Alliance for Safe Biologic Medicines Chairman Urges FDA to Ensure that Patient Safety is the Cornerstone of Biosimilar Pathway

WASHINGTON, May 11, 2012

Prepared Remarks Identify Clinical Trials, Global Supply Chain, Unique Naming, Clear Packaging Information, and Interchangeability as Areas for Careful Consideration

WASHINGTON, May 11, 2012 -- Dr. Richard Dolinar, chairman of the Alliance for Safe Biologic Medicines (Alliance) outlined five areas of concern that the U.S. Food and Drug Administration (FDA) should resolve before they allow biosimilar medications on the U.S. drug market in prepared testimony for the FDA's May 11th public hearing. The event addressed the FDA's recent draft guidelines for the development of biosimilar products.

"We applaud the FDA's efforts to bring biosimilars to the U.S. market, but would urge a deliberate approach that is becoming of FDA's critical role of ensuring the safety and efficacy of the nation's drug supply," Dr. Dolinar said. "The members of the Alliance support the goal of the health care law to bring broader access to biologic medicines to patients across the country and we want to ensure that biosimilar medicines are as safe as the innovator drugs they seek to replicate."

During his testimony, Dr. Dolinar, a practicing endocrinologist, outlined (1) the need for robust clinical testing; (2) the establishment of steps to monitor the global supply chain and manufacturing process; (3) the creation of track, trace and naming provisions; (4) the development of clear packaging, labeling and prescribing information; and (5) very close and deliberate scrutiny of a biosimilar before it is deemed interchangeable.

"Biologics are complex, large molecule drugs that are grown inside living cells using unique and proprietary processes," Dr. Dolinar said during his testimony. "For this reason, no two biologics made from different cell lines or using different processes can be identical based on today's science. Biologics are also highly sensitive to the manufacturing process. In fact, altering a single manufacturing parameter can change a compound's identity and/or the precise effect it has on the human body."

Dr. Dolinar's remarks to Dr. Rachel Sherman and other FDA panel members summarized the comments the Alliance submitted last month in response to the FDA's draft guidance on the approval of biosimilar medicines. The Alliance's written submission outlined clear, concrete and achievable ways to manage risk and prioritize patient safety.

To speak to Dr. Dolinar or another member of the Alliance for Safe Biologic Medicines, please email media@safebiologics.org.

About the Alliance for Safe Biologic Medicines

The Alliance for Safe Biologic Medicines (ASBM) is an organization composed of diverse healthcare groups and individuals from patients to physicians, innovative medical biotechnology companies, and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion. We serve as an authoritative resource center of information for the public, medical communities, the FDA and other state and federal policymakers during the implementation of the biosimilars pathway and beyond. Visit us at www.safebiologics.org.

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