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FOR MORE INFORMATION, CONTACT:
Karen Lightfoot (Waxman): (202) 225-5051
Eric Schultz (Schumer): (202) 224-7433
Sarah Gegenheimer (Clinton): (202) 224-2243

WAXMAN, SCHUMER, AND CLINTON UNVEIL BILL TO CREATE CLEAR PATHWAY FOR GENERIC BIOLOGIC DRUGS

"Access to Life-Saving Medicine Act" Would Lower Patient Drug Costs for Drugs Used to Treat Diseases Like Cancer, Diabetes, AIDS

WASHINGTON, DC — Today Rep. Henry A. Waxman, Sen. Charles E. Schumer, and Sen. Hillary Rodham Clinton, along with Rep. Jo Ann Emerson and Rep. Frank Pallone, introduced the "Access to Life-Saving Medicine Act," which will give Food and Drug Administration (FDA) the express legal authority to approve safe, lower cost copies of biotech drugs, also known as biologics or biopharmaceuticals. Biotech drugs, which are produced from living cell cultures rather than being synthesized chemically, are among the fastest growing and most expensive components of the nation's drug bill. Currently there is no statutory pathway for generic versions of biotech drugs to enter the market, even after all patents have expired. As a result, the manufacturers of biotech drugs can charge monopoly prices, indefinitely. In addition to the members listed above, Senators David Vitter, Debbie Stabenow, Patrick J. Leahy, Susan M. Collins and Representative Rahm Emanuel are original cosponsors of the legislation.

"We learned 22 years ago that generic drug competition brings consumers affordable, safe, and effective medicines," said **Rep. Waxman**. "The time has come to apply this competition to biotech drugs. This bill will give FDA the clear legal authority to approve safe and effective copies of biotech drugs."

"Biologics treat some of the most devastating diseases around and no one should be denied access to them because of they're too expensive," said **Sen. Schumer**. "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."

"We have witnessed dramatic scientific advances over the past twenty years in the field of biopharmaceuticals but our health care system has not kept pace. Biotech drugs hold great promise; however, we break that promise when costs push treatment out of reach for American families and employers. We should bring safe, effective and affordable generic versions of these medicines to patients. It will save money and save lives," said **Senator 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 "comparable" to previously approved brand name biological products and it gives the FDA the authority to require any additional clinical information it deems necessary.

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

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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 recently, 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.

"Generic drugs significantly lower medical costs for Americans and bring many life-saving drugs within affordable reach," said **Senator Vitter**. But biological-based drugs – which are among the most expensive on the market – cannot be produced generically under current law. Insulin is a prime example, and with Louisiana having the highest rate of diabetes in the United States, this bill is crucial to ensuring that life-saving medicines are reasonably priced."

"Generic biologics have the potential to save Medicare Part B $14 billion per year, according to the Pharmaceutical Care Management Association," said **Rep. Jo Ann Emerson**. These are often some of the most expensive medications in the marketplace, so the possibility of achieving savings for seniors and taxpayers is very important. As of today, there are no such alternatives to brand-name biologics on the market, some of whose patents expired seven to ten years ago. Bringing generic biologics should be a priority for this Congress, with a sharp eye to the future solvency of the Medicare program."

"Biologic drugs provide effective treatments for some of our most devastating diseases. Unfortunately, however, these drugs are often prohibitively expensive and can cost tens of thousands of dollars a year. It is my hope that by creating a process to bring safe and effective generic versions of biologic drugs to the market, we will increase access and dramatically reduce costs for patients, employers, and federal and state health programs," said **Senator Collins**.

"Families in Michigan and across the country are struggling with the skyrocketing cost of prescription drugs, and we need to do everything we can to keep those prices under control," said **Senator Stabenow**. "Lowering the cost of prescription drugs for America's employers is not only good for patients, it is the best way to protect our jobs and stay competitive in a global economy. By opening the market to generic biological drugs this bill will provide real savings to businesses and consumers on some of the most costly medications."

"Biologic therapies hold the promise of preventing, treating or curing otherwise inevitable, untreatable and incurable diseases," said **Senator Leahy**. This important legislation will facilitate the approval of safe and effective generic biological products that may serve as less expensive -- yet potent -- alternatives for consumers."

"Biologic drugs have the potential to improve the lives of millions of Americans, but their high costs often keep them out of reach for many," said **Representative Pallone**. "I support efforts to increase generic versions of these lifesaving products as long as we strike the right balance between safety and access, which I believe this bill does."

The bill has been endorsed by the AFL-CIO, Consumer's Union, Generic Pharmaceuticals Association, National Organization of Rare Disorders, General Motors, Coalition for a Competitive Pharmaceutical Market, Express Scripts, Inc., and Aetna.

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