BIOSIMILARS COUNCIL™
A DIVISION OF AAM

May 27, 2025

Dr. Marty Makary
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Makary:

On behalf of the Biosimilars Council, we write to express our strong support and appreciation for your recent comments advocating for the streamlining of biosimilar development and the removal of the interchangeability designation, which has hindered biosimilar competition and contributed to high drug prices.

Your acknowledgment that current requirements for biosimilar development and approval are duplicative and add time, cost, and complexity without offering meaningful additional assurances of safety or efficacy is both evidence-based and vital to accelerating patient access to safe, effective, and affordable biologic therapies.

The Biosimilars Council has long advocated for a more streamlined, science-driven regulatory paradigm. In collaboration with stakeholders across the biosimilars ecosystem, we have worked to remove barriers to biosimilar development and uptake, including through regulatory proposals that seek to align biosimilar development requirements with technological advancements and global best practices. We are encouraged that your comments reflect this direction, reinforcing the need for the U.S. to modernize its biosimilar approval process.

Your leadership adds a critical and respected voice on this important issue. The Biosimilars Council stands ready to collaborate in our efforts to advance policies that reflect the scientific progress made over the past decade and that support a robust, sustainable biosimilars market in the U.S.

Thank you for your continued commitment to patients and to ensuring access to safe, affordable medicines.

Sincerely,

John Murphy, III
President & CEO