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RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-3641
Minority (202) 225-2927

August 9, 2023

Dr. Lishan Aklog, M.D.
Chairman and Chief Executive Office of PAVmed
360 Madison Avenue, Floor 25
New York NY 10017

Dear Dr. Aklog:

Thank you for appearing before the Subcommittee on Health on Tuesday, July 18, 2023, to testify at the hearing entitled "Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology".

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Wednesday, August 23, 2023. Your responses should be mailed to Jolie Brochin, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Jolie.Brochin@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

The Honorable Dan Crenshaw

1) Dr. Aklog, can you speak to what you have seen in practice for your companies or based on your research and how this impacts investment? Does in your view TCET fix this issue?

2) Dr. Aklog, do investors believe the current FDA/CMS parallel review process is working?

3) To your knowledge, *before* restricting Medicare coverage of FDA-approved therapies and devices to participants in clinical trials and studies does, does CMS do any analysis of the potential impacts on access to rural or other underserved populations? If so, is that information publicly available?