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ONE HUNDRED NINETEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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July 29, 2025

Dr. Ronald T. Piervincenzi, PhD
Chief Executive Officer
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Dear Dr. Piervincenzi:

Thank you for appearing before the Subcommittee on Health on Wednesday, June 11, 2025, to testify at the hearing entitled "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain."

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 Tuesday, August 12, 2025. Your responses should be mailed to Annabelle Huffman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Annabelle.Huffman@mail.house.gov.

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

Sincerely,

H. Morgan Griffith
Chairman
Subcommittee on Health

cc: Diana DeGette, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Diana Harshbarger

1. Having naloxone as an over-the-counter (OTC) has been lifesaving for countless people but recent reporting highlights some of the inefficiencies at the Food and Drug Administration (FDA) in need of improvement. A recent study on Narcan's OTC switch found that FDA's review of the proposed tradename took 8 months, its review of the human factors study (HFS) protocol (assessing how well participants could use the NNS device) took 6 months, and the protocol revision took 4 more weeks. Narcan was supposed to meet a public health emergency.

    a. Why would it take so long for the FDA to act and what changes could be made at the agency to improve our healthcare supply chain?

2. The report also notes that despite FDA's verbal appeal to manufacturers in 2017, FDA denied the Sponsor's request for fast-track designation and priority review of the OTC application. The FDA only granted this request after the Sponsor went through an appeals process. How do you think these sorts of delays impact getting these products to market?

    a. How long does it take?

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1. *Having naloxone as an over-the-counter (OTC) has been lifesaving for countless people but recent reporting highlights some of the inefficiencies at the Food and Drug Administration (FDA) in need of improvement. A recent study on Narcan's OTC switch found that FDA's review of the proposed tradename took 8 months, its review of the human factors study (HFS) protocol (assessing how well participants could use the NNS device) took 6 months, and the protocol revision took 4 more weeks. Narcan was supposed to meet a public health emergency.*

   Why would it take so long for the FDA to act and what changes could be made at the agency to improve our healthcare supply chain?

   The availability of naloxone over-the-counter (OTC) has expanded access to this lifesaving intervention and continues to serve as a critical tool in preventing opioid-related deaths across the country.

   As you note, the FDA plays a central role in administering the complex evaluations needed to ensure such products are safe and effective and can be used safely and effectively by the general public without the supervision of a healthcare provider.

   It is hard to know, in the case of naloxone, how the emergence of COVID impacted the review process or contributed to regulatory delays, particularly with respect to the human factors protocol. Ensuring that these pathways function as intended or are updated to be appropriately responsive to the health needs of the nation is critically important.

   As FDA and industry begin their next round of user fees agreements, in earnest, there is likely to be debate over enhanced transparency, defined performance goals, and review predictability. Your questions are timely and represent important considerations. USP stands ready to work with your office ahead of Congress' review and authorization process.

2. *The report also notes that despite FDA's verbal appeal to manufacturers in 2017, FDA denied the Sponsor's request for fast-track designation and priority review of the OTC application. The FDA only granted this request after the Sponsor went through an appeals process. How do you think these sorts of delays impact getting these products to market? How long does it take?*

   The naloxone example raises important questions about how regulatory tools like Fast Track and Priority Review might be applied in future cases when the barrier is not the product itself, but the mode of access.

Continued dialogue between FDA, Congress, and public health stakeholders could help clarify whether existing expedited pathways are sufficient—or whether new mechanisms are needed—to better align regulatory processes with urgent public health needs.

Looking ahead, continued collaboration between FDA, industry, and public health stakeholders can help identify areas for process improvement while preserving the rigor that underpins public trust in the agency's decisions.