Chairman Frank Pallone, Jr.
Subcommittee on Health
Hearing
"Assessing the Impact of a Safe and Equitable Biosimilar Policy in the U.S."

Opening Statement

May 2, 2007

Good morning. Today the Subcommittee is meeting to hear about "Assessing the Impact of a Safe and Equitable Biosimilar Policy in the U.S.". Needless to say the topic of today's hearing is of great importance and has generated a lot of interest over the past few months.

Recent advancements in science have resulted in a new class of innovative medicines commonly referred to as biologics. These biotech drugs are complex molecules that are typically derived from living organisms, which are designed to treat a number of chronic and often debilitating diseases. While older versions of these products have existed for many years, manufacturers have made great strides in developing a broader range of biologic products that treat a greater number of conditions and illnesses.

Diabetes, cancer, heart disease, multiple sclerosis are among a range of devastating illnesses for which there are now new treatments because of improvements in the research and development of biologics. As a result, these life saving and life enhancing therapies have given patients and their families a renewed sense of hope for a longer and better life.

Because of the great promise biologics hold, they are one of the fastest growing components of the pharmaceutical market … unfortunately however they are also one of the most expensive.

The price of a biologic can be substantial, as well as prohibitive. Take insulin for example. It was noted in a recent New York Times article that the drug cost state Medicaid programs $500 million in 2005. Furthermore, people who suffer from diabetes in this country, as well as government and private insurers, spend a combined $3.3 billion a year on insulin. Researchers have suggested, however, that the price of insulin might drop twenty five percent if "generic" or "follow-on" versions were made available. The savings would accrue to many, including patients, employers, and insurers.

Competition from generic versions of chemical drugs has proven to be an effective way to help lower health care costs. As we all know, a generic drug can cost 30% to 80% less than its equivalent brand-name drug. In 2005, the average prescription filled with a brand-name product cost $95.54; the average cost for a generic drug was $28.71. That's a savings of nearly $70 on the average prescription. We need to apply what we have learned with generic versions of chemical drugs to biologic products, so that we can produce measurable savings.

That is what I believe Mr. Waxman has attempted to do by introducing his legislation, the Access to Life Saving Medicine Act. In 1984, Mr. Waxman paved the way for safe and affordable generic drugs to enter the market easily, while preserving incentives for brand name companies to develop new and innovative therapies. As we search for a way to lower costs and preserve innovation with biologics, Mr. Waxman is once again an authoritative voice in this debate and I thank him for directing our attention to this important issue. Congress needs to approve a pathway for generic biologics to be brought to market and this will be a priority for this Subcommittee.

I know many of my other Committee members (Mr. Inslee, Mr. Green, Ms. Baldwin and Ms. Eshoo) have also indicated their eagerness to address this important issue. I am looking forward to gathering their input as we move forward as well.

While I am a co-sponsor of the Access to Life Saving Medicine Act, I will be the first to admit, that the legislation is not without its controversy. Over the course of the past few months, I have heard from numerous stakeholders on this issue and believe that each side has its own merits. Several questions continue to arise.

What level of science should be used to determine comparability standards for these new products? What amount of science should be used to determine interchangeability? Who should make such determinations? Should it be Congress or the expert agency that we have typically charged with the regulation of drugs and biologics? How do we preserve innovation while achieving price competition? How do we strike a balance between protecting intellectual property, but ensure that generic versions of biologics are approved and enter the market in a timely manner? These are important questions whose answers will shape the debate and help us determine how FDA approves safe and effective "generic" or "follow on" versions of biologic products.

I would like to thank all of our witnesses for being here today. You represent the experts in the field and I will tell you that the members of this subcommittee are eager to hear what you have to say and ask questions of

you. So thank you for being here, I am certain that today's hearing will be extremely informative for all of us. I now recognize my good friend from Georgia, Mr. Deal, for five minutes for the purpose of making an opening statement.