(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 3204. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 355–1) is amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) accommodate different approved risk evaluation and mitigation strategies for a reference drug product and a drug that is the subject of an abbreviated new drug application.''; and

(2) in subsection (i)(1), by striking subparagraph (B) and inserting the following:

''(B) Elements to assure safe use, if required under subsection (f) for the listed drug.

''(i) Subject to clause (ii), a drug that is the subject of an abbreviated new drug application may use—

''(I) a single, shared system with the listed drug under subsection (f); or

''(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

''(ii) The Secretary may require a drug that is the subject of an abbreviated new drug application and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).''.

SA 5137. Mr. MCCONNELL (for himself and Mr. REID) proposed an amendment to the concurrent resolution H. Con. Res. 174, directing the Clerk of the House of Representatives to make a correction in the enrollment of H.R. 34; as follows:

Beginning on page 1, line 7, strike ''following correction:'' and all that follows and insert the following:

''following corrections:

''(1) Amend the long title so as to read: 'An Act to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.'.

''(2) Amend the section heading for section 1001 so as to read: '**BEAU BIDEN CANCER MOONSHOT AND NIH INNOVATION PROJECTS**'.

''(3) Amend the table of contents in section 1 so that the item relating to section 1001 reads as follows:

''''1001. Beau Biden Cancer Moonshot and NIH innovation projects.'.''.

ACTION VITIATED—H.R. 5602, S. 3336, AND CALENDAR NOS. 675 THROUGH 683

Mr. MORAN. Mr. President, I ask unanimous consent to vitiate all action taken during today's session of the Senate on H.R. 5602, S. 3336, and Calendar Nos. 675 through 683.

The PRESIDING OFFICER. Without objection, it is so ordered.

ORDERS FOR TUESDAY, DECEMBER 6, 2016

Mr. MORAN. Mr. President, I ask unanimous consent that when the Senate completes its business today, it adjourn until 10 a.m., Tuesday, December 6; that following the prayer and pledge, the morning hour be deemed expired, the Journal of proceedings be approved to date, and the time for the two leaders be reserved for their use later in the day; further, that following leader remarks, the Senate resume consideration of the House message to accompany H.R. 34 postcloture; finally, that all time during adjournment and recess of the Senate count postcloture on the motion to concur.

The PRESIDING OFFICER. Without objection, it is so ordered.

ADJOURNMENT UNTIL 10 A.M. TOMORROW

Mr. MORAN. Mr. President, if there is no further business to come before the Senate, I ask unanimous consent that it stand adjourned under the previous order.

There being no objection, the Senate, at 6:52 p.m., adjourned until Tuesday, December 6, 2016, at 10 a.m.