

ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

Opening Statement of Rep. Henry A. Waxman
Chairman, Committee on Energy and Commerce
Emerging Health Care Issues: Follow-on Biologic Drug Competition
Subcommittee on Health
June 11, 2009

Today we will hear from the Federal Trade Commission on an issue of paramount importance in the debate on a pathway for approval of follow-on biologics: How long a period of exclusive marketing we must give to biotech drugs to sustain innovation.

As was true when Congress passed the Waxman-Hatch Act 25 years ago, an effective follow-on biologics bill must maintain a balance between increasing consumer access to affordable medicines, on the one hand, and providing adequate incentives for innovation, on the other. Life-saving drugs are useless if no one can afford them. Yet, making today's drugs affordable does us little good if we cut off the supply of future breakthroughs.

We have made great progress in the last 3 years towards a consensus on how to ensure that follow-on biologics are safe and effective. Just 2 years ago, the drug industry argued that it was impossible to make follow-on biologics. Now there is agreement that it can be done.

But we remain divided on what incentives are needed for innovation. It's no longer a matter of whether patients will get generic versions of these life-saving medicines, but when.

In assessing how much exclusive marketing is needed to sustain innovation, I begin with a basic premise: the balance we struck in Waxman-Hatch has worked well for 25 years. It has given us access to affordable drugs and it has not damaged innovation. Pharmaceutical R&D expenditures have not just been maintained, but have steadily risen throughout those 25 years. Under Waxman-Hatch, innovative drugs get 5 years of exclusivity.

The drug industry has been engaged in a massive and expensive lobbying campaign to convince the members of this Committee that the supply of life-saving drugs will dry up if they don't get triple the monopoly protection available to all other drugs. The drug industry is demanding 12 or even 14 years of exclusivity for biotech drugs.

To support this extraordinary request, the industry makes two main arguments. First, that their patents are much weaker than drug patents and won't block competition from follow-ons. Second, that it takes between 12 and 16 years for biotech drugs to break even so that's the period of exclusivity they need. Though I have seen little or no persuasive evidence to support these arguments, the industry has blanketed Capitol Hill with them.

The outcome of this debate is too important for our nation's health to let lobbying clout decide it. The cost of reaching the wrong decision is simply too high. Instead, the appropriate length of exclusivity must be decided on the basis of evidence and analysis by objective experts. Experts who are not being paid by one side or the other.

That is why I am so pleased that the FTC has undertaken an in-depth review of all the evidence and argument on both sides of this debate. The FTC employs economists, patent lawyers, and experts in the pharmaceutical marketplace. Their job is to assess the impact of laws, regulations, and marketing practices on both competition and innovation in the prescription drug marketplace. The FTC has overseen this marketplace for decades and has produced highly-respected reports on generic drug competition and anti-competitive practices in the drug marketplace. For example in 2002, the FTC produced a report on abuses of Waxman-Hatch that inappropriately delayed consumer access to generic drugs. The report resulted in important amendments to Waxman-Hatch enacted the following year.

Today the FTC will tell us whether the methods we have always used to sustain innovation in the drug industry — patents, and market-based pricing, with perhaps a short period of exclusivity — are adequate to sustain innovation for biotech drugs. And they will tell us whether the arguments in favor of 12-14 years of exclusive marketing hold up to scrutiny.

The objective, evidence-based answers to these questions from the expert agency charged with overseeing competition and innovation in the drug marketplace will provide critical information to the Committee as we move forward.

I look forward to exploring the FTC's analysis and conclusions on these key questions.