AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 7667

OFFERED BY M__. _____

Page 182, after line 8, add the following:

SEC. 814. STRENGTHENING THE USE OF PATIENT-EXPERIENCE DATA WITHIN RISK-BENEFIT FRAMEWORK.

Section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A), by striking ''; and'' and inserting a semicolon;

(B) in subparagraph (B), by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(C) as part of the risk-benefit assessment framework in the new drug approval process described in section 505(d), considering patient experience data submitted by the medical product sponsor or another party.''; and

(2) in subsection (b)(1), by inserting '', including a description of how such data and information were considered in the risk-benefit assessment de-

scribed in section 505(d)'' before the period at the end.

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