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

April 18, 2024

Dr. Jeromie Ballreich, Ph.D. Associate Research Professor Johns Hopkins Bloomberg School of Public Health 624 North Broadway Baltimore, MD 21205

Dear Dr. Ballreich:

Thank you for appearing before the Subcommittee on Health on Thursday, February 29, 2024, to testify at the hearing entitled "Legislative Proposals to Support Patients with Rare Diseases."

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 with a transmittal letter by the close of business on Thursday, May 2, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

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

Sincerely,

Brest Author

Brett Guthrie Chair Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Gus Bilirakis

- 1. Your testimony states that "current Orphan Drug Act incentives help drive innovation in rare diseases." Does this include the pediatric rare Priority Review Voucher (PRV) program, especially in light of the FDA's recent study reflecting on the first ten years of the program?
- 2. Considering the PRV program has been in statute for the past 12 years, would you agree that extending the existing PRV program maintains the current incentives needed to continue to drive innovation in rare disease therapy development?