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Testimony for July 13th Meeting of the FDA Oncologic Drugs Advisory Committee (ODAC) regarding BLA 761028 for ABP 215, Genentech/Roche's AVASTIN (bevacizumab), submitted by Amgen Inc.

Committee Members,

I am Harry L. Gewanter, MD, a pediatric rheumatologist with over thirty years experience treating children and youth with rheumatic diseases and other chronic and disabling conditions. I am the current chairman of the Alliance for Safe Biologic Medicines (ASBM) and they are sponsoring my presence today. ASBM is an organization of patients, physicians, pharmacists, researchers, manufacturers of both innovator and biosimilar medicines, and others dedicated to ensuring patient safety remains at the forefront of all biosimilars policy discussion. Our members include multiple cancer patient advocacy groups, including several representing patients with colorectal and kidney cancer, two of the indications for which this proposed biosimilar to bevacizumab is seeking approval.

Biosimilars provide opportunities for increased access to more life-altering treatment options, at reduced cost to both the patient and society. We support the FDA's history of intense and appropriate scrutiny of all medications, both at the time of application as well as throughout the medications' lifespan. It is the only way to produce the high level of confidence necessary for biosimilars to be fully accepted and utilized by patients and their physicians.

We believe the approval of a biosimilar should be decided on a case-by-case basis for each potential indication based on sufficient supporting data rather than justifying an automatic blanket extrapolation to all indications.

Clear product identification is critical after approval to ensure safety and confidence in biologic medications. We strongly support distinguishable names for all biologics, innovator and biosimilar alike. We believe the FDA should use its role as the world's leading regulator to work with the World Health Organization to advance the WHO's BQ proposal and establish an international 4-letter suffix system. The BQ proposal is critical for global pharmacovigilance, and we hope the FDA would also encourage other regulatory authorities – Health Canada and the Australian TGA, for example - to do the same.

ASBM believes that unique, extensive, transparent and up-to-date labeling is also vital to ensure patient and provider confidence in the products. Our multiple surveys confirm that over 80% of prescribers agree with this position.

Comprehensive data collection on a biosimilar should not end with its approval. Strong post-market surveillance data improves care and limits risks. The FDA's leadership through post-approval pharmacovigilance will improve care, promote more efficient, safer and personalized use as well as provide further confidence in these important medications.

Patient and prescriber trust and confidence in biosimilars is essential to their success. It must be earned, and maintained, through high approval standards, distinguishable naming, transparent labeling, strong and comprehensive pharmacovigilance, manufacturer accountability and open communication.

Thank you for your diligence on behalf of all Americans. I appreciate the opportunity to provide our perspectives on this important issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, FACR
Chairman, The Alliance for Safe Biologic Medicines

ASBM Steering Committee Members:

Alliance for Patient Access
American Academy of Dermatology
American Autoimmune Related Diseases Association (AARDA)
Association of Clinical Research Organizations
Colon Cancer Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
Health HIV
Hepatitis Foundation International
International Cancer Advocacy Network
Kidney Cancer Association
Lupus and Allied Diseases Association, Inc.
National Hispanic Medical Association
National Psoriasis Foundation
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