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**New Senate Biosimilars Proposal Would Jeopardize
New Medical Advancements and Cures**

Washington, D.C. (July 8, 2009) – The following statement was issued today by the Biotechnology Industry Organization (BIO) regarding a proposal to establish a pathway for regulatory approval of biosimilars reportedly under consideration in the Senate Committee on Health, Education, Labor and Pensions (HELP):

“The Committee mark reportedly under consideration in the Senate HELP Committee would undermine hope for potential cures and new advanced medicines. The proposal would provide a limited and highly uncertain period of data exclusivity that would chill the investment required to improve existing drugs and develop the next generation of medicines and potential cures for patients.

“This proposal would represent a stark break from the agreement struck in the *Biologics Price Competition and Innovation Act of 2007*, S. 1695, introduced By Senator Kennedy and Senator Mike Enzi (R-WY) in the 110th Congress. The Senate should return to the original agreement.

“The new proposal purports to establish up to 13 years of data exclusivity but, in actuality, many biologics would receive zero years of exclusivity. The language as proposed provides 9 years of base data exclusivity only to a new ‘major’ substance. Any product that is even similar to a previously approved product, in some undefined way, could get zero years of exclusivity.

“In addition, the proposal provides 9 years of data exclusivity only to those new biologics approved after the bill’s passage. A product approved even one day before the bill becomes law would get zero years of exclusivity, providing no protection.

“Such an abbreviated and uncertain period of exclusivity could lead to a dead end for many new biomedical advancements and potential cures for devastating diseases such as cancer, Parkinson’s, Alzheimer’s, Multiple Sclerosis and a host of rare diseases. It also would jeopardize more than 7.5 million U.S. jobs driven by biotechnology and our nation’s leadership in biomedical innovation.

“In the end, this new proposal would provide fewer incentives for the uniquely American biotech industry than the European Union provides and it would create an incredibly complicated structure filled with

uncertainty that would scare off investors and, in turn, potentially stifle efforts to pursue medical advancements and breakthroughs for patients.

“We urge the HELP Committee to reject this proposal, if offered. We look forward to working with the Senate as it considers this vital issue.”

About BIO

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world’s largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

Upcoming BIO Events

[World Congress on Industrial Biotechnology & Bioprocessing](#)

July 19-22, 2009
Montreal, Quebec, Canada

[BIO Investor Forum](#)

October 28-29, 2009
San Francisco, CA

[Advanced Business Development Course](#)

October 30, 2009
Vienna, Austria

[BIO Europe International Partnering Conference](#)

November 2-4, 2009
Vienna, Austria

[Pacific Rim Summit on Industrial Biotechnology and Bioenergy](#)

November 8-11, 2009
Honolulu, HI

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