2204 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-0530
(202) 225-3976
www.house.gov/waxman

DISTRICT OFFICE:
8436 WEST THIRD STREET
SUITE 600
LOS ANGELES, CA 90048-4183
(323) 651-1040
(818) 878-7400
(310) 652-3095

CHAIRMAN
COMMITTEE ON OVERSIGHT
AND GOVERNMENT REFORM

MEMBER
COMMITTEE ON
ENERGY AND COMMERCE

Congress of the United States
House of Representatives
Washington, DC 20515-0530

HENRY A. WAXMAN
30TH DISTRICT, CALIFORNIA

**Statement of Henry A. Waxman**
**Introduction of the Access to Life-Saving Medicine Act**
**February 14, 2007**

Twenty-two years ago, I co-authored the bill that first gave Americans broad access to safe and effective generic drugs. Before that time, drug companies had what amounted to permanent monopolies on their products. Obsolete statutory barriers protected them from competition long after their patents expired. Creating a pathway for approval of generic drugs changed that. Drug companies had to face competition and Americans gained access to affordable drugs. The drug industry fought competition, arguing that generic drugs would harm patients and destroy incentives for innovation. The last 22 years have proven three things beyond a shadow of a doubt: First, generic competition in the prescription drug marketplace lowers drug prices. Second, generic drugs are good for patients, both medically and economically. Third, competition does not bankrupt the drug industry or squelch innovation.

What many don't realize is that there is still no generic competition for one of the fastest growing and most expensive categories of drugs: so-called biotech drugs, also known as biological drugs or biopharmaceuticals. These drugs are often life-saving. Unfortunately, they also frequently cost tens of thousands of dollars per year, even hundreds of thousands. And there is no pathway for approving low-cost competing versions of these drugs, even after patents have expired. As a result, the burden of paying for biotech medicines on employers, insurers, and the federal government is staggering.

Introducing fair competition for biotech drugs is essential to keep these life-saving treatments affordable. To be sure, many biotech drugs are complex and copying them raises more difficult scientific questions than copying standard drugs. But the FDA has already approved abbreviated applications for competing versions of several simple biotech products. And the science in this field is evolving rapidly, promising the ability to approve copies of more complex biotech products in the future. The science and the economics lead to the same conclusion: the time has come to establish a pathway for approving generic versions of biopharmaceuticals.

I want to stress something absolutely critical about this bill. It is, above all, intended to make sure that no generic biotech drug will be approved unless the FDA is confident that it is as safe and effective as the brand name product. The bill gives complete discretion to the FDA to decide when it is scientifically appropriate to approve a copy of a biotech drug, and complete discretion to decide what studies are necessary before the FDA will approve it. The drug industry has been telling people that the bill somehow requires the FDA to approve drugs

without adequate evidence of safety or effectiveness. This is such a gross distortion of the bill, it is a good indicator of how desperate they are to avoid competition.

I believe that this bill will lead to healthy competition and long-term savings for patients and payers. But no policy in this bill will undercut safety and effectiveness in the interests of saving money. The only way we can succeed in establishing robust competition for biotech drugs is with drugs that doctors and patients know they can count on. And that's exactly what this bill is designed to produce.