AMENDMENT OFFERED BY _____

TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2026

Beginning on page 1, line 4, amend section 2 to read as follows:

SEC. 2. FACILITATING EXCHANGE OF INFORMATION PRIOR TO APPROVAL.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) is amended—

(1) by redesignating subparagraph (2) as subparagraph (3);

(2) by inserting after subparagraph (1) the following:

''(2)(A) Health care economic information or scientific information provided to a payor, formulary, or other similar entity with knowledge and expertise in the area of health care economic analysis carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered false or misleading under this paragraph, if it is truthful, nonmisleading, nonpromotional, and based on competent and reliable scientific evidence and relates to an investigational use of an approved or licensed drug. Information that is relevant to

the substantiation of the health care economic information or scientific information presented pursuant to this paragraph shall be made available to the Secretary upon request.

''(B) In order for information relating to an investigational use of an approved or licensed drug to be provided pursuant to this subparagraph—

''(i) the study or studies the sponsor could objectively anticipate to be sufficient to support the approval or licensing of such use must have been conducted;

''(ii) the information must be—

''(I) derived from such study or studies;

''(II) unbiased, factual, and accurate; and

''(III) presented factually and with no characterizations or conclusions made regarding safety or effectiveness of the investigational use;

''(iii) the sponsor must have filed with the Secretary a submission for approval or licensing of the use;

''(iv) the information must include a conspicuous and prominent statement describing any material differences between the information provided and the labeling of the drug approved or li-

censed pursuant to section 505 of this Act or pursuant to section 351 of the Public Health Service Act;

''(v) the information must include a clear statement that the use is under investigation and that the safety or effectiveness has not been established; and

''(vi) the sponsor must provide additional information to a payor, formulary, or other similar entity when there is a significant change in information related to review status or clinical study results.

''(C) For purposes of this subparagraph, scientific information includes clinical and pre-clinical data and results relating a use that has not been approved or licensed and is being investigated or developed for an approved or licensed drug.''; and

(3) by adding at the end the following:

''(4) Nothing in this paragraph shall be construed to limit the ability of manufacturers or sponsors of drugs to engage in communications or activities not specified in subparagraph (2) or (3) that are otherwise permissible.''.

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