AMENDMENT TO SENATE AMENDMENT TO H.R. 5371

(CONTINUING APPROPRIATIONS, AGRICULTURE, LEGISLATIVE BRANCH, MILITARY CONSTRUCTION AND VETERANS AFFAIRS, AND EXTENSIONS ACT, 2026)

OFFERED BY MS. SCHOLTEN OF MICHIGAN

In the appropriate place in the bill, insert the following:

SEC. 1. Generic drugs for use with devices.

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

(1) in paragraph (2)(A)—

(A) in clause (v)—

(i) by striking "except for changes required because of differences" and inserting "except for changes required or appropriate, as determined by the Secretary, because of differences"; and

(ii) by inserting ", including changes as a result of differences that are otherwise permitted under this subsection, such as changes as a result of appropriate differences in the device for use with the new drug" before the semicolon;

(B) in clause (vii), by striking the "and" at the end;

(C) in clause (viii) by striking the period at the end and inserting "; and";

(D) by inserting after clause (viii) the following new clause:

"(ix) if the listed drug referred to in clause (i) is intended for use with a device, relevant information as determined by the Secretary to support that the new drug for use with the device can be expected to have the same clinical effect and safety profile as the listed drug for use with the device when administered to patients under the conditions specified in the labeling of the drug, which information—

"(I) shall be in addition to information under clauses (i) through (viii) that is relevant, as determined by the Secretary, to the evaluation of the new drug for use with the device and the device proposed for use with the new drug; and

"(II) may include—

“(aa) information (comparative and non-comparative) regarding the device and its performance, including information about the compatibility of the new drug with the device and information regarding the delivery of the new drug when used with the device;

“(bb) comparative analyses of the new drug for use with the device and the listed drug for use with its device, including information identifying any differences between the user interface of the new drug and listed drug; information identifying any differences between the user interface of the device proposed for use with the new drug and the device used with the listed drug; and information to show that, despite any such differences, the new drug when used with the device can be expected to have the same clinical effect and safety profile as the listed drug when used with the device when administered to patients under the conditions specified in the labeling of the drug; and

“(cc) comparative and non-comparative human factors studies.”; and

(E) in the matter following clause (ix), as inserted by subparagraph (D), by striking “through (viii)” and inserting “through (ix)”; and

(2) in paragraph (4)—

(A) in subparagraph (G)—

(i) by striking “except for changes required because of differences” and inserting “except for changes required or appropriate, as determined by the Secretary, because of differences”; and

(ii) by inserting “, including changes as a result of differences that are otherwise permitted under this subsection, such as changes as a result of appropriate differences in the device for use with the new drug” before the semicolon;

(B) by redesignating subparagraphs (J) through (K) as subparagraphs (K) through (L); and

(C) by inserting after subparagraph (I) the following:

“(J) if the listed drug is intended for use with a device, information submitted in the application is insufficient to show that the new drug for use with the device can be expected to have the same clinical effect and safety profile as the listed drug for use with the device when administered to patients under the conditions specified in the labeling of the drug;”.