THE ACCESS TO LIFE-SAVING MEDICINE ACT

I. Background

Generic drugs (first made possible under the 1984 Hatch-Waxman Amendments) have been extremely successful in bringing down the high cost of prescription drugs. Generic drugs save patients and payers $10 billion a year. But there is no generic competition for one of the fastest growing and most expensive category of drugs: so-called biotech drugs, also known as biological drugs or biopharmaceuticals. Biotech drugs, which are produced from living cell cultures rather than synthesized chemically, promise a new generation of life-saving treatments, but often at a prohibitive cost. It is common for these drugs to cost tens of thousands of dollars a year, even after patent expiration. Many patients are now denied access to these important drugs because even the co-payments can reach thousands of dollars a year. And the sky-rocketing cost of biotech medicines is imposing increasing burdens on employers, insurers, and the federal government.

Introducing fair competition for biotech drugs is essential to keep the life-saving treatments affordable. There is currently no statutory pathway for approving lower cost versions of biotech drugs licensed under the Public Health Services Act, even after all patents have expired. As a result, the manufacturers of biotech drugs can charge monopoly prices, indefinitely.

The Access to Life-Saving Medicine Act would allow FDA to approve abbreviated applications for generic versions of biotech drugs licensed under the Public Health Services Act, without repeating expensive and duplicative clinical trials. It would bring desperately needed competition into the biopharmaceutical marketplace and put an end to permanent monopolies. The bill establishes a scientifically rigorous process for approval of generic versions of biotech drugs, authorizing FDA to determine, on a product-by-product basis, what studies will be necessary to show that a new product is clinically comparable to the brand name product. The bill also creates an improved process for ensuring that patent disputes are resolved early to avoid delays in competition caused by endless or uncertain patent litigation.

II. Highlights of Bill

The legislation:

- Amends the Public Health Service Act to authorize the Secretary of HHS to approve abbreviated applications for biological products that are "comparable" to and "interchangeable" with previously approved (brand name) biological products.
- Comparable biologics must have "principal molecular structural features" that are highly similar to those of the brand name product and must have

- the same mechanism of action, if known. Comparable biologics can be approved on the basis of the safety and effectiveness of the brand name product, together with such additional evidence as the Secretary determines is necessary to show that there are no clinically meaningful differences between the two products (i.e., that the two products will produce the same effects in patients).
- Because biological products are very diverse, the Secretary has discretion on a case-by-case basis to determine what studies are necessary to establish comparability and interchangeability, and may require a clinical study or studies if necessary.
- An applicant for a comparable biological product may elect to establish that the new product can be substituted for the brand name product at the pharmacy level ("interchangeability"). To encourage the development of interchangeable products, the bill gives the first applicant to obtain approval of an interchangeable product a period of exclusive marketing during which no other interchangeable version of the product may be approved. In order to promote a robust marketplace, however, an approval may be granted for a comparable version of the brand name product if it has not yet been shown to be interchangeable.
- To encourage early resolution of patent disputes which might otherwise delay competition, a patent holder must disclose relevant patents in response to a request and bring a patent infringement suit 45 days of notice of a challenge or lose the right to certain remedies in court.