II

117TH CONGRESS
2D SESSION

S. 4390

To require summary approval information with respect to certain approved drugs and biological products.

IN THE SENATE OF THE UNITED STATES

JUNE 14, 2022

Mr. HICKENLOOPER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To require summary approval information with respect to certain approved drugs and biological products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Accelerated Approval Transparency Act''.

SEC. 2. SUMMARY APPROVAL INFORMATION.

With respect to each new drug application for a new molecular entity approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or biological product licensed under section 351(a) of the

Public Health Service Act (42 U.S.C. 262(a)) pursuant to accelerated approval under section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)), the Secretary of Health and Human Services shall provide for the drug or biologic action package a summary of the basis for approval, including, as relates to such new molecular entity, whether an advisory committee meeting was held and a rationale for a determination by the Secretary that a surrogate endpoint is reasonably likely to predict clinical benefit.

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