CATHY McMORRIS RODGERS,
WASHINGTON
CHAIR

FRANK PALLONE, JR., NEW JERSEY,
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. Todd Brinton, M.D.
Corporate Vice President, Advanced Technology
Chief Scientific Officer, Edwards Lifesciences
601 13th Street N.W., Suite 350S
Washington, DC 20005

Dear Dr. Brinton:

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 Cathy McMorris Rodgers

1) How long did it take for CMS to issue a national coverage determination (NCD) after TAVR was approved by the FDA?

    a. Can you elaborate on how the length of the process and resources dedicated to working within it affect your ability to deliver TAVR and other products to patients and your ability to competitively price them?

2) During your testimony, you mentioned the "success story" of TAVR. Could you elaborate on the lessons we learned during the TAVR experience? How can Congress and CMS ensure that future NCDs reflect and improve upon the TAVR experience and increase Medicare beneficiary access to innovative technologies?

3) In your testimony you note it is because of data collection through the CED requirements that you were able to identify disparities in patient access to TAVR. How can the TAVR registry help ensure access to the treatment for all patient populations, including those in rural settings?

4) How are rural areas impacted by CED requirements and the burden associated with reporting via a registry? What are the associated costs with reporting via a cardiovascular registry? Would eliminating CED requirements for patients located in rural areas increase access for these patients?

5) What are the benefits of "fit-for-purpose" data collection and how could that be different than a registry?

6) How should the criteria for truly innovative products be considered, and how do we ensure that both larger and smaller innovators can reasonably meet any reporting requirements or other policies to ensure patient safety and the merits of their products?

The Honorable Robert E. Latta

1) I want to reiterate my strong desire to work with this Committee in a bipartisan manner to ensure a robust and meaningful separate expedited pathway for coverage of innovative FDA-approved devices. I am concerned that CMS has moved in the wrong direction with this guidance and is instead expanding or refining the Coverage with Evidence Development process for those with inadequate evidence as the only pathway under TCET. This would be a significant departure from creating a separate pathway for accelerated coverage for the truly innovative products that may not need additional data for coverage due to existing sound clinical data, and for whom existing protracted coverage processes have led to significant delays in coverage. Do you agree that it is crucial that CMS and Congress to continue to work to modify this guidance, or do you think we need to find a legislative or administrative solution for a separate, predictable, and transparent pathway for expedited Medicare coverage of new devices that have existing significant clinical data?

The Honorable Dan Crenshaw

1) Dr. Brinton, can you speak more to how TCET differs from the MCIT proposal, specifically, the number of devices that CMS expects to even be eligible for this produce?

2) Dr. Brinton, what about those products with significant clinical evidence and clinical trials that do not have breakthrough designation?

3) Can you speak to what this will mean for investment in and access to these products for patients?

4) 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?