
Good Afternoon. My name is James Sykes and I am Director of Global Policy for The AIDS Institute, a not-for-profit organization located in Washington, DC whose mission is to promote action for social change through public policy research, advocacy, and education. As an advocacy organization for people living with and affected by HIV/AIDS specifically, and as advocates for patients living with or suffering from any disease or illness generally, we appreciate this opportunity to comment on the implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

The AIDS Institute, along with other community partners, advocated in support of comprehensive healthcare reform. We stood in support of Congress’ effort to provide quality health care for those who cannot afford it. We stood in opposition of any legislation would, in our opinion, block the flow of innovative drugs for the treatment of not only HIV/AIDS, but other diseases and conditions. The AIDS Institute stood in support of the 12 year period of data exclusivity relative to biologics and biosimilars. Since 1987, we have witnessed the development of approximately 32 drugs for the treatment of HIV/AIDS. These innovations have turned what was once a terminal illness into a potentially chronic, manageable condition. Technology, research, and innovation have expanded the horizon of possibilities for saving lives. The new frontier is in the area of biologics. We have witnessed the transformation of HIV/AIDS care and treatment from one drug (AZT) to over 31 drugs in just the past 23 years. We have seen the HIV drug regimen transformed from upwards of 15 pills a day to just 1 pill per day. Now, we are witnesses to the unlimited possibilities of biologics. Two such biologics, Procrit and Aranesp, are already being used to effectively treat HIV-related anemia as well as anemia related to kidney failure and chemotherapy.
As promising as biologics and biosimilars are, The AIDS Institute believes that the safety of these compounds should be of paramount concern. Biologics are large, complex proteins that are immunogenic and thereby able to elicit an immune response. We also know that no two biologics are the same. This was reason for our support for the 12 year period of data exclusivity – we felt that the industry needed that time to answer questions of patient safety. As the FDA develops guidance relative to biosimilars, The AIDS Institute thinks the FDA should set out clear and robust comparative testing requirements considering the current state of the science to demonstrate safety and efficacy. We also think that given the fact that no two biological products made by different manufacturers are identical, biosimilars must not be treated like generic drugs. There must be safeguards in place to help healthcare providers avoid inappropriate substitution of a biosimilar for the innovator product without physician knowledge and approval. Lastly, we think that biosimilars should be named different from the reference compound and other biosimilar products. This will help ensure that both healthcare professionals and patients can report any adverse events accurately and facilitate physician choice of compounds.

The AIDS Institute appreciates this opportunity to comment on implementation of the BPCI Act. We ask that patient safety be the major consideration in your deliberations when it comes to biologics and biosimilars. We believe that the best way forward for regulating biosimilars would be through a thoughtful and thorough open and transparent process that considers the current state of the science and that ensures patient safety.

Thank you.
Respectfully submitted,

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