

# A primer for follow-on biologics

## *What you should know*

**NATION** - In the coming months, you'll hear a lot about "follow-on biologics" from policymakers and pundits.

If you don't know anything about them, here's what you should know. We're all familiar with conventional drugs like Tylenol and Lipitor. Produced using chemical reactions, conventional drugs are comprised of small molecules and can be replicated easily.

For example, there's no difference between Tylenol and store-brand acetaminophen - both contain the same 20 atoms arranged the same way. That's why generic drugs are so popular. They're chemically identical to their brand-name counterparts and cost about 70% less. With health-care costs escalating, policymakers want to expand the use of generics. As part of that effort, lawmakers are considering a measure that would allow the generic drug industry to copy biologic drugs. Drugs made through biotechnology are today's most cutting-edge medicines and can cost tens of thousands of dollars

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 each year. So the production of generic biologics could save millions.

Unfortunately, it's scientifically impossible to create a "generic" biologic. Biologics are incredibly complex. Herceptin, a popular anti-cancer biologic, is comprised of about 25,000 atoms - more than a thousand times as many as Tylenol. The manufacturing process for biologics is extremely complicated. Most are

grown in living organisms, and many involve modified DNA. Each molecule of a biologic may have a slightly different structural pattern - even if it has the same chemical formula and is made according to the exact same process.

That's why it's impossible to copy biologics perfectly. Scientists call them "follow-on biologics," because at best, they're similar. Accordingly, government regulators have handled only extremely small biologics - like human-made insulin - as if they're conventional generics. That will likely change soon. But in the interest of safety and continued innovation, Congress must move forward with care.

For starters, lawmakers must recognize that follow-on biologics can cause unexpected physiological reactions, so they should have their own, distinct names to help doctors know exactly what a patient is taking. And follow-on biologics must demonstrate that they're safe and effective through their own clinical trials.

Lawmakers must also work to ensure that there's continued innovation. A simple patent can protect a conventional drug - the structure of acetaminophen's 20 atoms is concrete, as is the four-step chemical process for making it. But, a biologic can combine several patents - one on the giant molecule - and numerous others on the process for creating that molecule. Process patents are highly susceptible to challenge in court. That makes data exclusivity, or the amount of time that a drug maker can keep his data to secret, incredibly important.

It takes \$1.2 billion to develop an average biologic and another \$250-\$450 million to construct the facilities to produce it. Yet the



overall probability of success is only 30%. And, even if a biologic reaches the market, it may not make money. Of the 30 new biologics introduced between 1982 and 1994, only six accounted for 70% of industry sales in 2002.

Consequently, biologics must enjoy a significant period of data exclusivity. According to Duke University economist Henry Grabowski, most biologic companies don't recoup their research and development costs until their product has been on the market for 12.9 to 16.2 years. Given that, lawmakers should provide at least 14 years of protection. Without the appropriate protections, there will be little financial incentive to develop biologics.

That'd be a shame, because this cutting edge medical technology could allow people to live longer and healthier lives.

- SALLY C. PIPES

*(Publisher's note: Sally C. Pipes is President/CEO of the Pacific Research Institute)*

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