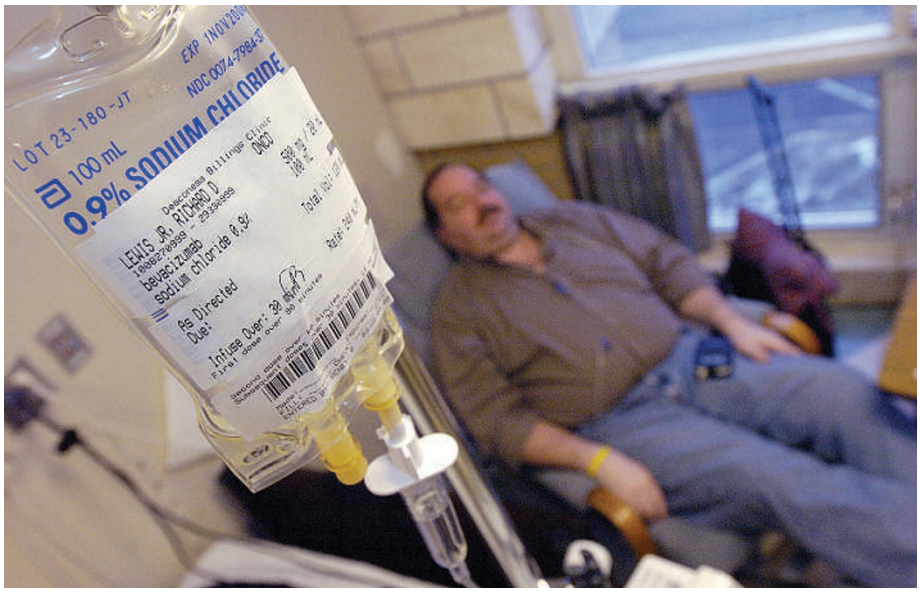
BUSINESS

Meeting in the middle

Support for copycat versions of biotechnology drugs is growing quickly in the US Congress. **Meredith Wadman** reports.



D. GRUBBS/AP

Cancer drug Avastin can help patients such as Richard Lewis — but at a cost of up to $100,000 a year.

In an immaculate, glass-fronted complex in a suburb of Seattle, Washington, more than a hundred scientists at the biotechnology company Amgen are busy cranking out a new generation of anticancer drugs, and honing manufacturing processes they hope will eventually deliver treatments to millions of patients.

And 3,000 miles away on Capitol Hill, congressman Jay Inslee (Democrat, Washington) — whose district is home to the Amgen facility — is busy with a project of his own: pushing a draft law that, he says, will enable the Amgens of the future to survive and prosper.

In April, Inslee introduced legislation that would insulate inventors of biologics — complicated, large-molecule drugs — from generic competition for 14 years. The bill is intended to fend off stricter legislation that, Inslee says, could cripple the whole industry. "We can create a pathway to lower-cost copies of biotech drugs without eliminating incentives to create breakthrough medicines," he says.

Other lawmakers see it differently. Bills introduced by Henry Waxman (Democrat, California) in the House and Hillary Clinton (Democrat, New York) in the Senate in February would allow biogenerics that are similar to brand-name biotech drugs — but not similar enough to infringe patents — to appear from the moment the original drugs hit the market. "This will lead to healthy competition and long-term savings for patients," says Waxman.

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> — Michael Werner

The bills reflect a growing momentum to get generic versions of biologics to market in a Congress controlled by Democrats since January. With the first generation of patents on biologics now expiring, and increasing public disquiet about drug prices, lawmakers say they are determined to make generic biologics a reality by writing a law giving the US Food and Drug Administration (FDA) the explicit authority to approve them for market.

In Congress, "the leading voices are talking more about how do we do this than whether we should do it," says Michael Werner, a former chief of policy at the Biotechnology Industry Organization (BIO) who now runs a consulting firm in Washington DC.

It is not only Democrats who are pushing for the change. A bipartisan group of senators, including Ted Kennedy (Democrat, Massachusetts), Orrin Hatch (Republican, Utah) and Mike Enzi (Republican, Wyoming) will next week unveil compromise biogenerics legislation that they hope to bring to a Senate vote by July. Biogenerics are "an issue whose time has come", says Craig Orfield, a spokesman for Enzi.

Finding a bill that can pass into law will involve balancing the interests of the still-risky biotech industry with those of employers, insurance companies and patients complaining about paying tens of thousands of dollars annually for biologics.

"Without generic competition, the cost of biologics is unsustainable," claims Missy Jenkins, a spokeswoman for the Coalition for a Competitive Pharmaceutical Market, an organization of employers and health insurers lobbying for action on biogenerics.

The coalition, which backs Waxman's bill, points to the price of drugs such as Avastin (bevacizumab), Genentech's cancer drug, which costs up to US$100,000 for a year's treatment.

Those who would like to produce the copycat drugs, meanwhile, point out that the makers of standard, small-molecule pharmaceuticals have prospered, despite the Hatch-Waxman Act that opened the door to generic versions of their products in 1984. "For more than 20 years, generic medicines have been improving lives," says Kathleen Jaeger, the president of the Generic Pharmaceutical Association in Arlington, Virginia.

The biotechnology industry, however, disputes claims that generic biologics could save billions of dollars in healthcare costs, arguing that the drugs they imitate operate in a limited, niche market. It also argues that biogenerics wouldn't offer new cures or treatments.

Biotech firms are at pains to point out that their very business model will be put at risk — and patients will suffer — if Congress acts without considering the costs to innovator companies. "Wall Street will evaluate [the legislation's] impact on the profitability of investing in biologics companies," says Jim Greenwood, president of BIO. "If that's likely to decline, it will reduce the amount of investment in these companies and we will have a commensurate reduction in new and spectacular products."

Among Greenwood's chief complaints is that the strictest bills would provide innovator companies no guarantee of any period of market dominance. BIO is calling for 14 generic-free years for innovator biologics — the same period written into Inslee's bill. Last year, the European Union settled on ten years as a suitable period for biologics to be insulated from generic competition (see *Nature Rev. Drug Disc.* **5,** 445; 2006).

And it looks as though Congress will pass a law that involves a similar compromise. "If Waxman's bill is the stake in the ground for the generic companies, Inslee's bill is the stake in the ground for the innovator companies," says Werner. "I think the final product will be somewhere in the middle." ■