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SENATOR EDWARD M. KENNEDY STATEMENT AT THE HEARING ON FOLLOW-ON BIOLOGICS

I welcome the members of our committee and our distinguished witnesses to today's hearing on the important question of whether Congress should give FDA the authority to approve follow-on versions of biologic medicines.

We are in a remarkable period of discovery in the life sciences. Unprecedented advances are taking place, and 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 for patients afflicted with serious illnesses.

Patients with leukemia who once faced a bleak future now have new hope, thanks to an extraordinary new medicine that can slow or even halt the progression of the disease.

Until recently, a diagnosis of Gaucher's ["go-SHAYS"] Disease meant a shorter life, full of disability and pain for the people it afflicted. Now, a remarkable breakthrough has produced drugs to treat this grave illness and extend life and reduce disability.

Similarly, a drug to stimulate the production of new blood cells is helping patients counteract the severe anemia caused by chemotherapy or renal disease.

These miracle medicines, called biologics, are complex molecules whose healing power has been brought to patients by dynamic biotechnology companies. Such drugs were once a rarity in the medical arsenal, but each day seems to bring new hope from new breakthrough biologics.

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 companies, or government programs.

Congress has faced similar challenges before. In the early 1980's, the cost of prescription drugs was spiraling upward. In response, Congress enacted legislation that balanced the need to reduce costs for consumers through increased competition with the requirement to promote innovation. That legislation is known universally by the names of its sponsors, Senator Orrin Hatch and Representative Henry Waxman. Our committee is honored that Senator Hatch is helping guide our deliberations. Congress and the

American people are indebted to his leadership on these important issues.

When the Hatch-Waxman law was enacted, Congress did not include biologics, because at the time such drugs were not providing the major innovations that advances in the biological sciences have brought over the past 20 years.

Now Congress must consider whether to authorize FDA to accept applications for follow-on versions of these path breaking medicines.

The stakes riding on the answer to this question are enormous, both for patients and for our economy, and the interest among our committee colleagues in this question is intense. One of our colleagues, Senator Clinton, has a proposal to allow FDA to approve follow-on biologics. I look forward to hearing her views on this question, and to receiving the testimony of the legislation's co-sponsor, Senator Schumer.

Many have recommended that the committee's legislation on drug safety and user fees should include a proposal to allow for follow-on biologics. Today's hearing will help to provide the information the committee needs to make the right decision on that important question.

Our committee should be guided by three basic principles.

First, we must be led by science. Acceptable legislation on follow-on biologics must not pre-judge science, but should enable the 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 given to patients – whether a conventional drug, an innovative biologic, or a follow-on product – is safe and effective.

Third, innovation must be valued and promoted. Just as it is essential to help patients afford the medicines of today, so too it is vital to provide incentives for the innovations that will bring the medical miracles of tomorrow.

I look forward to the recommendations and insights of our distinguished witnesses to provide guidance to our committee as we undertake these important deliberations.