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**LAWMAKERS PRAISE COMMITTEE PASSAGE OF BIOLOGICS LEGISLATION**

WASHINGTON, D.C.—Today, the United States Senate Health, Education, Labor and Pensions Committee passed The Biologics Price Competition and Innovation Act. The measure is sponsored by Chairman Edward M. Kennedy, Senators Orrin Hatch, Hillary Clinton, Mike Enzi and Charles Schumer. The legislation includes standards for the FDA to approve follow-on biologics, a procedure designed to help resolve patents in an expedited way, and strong but responsible incentives to encourage innovation and the development of new therapies.

Senator Kennedy said, "This bill reflects a balanced approach that enables patients to have safe, effective and affordable biological drugs, while preserving the incentives that have brought these life-saving advances to the American public. This century of the life sciences offers unlimited promise of new hope and new help for millions of patients. Congress has a responsibility to encourage the innovation that leads to these new medical miracles, and to see that they are affordable for the patients who need them. Our bipartisan legislation also includes strong and responsible incentives to encourage dynamic new biotechnology companies to invest in the innovations that will produce the cures of tomorrow."

"Biologics are the future of medicine, and this bill ensures that we will continue to lead the world in biotechnology," Hatch said. "We've achieved a good balance. We give incentives to continue biological development. We allow generic companies to do what they do best – bring low-cost versions to the market. And we ensure that patients and providers not only have access to low-cost biologics but that they're also safe."

"This has real life, real world consequences. As soon as we enact this bill, there are medications for Hepatitis C, multiple sclerosis, cancer and diabetes that will be available for generic versions that will be more affordable for many more people than currently is possible. With this committee's action today, I am proud that we will both continue the creativity and innovation that is absolutely essential to our pharmaceutical industry and the lifesaving treatments and interventions they are able to provide for us and create a generic path that will begin to lower prices and extend the availability of so many of these treatments to more who need them," said Senator Clinton.

"Biologics are the skyscrapers of the drug world. They are towering monuments to medicine, science and biotechnology that can't easily be duplicated, and the slightest differences can be fatal. Our bill recognizes the need to make sure that biologic therapies are both safe and affordable," Senator Enzi said. "In addition, the legislation we've approved today holds new hope that we can further expand access of these remarkable medicines to more patients who need help. 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."

"Giving the FDA authority to approve follow-on biologics is the first step to introducing competition into the market, and thus the first step to giving more people access to potentially life-saving drugs," said Senator Schumer. "This bill represents a solid compromise and shows the great strides we can make when working together, even on very complicated issues like biologics."

The bill gives the FDA the flexibility it needs to apply the latest scientific advances in the regulatory process, so that new follow-on products will be safe and effective. The bill also gives the FDA the flexibility to adapt to changes in scientific knowledge and does not freeze in place an inflexible regulatory structure.

A summary of the bill is below.

### **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 1 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 with 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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