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WAXMAN, SCHUMER, CLINTON INTRODUCE "ACCESS TO LIFE-SAVING MEDICINES ACT"

TO CREATE A NEW PATHWAY FOR AFFORDABLE VERSIONS OF BIOTECH DRUGS

WASHINGTON, DC — Today Rep. Henry A. Waxman, Sen. Charles E. Schumer, and Sen. Hillary Rodham Clinton introduced the "Access to Life-Saving Medicine Act," which will establish a process through which the Food and Drug Administration (FDA) will be able to approve lower cost copies of biotech drugs, also known as biologics or biopharmaceuticals. Biotech drugs, which are produced from living cell cultures rather than synthesized chemically, are among the fastest growing and most expensive components of the nation's drug bill. Currently there is no statutory pathway for biotech drugs, even after all patents have expired. As a result, the manufacturers of biotech drugs can charge monopoly prices, indefinitely.

"Generic versions of brand-name drugs have long been an essential way for patients to get the medicine they need at a price they can afford," said Rep. Waxman. "This bill will use competition to make biological drugs — which are often prohibitively expensive — available to those who suffer from diseases like cancer, diabetes, and AIDS."

"Biologics treat some of the most devastating diseases around and no one should be denied access to them because of they're too expensive," Sen. Schumer said. "Generic biologics can be a safe and affordable alternative to high-priced brand name biologics. Our legislation will allow all Americans to take advantage of these drugs by enabling competition in the market to lower the price and ending permanent monopolies over biologic products. It is high time for these vital treatments to become more affordable and our legislation is just what the doctor ordered."

"I am pleased to be leading an effort that will have dramatic impact in stemming the rising costs of prescription drugs and the squeeze they put on America's employers as they try to provide health insurance to their employees. This legislation will provide a critical and necessary pathway for approval of generic versions of biologic prescription drugs, which are among the most expensive medications. Today, Iressa, a biologic used in lung cancer treatment costs $2,000 per month and Remicade for rheumatoid arthritis and other inflammatory disorders costs more than $35,000 per year. Bringing generic versions of these prescription medicines to market will offer patients, employers, and the federal government dramatic cost savings. Achieving this goal is a top priority for me and I look forward to working with my colleagues to get it done," said Sen. Clinton.

Biotech drugs can cost tens of thousands of dollars a year, imposing financial burdens on patients, employers, insurers, and federal and state governments. The "Access to Life-Saving Medicine Act" will authorize FDA to approve abbreviated applications for biological products that are

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"comparable" to previously approved brand name biological products, without unnecessarily repeating expensive clinical trials.

This bill comes in response to years of recognition of the need for a new statutory pathway for approval of generic versions of biotech drugs. These products are not subject to the 1984 law that first authorized FDA to approve generic drugs. The EMEA, which is Europe's equivalent of the FDA, has had a legal framework in place for approval of "biosimilars" since 2004. In letters received today, both the AARP and the Coalition for a Competitive Pharmaceutical Market — composed of employers, health plans, generic drug companies, pharmacy benefit managers, and pharmacists — agree that legislation creating a pathway for approval of generic biologics is critically important to assure access to more affordable drugs.

Demonstrating that a generic version of a biotech drug is the same as the brand name product raises more complicated scientific issues than for traditional drugs. The bill therefore establishes a rigorous, case-by-case scientific process for approving these products to make sure they are as safe and as effective as their brand name counterparts. Recent approvals by FDA of similar products, like Omnitrope (a human growth hormone drug approved on the basis of abbreviated tests), show that this approach is scientifically feasible.

The bill has been endorsed by the Consumer's Union, the Consumer Federation, the AFL-CIO, and the Generic Pharmaceuticals Association.

For more information, including a detailed summary of the bill and the bill text, please visit www.waxman.house.gov.