AAM/Council Remarks at FDA Biosimilars Public Hearing on Insulin

Thank you for the opportunity to speak at today's Part 15 Hearing on considerations for biosimilar and interchangeable insulin. We look forward to responding in more detail to the FDA's posed questions in our submission to the docket.

As former FDA Commissioner Gottlieb noted, regulating insulin under the Public Health Service Act will allow for more efficient development of biosimilar and interchangeable insulin for America's 7.5 million diabetes patients that rely on insulin to manage their disease, a population that has doubled in the past two decades.

As we have seen in the biosimilars space to date, competition works to bring down monopoly prices for costly biologics. Marketed biosimilars are currently, on average, discounted 47% below their respective reference products list price and 18% lower in terms of net price (ASP) in Medicare Part B.

And as Congress has noted, competition is sorely needed in the insulin space. We look forward to working with the Agency and policymakers to achieve this goal. The insulin market in the U.S. is a direct reflection of issues facing biosimilar broadly. The current insulin market lacks significant competition to the detriment of patient access and health and has been characterized as a public health crisis. The combination of regulatory challenges, over-patenting to stave off competition, and anti-competitive rebating and contracting tactics by brand firms has been the cause of the lack of competition.

Six of the most highly-utilized brand-name insulins increased in list price by more than 500 percent from 2006 to 2015. Because patient cost-sharing is often based on the list price, before rebates or discounts, increases in list price directly impact a patient's ability to afford their medicines and can cause increased patient abandonment and lower adherence.

We applaud the FDA's recent efforts in this space to ensure insulin biosimilars are able to efficiently be developed and come to market post-March 2020. We support the Agency's timely guidance on interchangeability, particularly its streamlined data and study design requirements that allow flexibility and the use of global comparator products to support applications. While the interchangeability designation does not confer any additional quality or safety attributes for approved biosimilars, the statutory requirement under BPCIA makes the designation necessary for automatic substitution at the retail pharmacy. Interchangeability will be particularly important in the insulin space.

As the agency stated recently in response to a letter from Senators voicing concern over FDA's final guidance on the implementation of the "Deemed to be a License" provisions of the Biologics Price Competition and Innovation Act (BPCIA), FDA has considerable expertise and experience safely and effectively regulating insulin and with the "highly similar" regulatory standard that is applied to brand biologics after manufacturing changes as well as biosimilars. Further, insulin is a "simpler" molecule than other more complex biologics such as monoclonal antibodies and has been extensively characterized and significant real world evidence related to the safety and efficacy of insulin exists. To that end, we support the agency's step-wise approach to interchangeability outlined in the final interchangeability guidance.

Contrary to brand misinformation campaigns around the safety and efficacy of biosimilars, stakeholders to not need to "wait" for interchangeable biologics to use biosimilars with their patients. Significant evidence exists that a physician-led transition from a reference product to a non-interchangeable biosimilar does not result in a loss of safety or efficacy. In the insulin space, brand-to-brand switches across insulin types occur frequently at the direction of the provider, and, given the highly similar nature of a biosimilar to its reference product, the risk of diminished safety or efficacy from a transition is minimal or not present.

Availability of biosimilar insulin is likely to increase patient access and savings. To that end, in terms of the agency's educational efforts on biosimilar insulin, FDA should continue emphasizing that a transition from a reference product to a non-interchangeable biosimilar will not result in changes to safety or effectiveness.

To summarize our recommendations:

- FDA has significant experience with insulin and "highly similar" regulatory standard and should apply that experience to biosimilar insulin development.

- FDA should continue to highlight for stakeholders that interchangeability does not confer quality but is a statutory standard for automatic substitution at the pharmacy.

- FDA should continue emphasizing that a transition from a reference product to a non-interchangeable biosimilar will not result in changes to safety or effectiveness.

Thank you for the opportunity to speak today and your leadership in ensuring the development of a competitive biosimilars market in the U.S. I look forward to answering any questions you may have.