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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

Ms. Suzanne Wronsky
Alzheimer's Association Advocate
10008 Meyer Point Terrace
Potomac, MD 20854

Dear Ms. Wronsky:

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 Greg Pence**

Ms. Wronsky,

In Indiana, there are 110 thousand people aged 65 and older suffering from Alzheimer's, and 2,238 Hoosiers have tragically lost their lives to this terrible disease in 2021, according to the CDC. It is important CMS incentivize research and development by being transparent with the methodology and process used to determine coverage of drugs. I recently joined my colleagues in the Indiana delegation on a letter to the Biden Administration urging them to provide access to FDA-approved Alzheimer's therapeutics. While Medicare has traditionally covered all FDA-approved drugs, CMS has now set up a registry portal that could create logistical challenges for patients and caregivers as well as providers in rural areas.

1) Can you explain why opening a National Coverage Determination reconsideration is important to patients, particularly those in rural communities?

**The Honorable Dan Crenshaw**

1) 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?

2) How will CMS's decision to require beneficiaries to enroll in a clinical study in order to have Medicare coverage affect people's access to FDA-approved therapies shown to delay Alzheimer's progression? What barriers to people with Alzheimer's disease and their families face in terms of getting to the point of even qualifying for treatment, including challenges with identifying a health issue, seeking diagnosis, finding a provider, and the like?