Biosimilars
FORUM

STATEMENT FROM THE BIOSIMILARS FORUM

FDA Arthritis Advisory Committee Meeting

February 9, 2016

Good afternoon. My name is Matthew Banfield and I'm speaking on behalf of the Biosimilars Forum. The Forum appreciates the opportunity to comment at today's FDA public meeting of the Arthritis Advisory Committee. Education of the Advisory Committee members about the science of biosimilars is critical.

The Biosimilars Forum is a non-profit organization whose mission is to advance biosimilars in the United States with the intent of expanding access and availability of biological medicines and improving health care. It is comprised of manufacturers and other organizations that work on a consensus basis to develop policy positions to ensure the US has a competitive, safe, and sustainable biosimilars market, providing more options to patients and physicians. The Forum's mission includes providing evidence-based information to inform and support public policies that encourage access, awareness and adoption of biosimilars.

The founding members of the Forum represent the majority of companies with the most significant U.S. biosimilars development portfolios. In fact, about 70% of the 57 proposed biosimilar products currently advancing with the FDA are sponsored by members of the Forum.

Members of the Forum recognize there is a need for a sustained and unbiased biosimilars education and advocacy program in the U.S. That's why since its inception, the Forum has worked collaboratively with FDA on policy issues as well as designing mechanisms to educate physicians and patients about the science behind biosimilars.

Vital to our goal is the ability for biosimilar sponsors to engage with FDA and have a productive dialogue leading to timely product approvals. 2015 was a watershed year, as the agency approved the first ever biosimilar medicine for the US market. In 2016, we anticipate the review and approval of several more biosimilars, possibly including the first ever interchangeable biosimilar medicine.

The introduction of biosimilars in the U.S. can help expand access to high-quality treatment options for clinicians and patients as well as reduce costs to families, caregivers, payers, and the health care system.

We appreciate that FDA has worked hard to implement this new abbreviated licensure pathway taking steps that include issuing multiple guidance on biosimilars and we expect more in the coming months.

The biosimilars program is new and it is crucial that we maintain the current momentum and build on our experience as we move forward.

As FDA continues to implement the biosimilars approval pathway and we begin discussions surrounding review of - and possible changes to - the biosimilars user fee program, the Forum looks forward to a continued collaborative and excellent working relationship with the agency.

We encourage the agency to continue to work with industry as this field advances in the days ahead.