For Immediate Release

Contact: Craig Orfield
(202) 224-6770

Thursday, June 26, 2008

ENZI: BUDGET ESTIMATE CONFIRMS BIOSIMILAR BILL WILL REDUCE LONG TERM PRESCRIPTION DRUG COSTS

URGES HOUSE TO ACT, EXPAND ACCESS TO LIFE-SAVING DRUGS

Washington, D.C. - U.S. Senator Mike Enzi (R-WY), Ranking Member of the Senate Health, Education, Labor and Pensions (HELP) Committee, today said budget estimates confirm that HELP Committee legislation to allow the Food and Drug Administration (FDA) to approve biosimilar therapeutics in an expedited way would produce significant reductions in prescription drug costs over the next 10 years.

"This budget score confirms that our biosimilar therapeutics bill will save Americans billions of dollars in prescription drug costs," Enzi said. "Our bill preserves incentives to develop new, life-saving therapies. Most importantly, we protect patient safety every step of the way."

Senator Orrin Hatch (R-UT) said, "Biologics are the future of medicine, and S. 1695 ensures that we will continue to lead the world in biotechnology. The savings outlined in the CBO cost estimate underscores the absolute need to pass S. 1695. It is essential that the Congress consider this important legislation before adjourning for the year."

The Congressional Budget Office (CBO) released a cost estimate yesterday of the "Biologics Price Competition and Innovation Act of 2007," S. 1695, which the HELP Committee approved last year. CBO estimates that, if Congress enacts S. 1695, Americans will save approximately $25 billion on prescription drug costs over the next 10 years. The full CBO report is available at http://cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf.

"The Senate has put forth bipartisan, consensus legislation that will reduce costs, promote innovation, and protect patient safety," Enzi said. "If the Leadership of the House is serious about controlling long-term health costs, they will take steps to pass this legislation soon, not wait until the next Congress."

Biologics are protein-based, highly-engineered drugs that mimic key biochemical reactions in living cells. Biologics in common use today include: Humulin, a replacement

insulin for diabetics; Procrit, an anemia treatment for cancer patients; and Avonex, a therapy for persons with Multiple Sclerosis.

"Biologics already are making it possible for thousands of Americans to live productive lives and changing the way we treat deadly diseases like cancer and infectious diseases. Our bill holds new hope that we can further expand access of these remarkable medicines to more patients who need help combating deadly diseases. This bill is an important step to ensuring our aging population has access to innovative, affordable, and safe medicines."

The "Biologics Price Competition and Innovation Act" was introduced by Senator Enzi, Senator Ted Kennedy (D-MA), Chairman of the HELP Committee, Senator Orrin Hatch (R-UT), and Senator Hillary Clinton (D-NY).

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Biologics Price Competition and Innovation Act of 2007

This Act amends Section 351 of the "Public Health Service Act" to provide for an approval pathway for safe biosimilar and interchangeable biological products (relying in part on the previous approval of a brand product) while preserving the incentives that have fueled the development of these life-saving medicines.

Approval Process — A biosimilar applicant is required to demonstrate that there are no clinically meaningful differences in safety, purity and potency between its product and the brand product. A demonstration of biosimilarity includes analytical data, animal testing and one or more clinical studies, unless such a requirement is determined by the FDA to be unnecessary.

FDA may approve a biosimilar product as interchangeable, meaning it can be substituted for the brand product without the intervention of the health care provider who prescribed it. Showing interchangeability requires evidence that the biosimilar product will produce the same clinical result as the brand product in any given patient and that it presents no additional risk in terms of safety or diminished efficacy if a patient alternates or is switched between products.

The legislation allows, but does not require, the FDA to issue guidance documents to inform the public of the standards and criteria the agency will use in approving biosimilar and interchangeable products. Development of these guidance documents will require public input. Applications can be filed in the absence of guidance documents.

Exclusivities — The Act provides incentives for the development of both new life-saving biological products and interchangeable biosimilar products: 12 years of data exclusivity for the brand company during which a biosimilar product may not be approved, and 1 year of exclusivity for the first interchangeable biological product.

Patent Resolution — The legislation includes a multi-step process to identify and resolve patents that the biosimilar product may infringe. The biosimilar applicant must provide its application and information about its manufacturing process to the brand company. A series of informational exchanges then occur in which the biosimilar applicant and the brand company identify patents in question and explain their views as to their validity or infringement.

The two parties then either agree to a list of these patents to be litigated first or exchange lists when they can't, and the brand company must then sue the biosimilar applicant within 30 days to defend them. If the brand company wins a final court decision that a patent is valid and infringed by the biosimilar product before the 12-year data exclusivity has run, the court must enjoin infringement of the patent until it expires. For identified patents not included in this initial litigation, the biosimilar applicant must give the brand company notice 180 days before it intends to launch its product, and the brand company may then seek a preliminary injunction to block the launch.

If the brand company fails to identify a patent, it can't later enforce it against the biosimilar product. If it fails to defend a patent identified for initial litigation, the brand company may only later receive a reasonable royalty. If the biosimilar applicant fails at any step to do what it is required to do, the brand company may immediately defend its patents.

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