S.L.C.

AMENDMENT NO. 297	Calendar No
Purpose: To amend the Public Health Selish a pathway for the licensure of laproducts, to promote innovation in the	biosimilar biological
IN THE SENATE OF THE UNITED STATES—	111th Cong., 1st Sess.
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To make quality, affordable health care avicans, reduce costs, improve health cardisease prevention, and strengthen the force.	are quality, enhance
Referred to the Committee on ordered to be printed	and
Ordered to lie on the table and to	be printed
AMENDMENT intended to be proposed by Viz: and Ms. Hagan	Mr. Enzi, Mr. Hatch
1	
2 On page 596, after line 17, insert	the following:
3 SEC. 601. SHORT TITLE.	
4 This subtitle may be cited as the	he "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	"(ce) 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 additiona
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 (l)(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	"(A) EFFECTIVE DATE OF BIOSIMILAR AP-
2	PLICATION APPROVAL.—Approval of an applica-
3	tion under this subsection may not be made ef-
4	fective by the Secretary until the date that is
5	12 years after the date on which the reference
6	product was first licensed under subsection (a).
7	"(B) FILING PERIOD.—An application
8	under this subsection may not be submitted to
9	the Secretary until the date that is 4 years
10	after the date on which the reference product
11	was first licensed under subsection (a).
12	"(C) FIRST LICENSURE.—Subparagraphs
13	(A) and (B) shall not apply to a license for or
14	approval of—
15	"(i) a supplement for the biological
16	product that is the reference product; or
17	"(ii) a subsequent application filed by
18	the same sponsor or manufacturer of the
19	biological product that is the reference
20	product (or a licensor, predecessor in inter-
21	est, or other related entity) for—
22	"(I) a change (not including a
23	modification to the structure of the bi-
24	ological product) that results in a new
25	indication, route of administration,

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
9	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). "(C) LIMITATION ON DISCLOSURE.—No 6 7 person that receives confidential information 8 pursuant to subparagraph (B) shall disclose 9 any confidential information to any other person or entity, including the reference product 10 sponsor employees, outside scientific consult-11 12 ants, or other outside counsel retained by the 13 reference product sponsor, without the prior written consent of the subsection (k) applicant, 14 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

United States of the biological product that is

the subject of the application under subsection (k).

"(E) OWNERSHIP OF CONFIDENTIAL IN-FORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

"(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-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
0	making, using, offering to sell, selling, or
1	importing into the United States of the bi-
12	ological product that is the subject of the
13	subsection (k) application; and
4	"(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-
01	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-
9	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
4	(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-
8	logical product that is the subject of the sub-
9	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 or
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, it
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	(D) 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

reasonably be asserted by the reference produc-	t
sponsor if a person not licensed by the ref-	
erence product sponsor engaged in the making	,
using, offering to sell, selling, or importing into)
the United States of the biological product that	t
is the subject of the subsection (k) application	,
not later than 30 days after such issuance or licens-	
ing, the reference product sponsor shall provide to)
the subsection (k) applicant a supplement to the list	
provided by the reference product sponsor under	•
paragraph (3)(A) that includes such patent, not	9
later than 30 days after such supplement is pro-	
vided, the subsection (k) applicant shall provide a	ù
statement to the reference product sponsor in ac-	
cordance with paragraph (3)(B), and such patent	
shall be subject to paragraph (8).	
"(8) Notice of commercial marketing and	
PRELIMINARY INJUNCTION.—	
"(A) NOTICE OF COMMERCIAL MAR-	
KETING.—The subsection (k) applicant shall	
provide notice to the reference product sponsor	e
not later than 180 days before the date of the	
first commercial marketing of the biological	

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-
9	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	serting "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)"; and
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,

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- Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by inserting before the period at the end of the first sentence the following: "or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service 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.—
 - "(1) Non-interchangeable biosimilar biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.
 - "(2) Interchangeable biosimilar biological product that is interchangeable with a reference product under section 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 nor
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	355e);
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.