Editorial: Improper Efforts to Limit Competitive Drugs

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The New York Times

Two big biotechnology companies, Amgen and Genentech, are lobbying state legislatures to limit competition to their biological drugs that will lose patent protection in the next several years. Before taking any action, lawmakers should wait for guidance from the Food and Drug Administration, the agency that reviews all drugs and their generic versions for safety and effectiveness.

Biological drugs are made from large molecules, and the processes, involving living cells, are more complex than those used to make conventional drugs. The cheaper competitors to brand-name biological drugs are called "biosimilars" to indicate that they are not exact copies but are close enough to work the same way.

American consumers, insurers and health care providers could potentially save billions of dollars a year by using cheaper versions of brand-name biologicals that now cost tens or hundreds of thousands of dollars a year per patient. States should not move to limit access to biosimilar drugs before the F.D.A. has issued final guidelines on how to ensure their safety. In their lobbying campaign, revealed by Andrew Pollack in The Times recently, the two companies have persuaded legislators to introduce bills that would restrict the ability of pharmacists to substitute cheaper biosimilars in filling prescriptions.

The Affordable Care Act empowered the Food and Drug Administration to use an accelerated process to determine whether a biosimilar drug could be deemed "interchangeable" with the brand-name drug for clinical purposes. Once a biologic is deemed interchangeable, it can be substituted by pharmacists without permission from a doctor. Biosimilars are unlikely to be available in this country for at least two years, though more than a dozen have been approved in Europe with no evidence of adverse consequences.

Amgen and Genentech say they want state laws to protect patient safety. But it makes more sense for the states to see what the F.D.A. does first before imposing administrative hurdles on pharmacists and patients -- like requiring a patient's consent every time a substitution is made -- when using less expensive biosimilar drugs.

The New York Times

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Biotech Firms, Billions at Risk, Lobby States to Limit Generics

By ANDREW POLLACK

In statehouses around the country, some of the nation's biggest biotechnology companies are lobbying intensively to limit generic competition to their blockbuster drugs, potentially cutting into the billions of dollars in savings on drug costs contemplated in the federal health care overhaul law.

The complex drugs, made in living cells instead of chemical factories, account for roughly one-quarter of the nation's $320 billion in spending on drugs, according to IMS Health. And that percentage is growing. They include some of the world's best-selling drugs, like the rheumatoid arthritis and psoriasis drugs Humira and Enbrel and the cancer treatments Herceptin, Avastin and Rituxan. The drugs now cost patients — or their insurers — tens or even hundreds of thousands of dollars a year.

Two companies, Amgen and Genentech, are proposing bills that would restrict the ability of pharmacists to substitute generic versions of biological drugs for brand name products.

Bills have been introduced in at least eight states since the new legislative sessions began this month. Others are pending.

The Virginia House of Delegates already passed one such bill last week, by a 91-to-6 vote.

The companies and other proponents say such measures are needed to protect patient safety because the generic versions of biological drugs are not identical to the originals. For that reason, they are usually called biosimilars rather than generics.

Generic drug companies and insurers are taking their own steps to oppose or amend the state bills, which they characterize as pre-emptive moves to deter the use of biosimilars, even before any get to market.

"All of these things are put in there for a chilling effect on these biosimilars," said Brynna M. Clark, director of state affairs for the Generic Pharmaceutical Association. The limits, she said, "don't sound too onerous but undermine confidence in these drugs and are burdensome."

Genentech, which is owned by Roche, makes Rituxan, Herceptin and Avastin, the best-selling cancer drugs in the world. Amgen makes Enbrel, the anemia drugs Epogen and Aranesp, and the drugs Neupogen and Neulasta for protecting chemotherapy patients from infections. All have billions of dollars in annual sales and, with the possible exception of Enbrel, are expected to lose patent protection in the next several years.

The trench fighting at the state level is the latest phase in a battle over the rules for adding competition to the biotechnology drug market as called for in the Patient Protection and Affordable Care Act of 2010.

A related battle on the federal level is whether biosimilars will have the same generic name as the brand name product. If they did not, pharmacists could not substitute the biosimilar for the original, even if states allowed it.

Biosimilars are unlikely to be available in the United States for at least two more years, though they have been on the market in Europe for several years. And the regulatory uncertainty appears to be diminishing enthusiasm among some companies for developing such drugs.

"We're still dealing with chaos," said Craig A. Wheeler, the chief executive of Momenta Pharmaceuticals, which is developing biosimilars. "This is a pathway that neither industry nor the F.D.A. knows how to use."

Biotech drugs, known in the industry as biologics, are much more complex than pills like Lipitor or Prozac.

That makes it extremely difficult to tell if a copy of a biological drug is identical to the original. Even slight changes in the cells that make the proteins can change the drug's properties.

The 1984 law governing generics does not cover biologicals, which barely existed then. That is why it was addressed in the 2010 law.

One reason generic pills are so inexpensive is that state laws generally allow pharmacists to substitute a generic for a brand-name drug unless the doctor explicitly asks them not to. That means generic drug manufacturers need not spend money on sales and marketing.

The bills being proposed in state legislatures would expand state substitution laws to include biosimilars. So Amgen and Genentech say the bills support the development of biosimilars.

But the bills would impose restrictions that do not apply to chemically produced pills. For a

substitution, they say, the Food and Drug Administration must find a biosimilar "interchangeable" with the branded product. The F.D.A. has said interchangeability will be a higher standard than merely being similar to the branded product.

Some of the bills would also require patient consent for the substitution, for the pharmacist to notify the doctor if a switch is made and for the pharmacist and doctor to maintain records of the switch for years.

Backers say these safeguards are necessary to enable the tracing of any safety problems that might arise with a biosimilar.

"These are really complex, highly sensitive molecules," said State Senator Patricia Vance of Pennsylvania, who plans to introduce a bill. "We want to make sure we are not hurting people."

The generic drug association and insurers do not object to limiting substitution to drugs declared interchangeable by the F.D.A.

But they say that once the F.D.A. makes that determination, the other restrictions are unnecessary and are there merely to deter substitution.

Gillian Woollett, who tracks biosimilars for Avalere Health, a Washington advisory firm, said extra restrictions on substitution could put the state bills into conflict with the federal law, which defines interchangeability as meaning that a biosimilar can be substituted without the involvement of the prescribing doctor.

Ms. Woollett said the lobbying efforts by the biotech companies, which she characterized as "putting a few more tree trunks on the road," might not make much difference as long as insurers have policies encouraging use of the biosimilars. She noted that only a small percentage of biologicals are dispensed through retail pharmacies. Most are infused or injected in a hospital or doctor's office. That has not reduced the intensity of the skirmishes in state houses.

Dr. John O'Bannon III, a Republican delegate who introduced the bill that was passed last week in the Virginia House, said he did so because as a practicing neurologist, he was familiar with biologicals. Then he added, "The Amgen folks actually did come and talk to me."

Amgen gave $22,000 to Virginia state legislators in both 2011 and 2012, more than double the $11,000 it gave in 2010, according to the Virginia Public Access Project. Dr. O'Bannon received $1,500 over the last two years.

In North Dakota, a bill has cleared a committee in the State Senate, though it was amended to remove some restrictions.

"Genentech was the one that brought the bill to me," said State Senator Dick Dever, a Republican, who introduced the bill.

In Indiana on Monday, the House Public Health Committee approved a bill, but lawmakers, responding to objections from the generic association, removed the requirement that patients consent to any substitution. Ed Clere, chairman of the committee and author of the bill, said the bill "doesn't do anything to prevent or discourage the use of biosimilars." He said the bill had been brought to him by Genentech and supported by Eli Lilly, which is based in Indiana.

Also supporting the push for such legislation is the Alliance for Safe Biologic Medicines.

This is not the first time drug companies have turned to states to try to blunt generic competition. In the late 1990s, DuPont Merck Pharmaceutical pushed for laws that would restrict substitution for its blood-thinning drug Coumadin, known generically as warfarin, on the grounds that the drug was extremely difficult to use safely.

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Biosimilars – Premature and Unnecessary

Vote NO on HB 2705 + SB 460

Oregon's House Bill 2705 + Senate Bill 460 will limit the substitution of biosimilars, which are expected to save patients and payers millions of dollars.

What are biologics and biosimilars?

Biologic and biosimilar are terms used to describe products that are generally produced using a living system or organism. They may be manufactured through biotechnology, derived from natural sources, or produced synthetically. This is in contrast to pharmaceutical drugs which are manufactured from chemical processes. A biosimilar is a biological product that is highly similar to a biological product notwithstanding minor differences in clinically inactive compounds. **A biosimilar can have no clinically meaningful differences from the biologic product in terms of safety, purity and potency, similar to requirements for generic substitution of name brand drugs.**

Current Status

The U.S. Food and Drug Administration (FDA) is working to create a process for the approval of biosimilars and determining interchangeability. The FDA is fully cognizant of the complex nature of biologics and has made clear that the standards they develop for determining whether a biosimilar is interchangeable with an approved reference product will be rigorous.

Big biotechnology drug companies don't want to wait for the FDA to rule on biosimilar drugs. They are pushing legislation in several states, including Oregon, in order to limit competition by promoting fear in patients and creating artificial barriers to their use.

Unnecessary and Premature

- **It's premature to act.** The Affordable Care Act of 2010 empowered the FDA to review whether a biosimilar drug can be both effectively and safely substituted. The FDA has not yet finished this work and any state law passed now may conflict with national standards later.
- **No immediate safety issue.** While more than a dozen biosimilar drugs have been approved and are prescribed in Europe with no evidence of adverse consequences, it will be at least two years before they are available in the U.S.
- **It's self-serving.** Any legislation that impedes or limits biosimilar substitution is nothing more than an attempt by brand manufacturers to pre-emptively protect profit margins at the expense of consumers and payers.