

FOR IMMEDIATE RELEASE
June 27, 2007

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**SUMMARY INCLUDED

**STATEMENT OF SENATOR EDWARD M. KENNEDY ON THE BIOLOGICS PRICE
COMPETITION AND INNOVATION ACT**

Executive Session of the Senate Health, Education, Labor and Pensions

Today, our Committee considers important legislation to carry on the work begun over two decades ago when the landmark Hatch-Waxman law was enacted in 1984. That bipartisan initiative to deal with out-of-control drug prices combined patent reform incentives to encourage competition with new incentives to encourage innovation. It's brought new drug discoveries to help patients and generic versions of vital drugs to make them more affordable.

At that time, however the complex biological molecules that form many important drugs we have today did not exist, and there was no need for an abbreviated pathway to approve follow-on versions of such drugs.

Now, with the ongoing life sciences revolution, advances in our understanding of biology and biotechnology have created a need for safe versions of follow-on biological drugs.

The Biologics Price Competition and Innovation Act we are considering establishes a regulatory pathway for FDA to approve safe and effective follow-on and interchangeable biological drugs while maintaining the incentives that spur innovation. This Act will ensure that many more Americans will be able to get the life-saving drugs that are transforming health care today.

Senator Hatch, Senator Clinton, Senator Enzi and also Senator Schumer have all been leaders in preparing this bill. Three basic principles guided our work.

First, we must be led by science. Acceptable legislation on follow-on biologics must not pre-judge science, but should enable FDA to make the best decisions based on the most complete science reasonably available.

Second, protecting patient safety is essential. Congress must make certain that any drug available to patients is safe and effective.

Third, innovation must be valued and promoted. It's essential to help patients afford the drugs they need, but it's also essential to provide incentives for the innovations that will produce the medical miracles of the future.

The bill gives the FDA the flexibility it needs to apply the latest scientific advances in the regulatory process, so that these new follow-on products will be safe and effective.

It also gives the FDA the flexibility to adapt to changes in scientific knowledge and does not freeze in place an inflexible regulatory structure.

Unprecedented scientific advances are taking place, and seriously ill patients have already begun to see the benefits of this new era through new wonder drugs that can make the difference between life and death.

These biological products are complex molecules whose healing power is being brought to patients by dynamic biotechnology companies. Such drugs were once a rarity in medicine, but each day now brings new hope from new breakthroughs.

With this extraordinary progress comes a challenge to public policy. Due to the cost of developing and manufacturing new biologics, their price is often steep. They can cost patients tens or even hundreds of thousands of dollars a year, putting an extraordinary strain on the budgets of those who must pay the bills –patients, insurers, and government programs.

This Act will save American families and the American government billions of dollars by allowing follow-on and interchangeable products to come to market at reduced prices but with the same high level of safety.

The bill also recognizes that these incredible advances come only when sufficient incentives exist to encourage their development and that is why we have included 12 years of data exclusivity.

It is essential to have a clear understanding of the circumstances in which this exclusivity applies. The 12 years of exclusivity applies only to products that are analogous to a “new chemical entity”. Once a product is first approved under Section 351(a) of the Public Health Service Act, it is granted 12 years of data exclusivity. Subsequent supplemental applications – or even new applications containing a new indication, dosage form, route of administration or strength do not generate a new 12 years of exclusivity.

This is an area of law where it is vital to be precise in legislative drafting. In the bill as filed, we used the phrase “first licensed” to make clear that 12 years of exclusivity applied solely to the initial approval of a product, not to subsequent minor modifications. In the Chairman’s Mark, we added a new provision to provide greater clarity, specifying that this phrase “first licensed” does not apply to any supplemental application or even a new license for a “new indication, route of administration, dosage form or strength.”

We welcome the views of experts on these provisions. I look forward to working with my colleagues to see that the language is as sharp and precise as it can possibly be, and staff are authorized to make changes to achieve the utmost in precision.

The bill also establishes a new process for rapidly identifying patents that could be disputed between the brand company and the biosimilar applicant. It recognizes the inherent complexity of the patents on these intricate biological molecules, and it also expedites the patent resolution process.

That process, like much of the rest of the bill, is a balance between competing concerns. The brand company must be able to assert its patent rights on all appropriate patents. But the process shouldn’t be a roadblock for the approval follow-on products.

This legislation strikes the appropriate balance. It includes incentives for both parties to seek expeditious resolution of patent issues, and it includes deterrents for all participants not to game the system.

Overall, the 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.

We have a number of amendments that members of the committee have offered and I look forward to discussing them with you.

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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