



Biotech firms win vote over generics

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(08-03) 17:59 PDT -- Biotech firms won a victory last week when a House panel said any future rules for creating generic versions of biological medicines must guarantee 12 years of exclusive market access to the company that developed the treatment.

In an amendment that passed 47-11 Friday, the House Energy and Commerce Committee rejected the Obama administration's suggested limit of seven years, and instead gave biotech innovators the same protection from competition as a companion measure that has already cleared a Senate committee.

The House and Senate amendments dealing with generic versions of biotech medicines are part of the administration's \$2.5 trillion health care system overhaul, which is on hold until after Congress ends its summer recess.

Biological medicines, or biologics, are generally administered by injection and are developed using different processes than drugs that come in pill form.

In 1984, Congress created a process for winning Food & Drug Administration approval for generic pills once new drugs lose their patent protection.

That law guaranteed at least five years of exclusive market access after FDA approval to make sure the drugmakers had enough time to recoup their development expenses.

The United States does not have rules for creating generic biologics and the House and Senate amendments to the health care bill are designed to outline such a process.

One flash point in that debate has been the length of the exclusivity period after biologics win FDA approval.

Biotech advocates say 12 years of exclusive access is needed to give investors the incentive to bankroll the development of new medicines, while consumer representatives argued for a period as brief as five years so that less-costly generic biologics can get to market faster.

Matt Gardner, president of BayBio, a trade organization representing about 500 biotech firms in the region, said the House and Senate committees made the right call with 12 years.

"This removes some of the uncertainty at a time when the financial system is in turmoil," he said. "We look at the period after product approval as recovering the 15 years of development that goes into creating biotech medicines."

Nora Super, a lobbyist for AARP, said the senior group thinks the longer exclusivity period will discourage generic manufacturers from creating alternatives to biologics, which are already a costly and growing burden on the health care system.

"Because there are no generic equivalents for biologics, the cost of biologics have been growing at least 15 percent a year," Super said.

"Arguments about exclusivity are designed to protect the profits of the biotech industry."

Friday's House vote was a victory for Rep. Anna Eshoo, D-Palo Alto, who co-authored the amendment which, she said, "sets forth a straightforward, scientific process for approval" of generic biologics.

On the losing side was Rep. Henry Waxman, D-Los Angeles, who co-authored the 1984 legislation on generic pills and is now chairman of the Energy and Commerce Committee. "This amendment is exactly the wrong way to increase competition and reduce prices," he said after Friday's vote.

Chronicle news services contributed to this report. E-mail Tom Abate at tabate@sfchronicle.com.

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