AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

Comments of Stacey L. Worthy
On Behalf of Aimed Alliance

"Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments"

Good afternoon. I'm Stacey Worthy, counsel to Aimed Alliance. We're a nonprofit that works to improve access to quality health care to create awareness of, initiate, and enforce consumer protections. Thank you for this opportunity to provide public comment.

We commend the FDA on its efforts to preserve safety while also speeding up the approval process for new biologic products. The agency should be proud of its work in creating competition in the drug marketplace and helping patients access effective and affordable treatments.

A. Steps to Ensure Confidence

To ensure confidence among stakeholders, we encourage the FDA to preserve safety over speed. Although there is urgency to bring about cost-savings, we must prioritize scientific rigor given the complexity of large molecule drugs. In particular, the FDA should not lower the standards for interchangeability. The U.S. is the only country with a formal interchangeability designation, making us a leader among nations. In that role, patient safety must be the top priority.

Additionally, the FDA should consider how cross-interchangeability may impact patients. In the near future, patients may be switched from an initial reference product to an interchangeable biosimilar, and again to a second interchangeable biosimilar. While the two biosimilar products may be deemed interchangeable with the reference product, they may not be interchangeable with each other. These switches could result in an immune response, and the patient's body could reject the drug. We need data, protections, or at a minimum, educational awareness about the implications of cross-switching patients between biosimilars that are not interchangeable with each other to prevent any harm.

B. Education and Awareness

Building on the FDA's Biosimilar Education and Outreach Campaign, the FDA should also take steps to improve awareness of interchangeability designation by creating educational materials for various audiences, including insurers, health systems, pharmacies, and practitioners. The agency should provide practitioners with data on the safety of switching a patient from a biologic to a biosimilar so they can make educated decisions. However, it is also important to discourage insurers and health systems from forcing practitioners to switch stable patients from reference products to biosimilars for nonmedical reasons.

Additionally, some health systems' pharmacy and therapeutic ("P&T") committees have been deeming products "interchangeable" for purposes of setting up their formularies. Given that only the FDA has the authority to make a formal interchangeability designation, it can be confusing and misleading for a P&T committee to use the same verbiage. Moreover, as a result some pharmacies have stopped stocking reference biologics, and health systems are mandating that practitioners switch their stable patients from their current medications to different products regardless of whether the practitioner deems such a switch medically appropriate. Nonmedical switching should be discouraged.

Additional awareness efforts can include educating practitioners on the nonproprietary naming convention for biological products, especially so practitioners can identify any adverse events. It is important to identify which medications result in adverse events for reporting purposes, especially if a patient is switched more than once.

C. Additional Information for the Purple Book

Regarding the purple book, we recommend including information on biologic drug indication, use, strength, administration, whether the product has received an interchangeable designation and with which other medications it is interchangeable, and any adverse events that have occurred with substitution. This will allow practitioners who determine that it is medically appropriate to switch their patients to do so with confidence.

D. Facilitating an Evolution in the Marketplace

Finally, an evolution in the marketplace will require reform among payers. We were encouraged to hear Commissioner Gottlieb's recent comments, in which he noted that rebates should be applied directly to lower the out-of-pocket costs for patients who need biologics and biosimilars rather than allowing pharmacy benefit managers and insurers to pocket rebates as additional profits or spreading the benefit of rebates across all plan members. As he noted, high copays are not going to discourage overutilization among individuals with cancer who have limited treatment options. Therefore, rebate reform can have a meaningful impact on the increased use of both biologic and biosimilar medications.

Thank you.