Testimony of Senator Charles E. Schumer
HELP Committee Hearing on Follow-On Biologics
March 8, 2007

Thank you, Mr. Chairman, for allowing me to testify before the committee today, and for holding a hearing on this very important issue.

I am the sponsor, along with my friend Senator Clinton here in this committee and with Congressman Waxman in the House, of the Access to Life-Saving Medicine Act, which would establish a pathway for competition in the market for biologic products.

As I sit here today, I'm reminded of the laudable work of my colleague Senator Hatch here and of Congressman Waxman to establish the first pathway for competition in the chemical drug market over twenty years ago.

Back then, they were told that the science wasn't there. Back then, they were told that generic drugs would put the safety of consumers at risk. But their opponents were wrong then, and are still wrong today when they make the same arguments about follow-on biologics.

Mr. Chairman, biologics are a large and growing sector of the pharmaceutical market. They provide treatments for devastating diseases such as cancer and its complications, and have provided some of the most important innovations in medicine in the last 100 years. But these innovations are only useful to the public if there is competition in the market that lowers the price and makes the drugs available to everyday people.

Treating a patient with a biologic drug can cost $100,000 per year, at a total cost to the nation of $32 billion per year. Even if introducing competition to this market only lowers prices of biologic drugs by 10% to 25%, the savings on products this expensive will still be astronomical. Studies have estimated the potential savings of the Waxman-Schumer-Clinton bill at tens of billions of dollars every year.

We know that this field of science is complicated. We know that we won't see the savings all at once. But currently, FDA's hands are tied, and they have no statutory authority to approve a lower-cost biologic product even if all the evidence is there to show that the product is just as safe, pure, and potent as the innovator's product. To get this process started, we must provide FDA with the authority to act, and this first step is long overdue.

That's exactly what our bill does. The Access to Life-Saving Medicine Act gives FDA the authority to approve follow-on biologics and the discretion to determine what kind of information is needed to ensure that they are safe and effective.

I understand that a great deal of debate has been generated by this piece of legislation, and I welcome it. Certainly none of us wants a new law that does not adequately protect

the consumer, or a law that stifles innovation by making biologic drugs unprofitable for the brand industry.

So as we move forward with this debate, I would like to make two points, one on the EU system, and the other on patents.

I'd like to welcome Mr. Rossignol from the European Union to this hearing, and since the EU has already moved forward on approving what they refer to as "biosimilars," I think their experience is valuable.

But I would urge the Committee to consider this experience carefully. There may be valuable lessons to be learned from a system that is already in place, but we must fully understand how that model might work in our own market.

As it stands today, the EU has a highly-regulated process in place that has arguably been unnecessarily burdensome to competitors and has only resulted in two approvals to date. This process was not established by the legislation that was passed by the European equivalent of Congress, however. The statute that created a pathway to biosimilars in the EU was written in broad language which gave Europe's equivalent of the FDA discretion to flesh out the details.

So when we think about this model, I agree that we should pass legislation that would give the FDA the discretion to establish a scientific approval process as they see fit. But why would the United States of America deprive the FDA of the ability to draft its own regulations, and force them to swallow a complex set of regulations that has been created by another system of government? A system of government, I might add, that has price controls and a generic drug market that is not as robust as our own.

And finally, I'll spend a moment on patents. As I mentioned earlier, we need to strike a balance between rewarding innovation and increasing access to lower-cost pharmaceuticals.

I'm sure many people in and out of this room have ideas on how they'd like that to happen.

But let me just point out that in 1984, when Hatch-Waxman law was passed, it struck a balance between the innovators and the generics for traditional chemical drugs, but also created an imbalance for biologic drugs.

It gave biologic manufacturers the same five-year patent extension that chemical manufacturers received, and also gave them the same access to seven years of exclusivity under the Orphan Drug Act, but did not set up an abbreviated pathway for approval of biologic competitors.

Therefore, I would argue that the Waxman-Schumer-Clinton bill is not imbalanced, but rather is restoring balance in a sector of the pharmaceutical market that has never faced competition.

I know that some of my colleagues are concerned that we are moving too quickly. I am concerned that we have not moved quickly enough. We have already waited for years for the FDA to issue a white paper on follow-on biologics. The science is there, the groundwork has been laid, and every day that we deny the FDA this authority means more delay in savings on vital medicines for consumers.

Thank you, Mr. Chairman.