SUPPORT THE "ACCESS TO LIFE-SAVING MEDICINE ACT"

February 14, 2007

Dear Representative:

We strongly urge you to support and cosponsor the "Access to Life Saving Medicine Act," introduced by Reps. Henry Waxman, Joanne Emerson and Frank Pallone. The bill would provide a "roadmap" for the Food and Drug Administration (FDA) to allow generic versions of biological drugs (also known as biotech drugs or biopharmaceuticals) to be sold in the U.S. To protect the safety of the public, the bill establishes a rigorous, case-by-case scientific process for approving these products to make sure they are as safe and effective as their brand name counterparts. Under the bill FDA will have full authority to decide what testing is appropriate for these products.

Biologics, which are different from traditional pharmaceutical products because they are produced from living cell cultures rather than synthesized chemically, promise a new generation of life-saving treatments for diseases like cancer, diabetes, AIDS, Alzheimer's disease, heart disease, multiple sclerosis, and arthritis. The FDA has already approved more than 150 biologics and there are currently more than 300 biologic drug products and vaccines in clinical trials.

Unfortunately, it is common for these drugs to cost tens of thousands of dollars a year, keeping them out of reach of many Americans. Some can cost as much as $200,000 annually. Furthermore, America's biotechnology industry is one of the fastest-growing segments of U.S. healthcare. According to some estimates, sales of biotech drugs could exceed $60 billion by 2010.

The Access to Lifesaving Medicine Act could substantially lower health care costs to patients, employers, insurers and the government by allowing competition and ending the permanent monopoly pricing of biologics. Many biologics have already reached the end of their patent terms, and more than $10 billion worth of biologics are expected to come off patent in the next five years. If these were traditional chemical-based drugs, generic versions would be available to consumers at the end of these patent terms, providing savings of billions of dollars.

Currently, there is no statutory framework for the approval of generic alternatives to biologics, even after all patents have expired. As a result, the manufacturers of these drugs can charge *monopoly prices indefinitely*. The Access to Life-Saving Medicine Act would provide such a statutory framework, which could save patients and our health care system billions of dollars a year in drug costs and provide access to life-saving drugs to those who need them. Even a modest 20 percent price reduction could save U.S. taxpayers and consumers $1 to $2 billion a year.

The biotech industry argues that biologic drugs are too complicated to be duplicated precisely and that generic companies lack the scientific and medical ability to produce safe and effective products. In fact, many biologics can be fully and safely replicated with currently available scientific methods. Europe has established a structure for approving generic alternatives to biologics, and two biogenerics have already been approved under these procedures. Biologics are on the market in many other countries as well, including Mexico, China, India, Egypt, Argentina and Brazil. In this country, the FDA has approved a comparable version of human growth hormone. Furthermore, many generic pharmaceutical companies have highly sophisticated research and development operations and manufacturing capabilities. In fact, a significant number of these companies already develop and market proprietary products just as brand companies do.

The Access to Lifesaving Medicine Act grants the FDA the freedom to evaluate biologics and approve them only if they meet comparability or interchangeability standards. The bill leaves it to the FDA to determine the appropriate level of data required for approval on a product-by-product basis. If the FDA finds that current science is insufficient to ensure the safety and efficacy of a biogeneric, the agency would be required to deny approval.

The Access to Life-Saving Medicine Act will lead to lower drug costs for consumers and a more affordable health care system for America. We urge you to support this important legislation and look forward to working with you on this critical issue.

Sincerely,

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Consumer Federation of America
Consumers Union
Department for Professional Employees, AFL-CIO
Families USA
National Consumers League
National Research Center for Women & Families
National Women's Health Network
Public Citizen
Service Employees International Union (SEIU)
Spastic Paraplegia Foundation
U.S. Public Interest Research Group