In the Senate of the United States,

December 10, 2020.

Resolved, That the bill from the House of Representatives (H.R. 1520) entitled "An Act to amend the Public Health Service Act to provide for the publication of a list of licensed biological products, and for other purposes.", do pass with the following

AMENDMENT:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

The Act may be cited as the "Purple Book Continuity Act of 2020".

SEC. 2. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.

(a) IN GENERAL.—Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended by adding at the end the following:

"(9) PUBLIC LISTING.—

"(A) IN GENERAL.—

"(i) INITIAL PUBLICATION.—Not later than 180 days after the date of enactment of the Purple Book Continuity Act of 2020, the Secretary shall publish and make available to the public in a searchable, electronic format—

"(I) a list of each biological product, by nonproprietary name (proper name), for which, as of such date of enactment, a biologics license under subsection (a) or this subsection is in effect, or that, as of such date of enactment, is deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009;

"(II) the date of licensure of the marketing application and the application number; and

"(III) with respect to each biological product described in subclause (I), the licensure status, and, as available, the marketing status.

"(ii) REVISIONS.—Every 30 days after the publication of the first list under clause

(i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period or deemed licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

"(iii) PATENT INFORMATION.—Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference

product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

"(iv) LISTING OF EXCLUSIVITIES.—For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period under paragraph (6) or paragraph (7) for which the Secretary has determined such biological product to be eligible and that has not concluded.

"(B) REVOCATION OR SUSPENSION OF LICENSE.—If the license of a biological product is determined by the Secretary to have been revoked or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If such revocation or suspension occurred after inclusion of such biological product in the list published under subparagraph (A), the reference product sponsor shall notify the Secretary that—

"(i) the biological product shall be immediately removed from such list for the

same period as the revocation or suspension; and

"(ii) a notice of the removal shall be published in the Federal Register.".

(b) REVIEW AND REPORT ON TYPES OF INFORMATION TO BE LISTED.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) solicit public comment regarding the type of information, if any, that should be added to or removed from the list required by paragraph (9) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as added by subsection (a); and

(2) transmit to Congress an evaluation of such comments, including any recommendations about the types of information that should be added to or removed from the list.

Attest:

Secretary.

116TH CONGRESS
2D SESSION

H.R. 1520

AMENDMENT