

Follow-On Biologics, Patient Safety and Policy, Focus of JSPH Program in DC

National Press Club

April 21, 2009

On April 21st, JSPH sponsored an event at the National Press Club in Washington, DC entitled: “*Regulation of Follow-on Biologics: Ensuring Quality and Patient Safety.*” Supported by an unrestricted educational grant from sanofi-aventis, the event brought together a wide range of experts in the medical field including doctors, scientists, economists and others who discussed the quality and safety issues surrounding the creation of a regulatory pathway to bring follow-on biologic drugs to market in the United States.

Featured speakers included: Michael McCaughan, Editor in Chief of the Pink Sheet; Ann Witt, JD, Health Counsel to Rep. Henry A. Waxman; Brian Harvey, MD, PhD, VP, Regulatory Policy, sanofi-aventis; Terry Hisey, Vice Chairman, U.S. Life Sciences Leader, Deloitte LLP; and Geno Merli, MD, FACP, FHM, Chief Medical Officer, Thomas Jefferson University Hospital and Director, Jefferson Center for Vascular Diseases at Jefferson Medical College.

Research and development costs for biologics are very high and, as a result, therapy with these agents for patients with chronic diseases is very expensive. Because these products are derived by modifying living organisms, the end product is especially sensitive to damage or contamination, and small differences in the manufacturing process may have unforeseen and unintended effects on therapeutic action.

There is a movement to spur the development of “follow-on” biologics (FOBs) similar to the original products in an effort to improve access and lower overall costs to the health care system. Congress is intent on passing legislation enabling the Food and Drug Administration (FDA) to develop a regulatory pathway for FOBs similar to the pathway for generic forms of traditional drugs. Well crafted legislation for FOBs will afford an opportunity to reduce drug costs and make better quality healthcare more affordable for millions of American families.

On April 21st, JSPH sponsored an event at the National Press Club in Washington, DC entitled: “*Regulation of Follow-on Biologics: Ensuring Quality and Patient Safety.*” Supported by an unrestricted educational grant from sanofi-aventis, the event brought together a wide range of experts in the medical field including doctors, scientists, economists and others who discussed the quality and safety issues surrounding the creation of a regulatory pathway to bring follow-on biologic drugs to market in the United States.

Featured speakers included: Michael McCaughan, Editor in Chief of the Pink Sheet; Ann Witt, JD, Health Counsel to Rep. Henry A. Waxman; Brian Harvey, MD, PhD, VP, Regulatory Policy, sanofi-aventis; Terry Hisey, Vice Chairman, U.S. Life Sciences Leader, Deloitte LLP; and Geno Merli, MD, FACP, FHM, Chief Medical Officer, Thomas Jefferson University Hospital and Director, Jefferson Center for Vascular Diseases at Jefferson Medical College.

Research and development costs for biologics are very high and, as a result, therapy with these agents for patients with chronic diseases is very expensive. Because these products are derived by modifying living organisms, the end product is especially sensitive to damage or contamination, and small differences in the manufacturing process may have unforeseen and unintended effects on therapeutic action.

There is a movement to spur the development of “follow-on” biologics (FOBs) similar to the original products in an effort to improve access and lower overall costs to the health care system. Congress is intent on passing legislation enabling the Food and Drug Administration (FDA) to develop a regulatory pathway for FOBs similar to the pathway for generic forms of traditional drugs. Well crafted legislation for FOBs will afford an opportunity to reduce drug costs and make better quality healthcare more affordable for millions of American families.

Currently, there are competing bills under consideration in the House; one authored by Rep. Henry A. Waxman (D-Calif.), Chairman of the House Energy and Commerce Committee, and the other drafted by Rep. Anna Eshoo (D-Calif.). In the Senate, Charles Schumer (D-NY) has introduced a companion to the Waxman proposal.

At the conference, there was broad support for greater accessibility of FOBs. However, significant concerns were expressed for patient-safety, “interchangeability” problems and product testing issues that must be thoroughly addressed.

Some key themes on patient safety which emerged from the event are as follows:

1. Patient safety must be the number one priority, including adequate safety testing prior to the approval of any FOB.
2. The US should adopt some of the more successful and proven provisions of European regulation, such as its clarity around the circumstances and extent of testing required of FOBs.
3. An FOB approval pathway must be comprehensive and recognize the complex nature of all biologic medications, including proteins and polysaccharides.
4. Biologic efficacy is not the same as biologic effectiveness. FOBs must be evaluated for patient outcomes.

The outcome of this debate is likely to have far-reaching implications with regard to access, cost, safety, and therapeutic impact for thousands of patients with serious, life-threatening, and chronic diseases. ■

The conference webcast has been archived and can be accessed online at:
www.visualwebcaster.com/FOB-Policy-Forum.