9                   erence product sponsor engaged in the  
10                  making, using, offering to sell, selling, or  
11                  importing into the United States of the bi-  
12                  ological product that is the subject of the  
13                  subsection (k) application; and

14                  “(ii) an identification of the patents  
15                  on such list that the reference product  
16                  sponsor would be prepared to license to the  
17                  subsection (k) applicant.

18                  “(B) LIST AND DESCRIPTION BY SUB-  
19                  SECTION (k) APPLICANT.—Not later than 60  
20                  days after receipt of the list under subpara-  
21                  graph (A), the subsection (k) applicant—

22                  “(i) may provide to the reference  
23                  product sponsor a list of patents to which  
24                  the subsection (k) applicant believes a  
25                  claim of patent infringement could reason-

1 ably be asserted by the reference product  
2 sponsor if a person not licensed by the ref-  
3 erence product sponsor engaged in the  
4 making, using, offering to sell, selling, or  
5 importing into the United States of the bi-  
6 ological product that is the subject of the  
7 subsection (k) application;

8 “(ii) shall provide to the reference  
9 product sponsor, with respect to each pat-  
10 ent listed by the reference product sponsor  
11 under subparagraph (A) or listed by the  
12 subsection (k) applicant under clause (i)—

13 “(I) a detailed statement that de-  
14 scribes, on a claim by claim basis, the  
15 factual and legal basis of the opinion  
16 of the subsection (k) applicant that  
17 such patent is invalid, unenforceable,  
18 or will not be infringed by the com-  
19 mercial marketing of the biological  
20 product that is the subject of the sub-  
21 section (k) application; or

22 “(II) a statement that the sub-  
23 section (k) applicant does not intend  
24 to begin commercial marketing of the

1 biological product before the date that  
2 such patent expires; and

3 “(iii) shall provide to the reference  
4 product sponsor a response regarding each  
5 patent identified by the reference product  
6 sponsor under subparagraph (A)(ii).

7 “(C) DESCRIPTION BY REFERENCE PROD-  
8 UCT SPONSOR.—Not later than 60 days after  
9 receipt of the list and statement under subpara-  
10 graph (B), the reference product sponsor shall  
11 provide to the subsection (k) applicant a de-  
12 tailed statement that describes, with respect to  
13 each patent described in subparagraph  
14 (B)(ii)(I), on a claim by claim basis, the factual  
15 and legal basis of the opinion of the reference  
16 product sponsor that such patent will be in-  
17 fringed by the commercial marketing of the bio-  
18 logical product that is the subject of the sub-  
19 section (k) application and a response to the  
20 statement concerning validity and enforceability  
21 provided under subparagraph (B)(ii)(I).

22 “(4) PATENT RESOLUTION NEGOTIATIONS.—

23 “(A) IN GENERAL.—After receipt by the  
24 subsection (k) applicant of the statement under  
25 paragraph (3)(C), the reference product spon-

1           sor and the subsection (k) applicant shall en-  
2           gage in good faith negotiations to agree on  
3           which, if any, patents listed under paragraph  
4           (3) by the subsection (k) applicant or the ref-  
5           erence product sponsor shall be the subject of  
6           an action for patent infringement under para-  
7           graph (6).

8                   “(B) FAILURE TO REACH AGREEMENT.—  
9           If, within 15 days of beginning negotiations  
10          under subparagraph (A), the subsection (k) ap-  
11          plicant and the reference product sponsor fail to  
12          agree on a final and complete list of which, if  
13          any, patents listed under paragraph (3) by the  
14          subsection (k) applicant or the reference prod-  
15          uct sponsor shall be the subject of an action for  
16          patent infringement under paragraph (6), the  
17          provisions of paragraph (5) shall apply to the  
18          parties.

19                   “(5) PATENT RESOLUTION IF NO AGREE-  
20          MENT.—

21                   “(A) NUMBER OF PATENTS.—The sub-  
22          section (k) applicant shall notify the reference  
23          product sponsor of the number of patents that  
24          such applicant will provide to the reference  
25          product sponsor under subparagraph (B)(i)(I).

1 “(B) EXCHANGE OF PATENT LISTS.—

2 “(i) IN GENERAL.—On a date agreed  
3 to by the subsection (k) applicant and the  
4 reference product sponsor, but in no case  
5 later than 5 days after the subsection (k)  
6 applicant notifies the reference product  
7 sponsor under subparagraph (A), the sub-  
8 section (k) applicant and the reference  
9 product sponsor shall simultaneously ex-  
10 change—

11 “(I) the list of patents that the  
12 subsection (k) applicant believes  
13 should be the subject of an action for  
14 patent infringement under paragraph  
15 (6); and

16 “(II) the list of patents, in ac-  
17 cordance with clause (ii), that the ref-  
18 erence product sponsor believes should  
19 be the subject of an action for patent  
20 infringement under paragraph (6).

21 “(ii) NUMBER OF PATENTS LISTED BY  
22 REFERENCE PRODUCT SPONSOR.—

23 “(I) IN GENERAL.—Subject to  
24 subclause (II), the number of patents  
25 listed by the reference product spon-



1                   sor under clause (i)(II) may not ex-  
2                   ceed the number of patents listed by  
3                   the subsection (k) applicant under  
4                   clause (i)(I).

5                   “(II) EXCEPTION.—If a sub-  
6                   section (k) applicant does not list any  
7                   patent under clause (i)(I), the ref-  
8                   erence product sponsor may list 1 pat-  
9                   ent under clause (i)(II).

10                  “(6) IMMEDIATE PATENT INFRINGEMENT AC-  
11                  TION.—

12                  “(A) ACTION IF AGREEMENT ON PATENT  
13                  LIST.—If the subsection (k) applicant and the  
14                  reference product sponsor agree on patents as  
15                  described in paragraph (4), not later than 30  
16                  days after such agreement, the reference prod-  
17                  uct sponsor shall bring an action for patent in-  
18                  fringement with respect to each such patent.

19                  “(B) ACTION IF NO AGREEMENT ON PAT-  
20                  ENT LIST.—If the provisions of paragraph (5)  
21                  apply to the parties as described in paragraph  
22                  (4)(B), not later than 30 days after the ex-  
23                  change of lists under paragraph (5)(B), the ref-  
24                  erence product sponsor shall bring an action for

1 patent infringement with respect to each patent  
2 that is included on such lists.

3 “(C) NOTIFICATION AND PUBLICATION OF  
4 COMPLAINT.—

5 “(i) NOTIFICATION TO SECRETARY.—  
6 Not later than 30 days after a complaint  
7 is served to a subsection (k) applicant in  
8 an action for patent infringement described  
9 under this paragraph, the subsection (k)  
10 applicant shall provide the Secretary with  
11 notice and a copy of such complaint.

12 “(ii) PUBLICATION BY SECRETARY.—  
13 The Secretary shall publish in the Federal  
14 Register notice of a complaint received  
15 under clause (i).

16 “(7) NEWLY ISSUED OR LICENSED PATENTS.—  
17 In the case of a patent that—

18 “(A) is issued to, or exclusively licensed by,  
19 the reference product sponsor after the date  
20 that the reference product sponsor provided the  
21 list to the subsection (k) applicant under para-  
22 graph (3)(A); and

23 “(B) the reference product sponsor reason-  
24 ably believes that, due to the issuance of such  
25 patent, a claim of patent infringement could

1           reasonably be asserted by the reference product  
2           sponsor if a person not licensed by the ref-  
3           erence product sponsor engaged in the making,  
4           using, offering to sell, selling, or importing into  
5           the United States of the biological product that  
6           is the subject of the subsection (k) application,  
7           not later than 30 days after such issuance or licens-  
8           ing, the reference product sponsor shall provide to  
9           the subsection (k) applicant a supplement to the list  
10          provided by the reference product sponsor under  
11          paragraph (3)(A) that includes such patent, not  
12          later than 30 days after such supplement is pro-  
13          vided, the subsection (k) applicant shall provide a  
14          statement to the reference product sponsor in ac-  
15          cordance with paragraph (3)(B), and such patent  
16          shall be subject to paragraph (8).

17           “(8) NOTICE OF COMMERCIAL MARKETING AND  
18          PRELIMINARY INJUNCTION.—

19           “(A) NOTICE OF COMMERCIAL MAR-  
20          KETING.—The subsection (k) applicant shall  
21          provide notice to the reference product sponsor  
22          not later than 180 days before the date of the  
23          first commercial marketing of the biological  
24          product licensed under subsection (k).

1           “(B) PRELIMINARY INJUNCTION.—After  
2           receiving the notice under subparagraph (A)  
3           and before such date of the first commercial  
4           marketing of such biological product, the ref-  
5           erence product sponsor may seek a preliminary  
6           injunction prohibiting the subsection (k) appli-  
7           cant from engaging in the commercial manufac-  
8           ture or sale of such biological product until the  
9           court decides the issue of patent validity, en-  
10          forcement, and infringement with respect to any  
11          patent that is—

12                   “(i) included in the list provided by  
13                   the reference product sponsor under para-  
14                   graph (3)(A) or in the list provided by the  
15                   subsection (k) applicant under paragraph  
16                   (3)(B); and

17                   “(ii) not included, as applicable, on—

18                           “(I) the list of patents described  
19                           in paragraph (4); or

20                           “(II) the lists of patents de-  
21                           scribed in paragraph (5)(B).

22           “(C) REASONABLE COOPERATION.—If the  
23           reference product sponsor has sought a prelimi-  
24           nary injunction under subparagraph (B), the  
25           reference product sponsor and the subsection

1 (k) applicant shall reasonably cooperate to ex-  
2 pedite such further discovery as is needed in  
3 connection with the preliminary injunction mo-  
4 tion.

5 “(9) LIMITATION ON DECLARATORY JUDGMENT  
6 ACTION.—

7 “(A) SUBSECTION (k) APPLICATION PRO-  
8 VIDED.—If a subsection (k) applicant provides  
9 the application and information required under  
10 paragraph (2)(A), neither the reference product  
11 sponsor nor the subsection (k) applicant may,  
12 prior to the date notice is received under para-  
13 graph (8)(A), bring any action under section  
14 2201 of title 28, United States Code, for a dec-  
15 laration of infringement, validity, or enforce-  
16 ability of any patent that is described in clauses  
17 (i) and (ii) of paragraph (8)(B).

18 “(B) SUBSEQUENT FAILURE TO ACT BY  
19 SUBSECTION (k) APPLICANT.—If a subsection  
20 (k) applicant fails to complete an action re-  
21 quired of the subsection (k) applicant under  
22 paragraph (3)(B)(ii), paragraph (5), paragraph  
23 (6)(C)(i), paragraph (7), or paragraph (8)(A),  
24 the reference product sponsor, but not the sub-  
25 section (k) applicant, may bring an action

1 under section 2201 of title 28, United States  
2 Code, for a declaration of infringement, validity,  
3 or enforceability of any patent included in the  
4 list described in paragraph (3)(A), including as  
5 provided under paragraph (7).

6 “(C) SUBSECTION (k) APPLICATION NOT  
7 PROVIDED.—If a subsection (k) applicant fails  
8 to provide the application and information re-  
9 quired under paragraph (2)(A), the reference  
10 product sponsor, but not the subsection (k) ap-  
11 plicant, may bring an action under section 2201  
12 of title 28, United States Code, for a declara-  
13 tion of infringement, validity, or enforceability  
14 of any patent that claims the biological product  
15 or a use of the biological product.”

16 (b) DEFINITIONS.—Section 351(i) of the Public  
17 Health Service Act (42 U.S.C. 262(i)) is amended—

18 (1) by striking “In this section, the term ‘bio-  
19 logical product’ means” and inserting the following:

20 “In this section:

21 “(1) The term ‘biological product’ means”;

22 (2) in paragraph (1), as so designated, by in-  
23 sserting “protein (except any chemically synthesized  
24 polypeptide),” after “allergenic product,”; and

25 (3) by adding at the end the following:

1           “(2) The term ‘biosimilar’ or ‘biosimilarity’, in  
2 reference to a biological product that is the subject  
3 of an application under subsection (k), means—

4           “(A) that the biological product is highly  
5 similar to the reference product notwith-  
6 standing minor differences in clinically inactive  
7 components; and

8           “(B) there are no clinically meaningful dif-  
9 ferences between the biological product and the  
10 reference product in terms of the safety, purity,  
11 and potency of the product.

12           “(3) The term ‘interchangeable’ or ‘inter-  
13 changeability’, in reference to a biological product  
14 that is shown to meet the standards described in  
15 subsection (k)(4), means that the biological product  
16 may be substituted for the reference product without  
17 the intervention of the health care provider who pre-  
18 scribed the reference product.

19           “(4) The term ‘reference product’ means the  
20 single biological product licensed under subsection  
21 (a) against which a biological product is evaluated in  
22 an application submitted under subsection (k).”.

23           (c) CONFORMING AMENDMENTS RELATING TO PAT-  
24 ENTS.—

1           (1) PATENTS.—Section 271(e) of title 35,  
2 United States Code, is amended—

3           (A) in paragraph (2)—

4                 (i) in subparagraph (A), by striking  
5 “or” at the end;

6                 (ii) in subparagraph (B), by adding  
7 “or” at the end; and

8                 (iii) by inserting after subparagraph  
9 (B) the following:

10                 “(C)(i) with respect to a patent that is identi-  
11 fied in the list of patents described in section  
12 351(l)(3) of the Public Health Service Act (including  
13 as provided under section 351(l)(7) of such Act), an  
14 application seeking approval of a biological product,  
15 or

16                 “(ii) if the applicant for the application fails to  
17 provide the application and information required  
18 under section 351(l)(2)(A) of such Act, an applica-  
19 tion seeking approval of a biological product for a  
20 patent that could be identified pursuant to section  
21 351(l)(3)(A)(i) of such Act,”; and

22                 (iv) in the matter following subpara-  
23 graph (C) (as added by clause (iii)), by  
24 striking “or veterinary biological product”



1 and inserting “, veterinary biological prod-  
2 uct, or biological product”;

3 (B) in paragraph (4)—

4 (i) in subparagraph (B), by—

5 (I) striking “or veterinary bio-  
6 logical product” and inserting “, vet-  
7 erinary biological product, or biologi-  
8 cal product”; and

9 (II) striking “and” at the end;

10 (ii) in subparagraph (C), by—

11 (I) striking “or veterinary bio-  
12 logical product” and inserting “, vet-  
13 erinary biological product, or biologi-  
14 cal product”; and

15 (II) striking the period and in-  
16 serting “, and”;

17 (iii) by inserting after subparagraph

18 (C) the following:

19 “(D) the court shall order a permanent injunc-  
20 tion prohibiting any infringement of the patent by  
21 the biological product involved in the infringement  
22 until a date which is not earlier than the date of the  
23 expiration of the patent that has been infringed  
24 under paragraph (2)(C), provided the patent is the  
25 subject of a final court decision, as defined in sec-

1       tion 351(k)(6) of the Public Health Service Act, in  
2       an action for infringement of the patent under sec-  
3       tion 351(l)(6) of such Act, and the biological prod-  
4       uct has not yet been approved because of section  
5       351(k)(7) of such Act.”; and

6                   (iv) in the matter following subpara-  
7                   graph (D) (as added by clause (iii)), by  
8                   striking “and (C)” and inserting “(C), and  
9                   (D)”;

10                   (C) by adding at the end the following:

11       “(6)(A) Subparagraph (B) applies, in lieu of para-  
12       graph (4), in the case of a patent—

13                   “(i) that is identified, as applicable, in the list  
14       of patents described in section 351(l)(4) of the Pub-  
15       lic Health Service Act or the lists of patents de-  
16       scribed in section 351(l)(5)(B) of such Act with re-  
17       spect to a biological product; and

18                   “(ii) for which an action for infringement of the  
19       patent with respect to the biological product—

20                   “(I) was brought after the expiration of  
21       the 30-day period described in subparagraph  
22       (A) or (B), as applicable, of section 351(l)(6) of  
23       such Act; or

24                   “(II) was brought before the expiration of  
25       the 30-day period described in subclause (I),

1 but which was dismissed without prejudice or  
2 was not prosecuted to judgment in good faith.

3 “(B) In an action for infringement of a patent de-  
4 scribed in subparagraph (A), the sole and exclusive remedy  
5 that may be granted by a court, upon a finding that the  
6 making, using, offering to sell, selling, or importation into  
7 the United States of the biological product that is the sub-  
8 ject of the action infringed the patent, shall be a reason-  
9 able royalty.

10 “(C) The owner of a patent that should have been  
11 included in the list described in section 351(l)(3)(A) of  
12 the Public Health Service Act, including as provided under  
13 section 351(l)(7) of such Act for a biological product, but  
14 was not timely included in such list, may not bring an  
15 action under this section for infringement of the patent  
16 with respect to the biological product.”.

17 (2) CONFORMING AMENDMENT UNDER TITLE  
18 28.—Section 2201(b) of title 28, United States  
19 Code, is amended by inserting before the period the  
20 following: “, or section 351 of the Public Health  
21 Service Act”.

22 (d) CONFORMING AMENDMENTS UNDER THE FED-  
23 ERAL FOOD, DRUG, AND COSMETIC ACT.—

24 (1) CONTENT AND REVIEW OF APPLICA-  
25 TIONS.—Section 505(b)(5)(B) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is  
2 amended by inserting before the period at the end  
3 of the first sentence the following: “or, with respect  
4 to an applicant for approval of a biological product  
5 under section 351(k) of the Public Health Service  
6 Act, any necessary clinical study or studies”.

7 (2) NEW ACTIVE INGREDIENT.—Section 505B  
8 of the Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 355c) is amended by adding at the end the  
10 following:

11 “(n) NEW ACTIVE INGREDIENT.—

12 “(1) NON-INTERCHANGEABLE BIOSIMILAR BIO-  
13 LOGICAL PRODUCT.—A biological product that is  
14 biosimilar to a reference product under section 351  
15 of the Public Health Service Act, and that the Sec-  
16 retary has not determined to meet the standards de-  
17 scribed in subsection (k)(4) of such section for inter-  
18 changeability with the reference product, shall be  
19 considered to have a new active ingredient under  
20 this section.

21 “(2) INTERCHANGEABLE BIOSIMILAR BIOLOGI-  
22 CAL PRODUCT.—A biological product that is inter-  
23 changeable with a reference product under section  
24 351 of the Public Health Service Act shall not be

1       considered to have a new active ingredient under  
2       this section.”.

3       (e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-  
4       TION 505.—

5             (1) REQUIREMENT TO FOLLOW SECTION 351.—  
6       Except as provided in paragraph (2), an application  
7       for a biological product shall be submitted under  
8       section 351 of the Public Health Service Act (42  
9       U.S.C. 262) (as amended by this Act).

10            (2) EXCEPTION.—An application for a biologi-  
11       cal product may be submitted under section 505 of  
12       the Federal Food, Drug, and Cosmetic Act (21  
13       U.S.C. 355) if—

14             (A) such biological product is in a product  
15       class for which a biological product in such  
16       product class is the subject of an application  
17       approved under such section 505 not later than  
18       the date of enactment of this Act; and

19             (B) such application—

20               (i) has been submitted to the Sec-  
21       retary of Health and Human Services (re-  
22       ferred to in this Act as the “Secretary”)  
23       before the date of enactment of this Act;  
24       or

1                   (ii) is submitted to the Secretary not  
2                   later than the date that is 10 years after  
3                   the date of enactment of this Act.

4           (3) LIMITATION.—Notwithstanding paragraph  
5           (2), an application for a biological product may not  
6           be submitted under section 505 of the Federal Food,  
7           Drug, and Cosmetic Act (21 U.S.C. 355) if there is  
8           another biological product approved under sub-  
9           section (a) of section 351 of the Public Health Serv-  
10          ice Act that could be a reference product with re-  
11          spect to such application (within the meaning of  
12          such section 351) if such application were submitted  
13          under subsection (k) of such section 351.

14          (4) DEEMED APPROVED UNDER SECTION  
15          351.—An approved application for a biological prod-  
16          uct under section 505 of the Federal Food, Drug,  
17          and Cosmetic Act (21 U.S.C. 355) shall be deemed  
18          to be a license for the biological product under such  
19          section 351 on the date that is 10 years after the  
20          date of enactment of this Act.

21          (5) DEFINITIONS.—For purposes of this sub-  
22          section, the term “biological product” has the mean-  
23          ing given such term under section 351 of the Public  
24          Health Service Act (42 U.S.C. 262) (as amended by  
25          this Act).

1 (f) FOLLOW-ON BIOLOGICS USER FEES.—

2 (1) DEVELOPMENT OF USER FEES FOR BIO-  
3 SIMILAR BIOLOGICAL PRODUCTS.—

4 (A) IN GENERAL.—Beginning not later  
5 than October 1, 2010, the Secretary shall de-  
6 velop recommendations to present to Congress  
7 with respect to the goals, and plans for meeting  
8 the goals, for the process for the review of bio-  
9 similar biological product applications sub-  
10 mitted under section 351(k) of the Public  
11 Health Service Act (as added by this Act) for  
12 the first 5 fiscal years after fiscal year 2012. In  
13 developing such recommendations, the Sec-  
14 retary shall consult with—

15 (i) the Committee on Health, Edu-  
16 cation, Labor, and Pensions of the Senate;

17 (ii) the Committee on Energy and  
18 Commerce of the House of Representa-  
19 tives;

20 (iii) scientific and academic experts;

21 (iv) health care professionals;

22 (v) representatives of patient and con-  
23 sumer advocacy groups; and

24 (vi) the regulated industry.

1           (B) PUBLIC REVIEW OF RECOMMENDA-  
2           TIONS.—After negotiations with the regulated  
3           industry, the Secretary shall—

4                   (i) present the recommendations de-  
5                   veloped under subparagraph (A) to the  
6                   Congressional committees specified in such  
7                   subparagraph;

8                   (ii) publish such recommendations in  
9                   the Federal Register;

10                   (iii) provide for a period of 30 days  
11                   for the public to provide written comments  
12                   on such recommendations;

13                   (iv) hold a meeting at which the pub-  
14                   lic may present its views on such rec-  
15                   ommendations; and

16                   (v) after consideration of such public  
17                   views and comments, revise such rec-  
18                   ommendations as necessary.

19           (C) TRANSMITTAL OF RECOMMENDA-  
20           TIONS.—Not later than January 15, 2012, the  
21           Secretary shall transmit to Congress the revised  
22           recommendations under subparagraph (B), a  
23           summary of the views and comments received  
24           under such subparagraph, and any changes



1           made to the recommendations in response to  
2           such views and comments.

3           (2) ESTABLISHMENT OF USER FEE PRO-  
4           GRAM.—It is the sense of the Senate that, based on  
5           the recommendations transmitted to Congress by the  
6           Secretary pursuant to paragraph (1)(C), Congress  
7           should authorize a program, effective on October 1,  
8           2012, for the collection of user fees relating to the  
9           submission of biosimilar biological product applica-  
10          tions under section 351(k) of the Public Health  
11          Service Act (as added by this Act).

12          (3) TRANSITIONAL PROVISIONS FOR USER FEES  
13          FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

14                (A) APPLICATION OF THE PRESCRIPTION  
15                DRUG USER FEE PROVISIONS.—Section  
16                735(1)(B) of the Federal Food, Drug, and Cos-  
17                metic Act (21 U.S.C. 379g(1)(B)) is amended  
18                by striking “section 351” and inserting “sub-  
19                section (a) or (k) of section 351”.

20                (B) EVALUATION OF COSTS OF REVIEWING  
21                BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-  
22                TIONS.—During the period beginning on the  
23                date of enactment of this Act and ending on  
24                October 1, 2010, the Secretary shall collect and  
25                evaluate data regarding the costs of reviewing

1 applications for biological products submitted  
2 under section 351(k) of the Public Health Serv-  
3 ice Act (as added by this Act) during such pe-  
4 riod.

5 (C) AUDIT.—

6 (i) IN GENERAL.—On the date that is  
7 2 years after first receiving a user fee ap-  
8 plicable to an application for a biological  
9 product under section 351(k) of the Public  
10 Health Service Act (as added by this Act),  
11 and on a biennial basis thereafter until Oc-  
12 tober 1, 2013, the Secretary shall perform  
13 an audit of the costs of reviewing such ap-  
14 plications under such section 351(k). Such  
15 an audit shall compare—

16 (I) the costs of reviewing such  
17 applications under such section  
18 351(k) to the amount of the user fee  
19 applicable to such applications; and

20 (II)(aa) such ratio determined  
21 under subclause (I); to

22 (bb) the ratio of the costs of re-  
23 viewing applications for biological  
24 products under section 351(a) of such  
25 Act (as amended by this Act) to the

1 amount of the user fee applicable to  
2 such applications under such section  
3 351(a).

4 (ii) ALTERATION OF USER FEE.—If  
5 the audit performed under clause (i) indi-  
6 cates that the ratios compared under sub-  
7 clause (II) of such clause differ by more  
8 than 5 percent, then the Secretary shall  
9 alter the user fee applicable to applications  
10 submitted under such section 351(k) to  
11 more appropriately account for the costs of  
12 reviewing such applications.

13 (iii) ACCOUNTING STANDARDS.—The  
14 Secretary shall perform an audit under  
15 clause (i) in conformance with the account-  
16 ing principles, standards, and requirements  
17 prescribed by the Comptroller General of  
18 the United States under section 3511 of  
19 title 31, United State Code, to ensure the  
20 validity of any potential variability.

21 (4) AUTHORIZATION OF APPROPRIATIONS.—  
22 There is authorized to be appropriated to carry out  
23 this subsection such sums as may be necessary for  
24 each of fiscal years 2010 through 2012.

1 (g) ALLOCATION OF SAVINGS; SPECIAL RESERVE  
2 FUND.—

3 (1) DETERMINATION OF SAVINGS.—The Sec-  
4 retary of the Treasury, in consultation with the Sec-  
5 retary, shall for each fiscal year determine the  
6 amount of the savings to the Federal Government as  
7 a result of the enactment of this Act and shall trans-  
8 fer such amount to the Fund established under  
9 paragraph (2) pursuant to a relevant appropriations  
10 Act.

11 (2) SPECIAL RESERVE FUND.—

12 (A) IN GENERAL.—There is established in  
13 the Treasury of the United States a fund to be  
14 designated as the “Biological Product Savings  
15 Fund” to be made available to the Secretary  
16 without fiscal year limitation.

17 (B) USE OF FUND.—The amounts made  
18 available to the Secretary through the Fund  
19 under subparagraph (A) shall be expended on  
20 activities authorized under the Public Health  
21 Service Act.

22 (3) AUTHORIZATION OF APPROPRIATIONS.—  
23 There is authorized to be appropriated for each fis-  
24 cal year to the Fund established under paragraph

1 (2), the amount of the savings determined for such  
2 fiscal year under paragraph (1).

3 (h) GOVERNMENT ACCOUNTABILITY OFFICE  
4 STUDY.—

5 (1) IN GENERAL.—Not later than 3 years after  
6 the date of enactment of this Act, the Comptroller  
7 General of the United States shall study and report  
8 to Congress regarding—

9 (A) the extent to which pediatric studies of  
10 biological products are being required under the  
11 Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 301 et seq.); and

13 (B) any pediatric needs not being met  
14 under existing authority.

15 (2) CONTENT OF STUDY.—The study under  
16 paragraph (1) shall review and assess—

17 (A) the extent to which pediatric studies of  
18 biological products are required under sub-  
19 sections (a) and (b) of section 505B of the Fed-  
20 eral Food, Drug and Cosmetic Act (21 U.S.C.  
21 355c);

22 (B) the extent to which pediatric studies of  
23 biological products are required as part of risk  
24 evaluation and mitigation strategies under such  
25 Act;

1 (C) the number, importance, and  
2 prioritization of any biological products that are  
3 not being tested for pediatric use; and

4 (D) recommendations for ensuring pedi-  
5 atric testing of products identified in subpara-  
6 graph (C), including the consideration of any  
7 incentives, such as those provided under the  
8 Best Pharmaceuticals for Children Act.

9 (i) ORPHAN PRODUCTS.—If a reference product, as  
10 defined in section 351 of the Public Health Service Act  
11 (42 U.S.C. 262) (as amended by this Act) has been des-  
12 ignated under section 526 of the Federal Food, Drug, and  
13 Cosmetic Act (21 U.S.C. 360bb) for a rare disease or con-  
14 dition, a biological product seeking approval for such dis-  
15 ease or condition under subsection (k) of such section 351  
16 as biosimilar to, or interchangeable with, such reference  
17 product may be licensed by the Secretary only after the  
18 expiration for such reference product of the later of—

19 (1) the 7-year period described in section  
20 527(a) of the Federal Food, Drug, and Cosmetic Act  
21 (21 U.S.C. 360cc(a)); and

22 (2) the 12-year period described in subsection  
23 (k)(7) of such section 351.