The Washington Post
Business

‘Marketers are having a field day’: Patients stuck in corporate fight against generic drugs

By Christopher Rowland
January 9

Health-care and government officials are growing concerned that the makers of the most advanced drug therapies are using scare tactics to ward off emerging generic versions of their products, a bid to protect profits that has enormous implications for the nation’s efforts to control health-care costs.

Doctors, drug companies and the nation’s top drug regulator say the companies that make costly name-brand biologic drugs, which are grown from living cells, are sowing doubt about the wisdom of switching to cheaper, unbranded versions of their medicines — even though the Food and Drug Administration has certified they are safe and effective.

Biologics have led to breakthroughs against cancer, rheumatoid arthritis and other serious diseases. But they are hugely expensive — typically tens of thousands of dollars a year for a single patient — and concern is building that an industry misinformation campaign will discourage market acceptance of lower-cost copies.

The campaign against those cheaper versions, known as biosimilars, could delay affordable access to a host of novel therapies, hurting patients and driving up health-care costs.

“I am worried that there are either deliberate or unintentional efforts by branded companies to create confusion” about the safety and effectiveness of unbranded biologic drugs, FDA Commissioner Scott Gottlieb said in an interview with The Washington Post. The messages “can potentially undermine consumer confidence in biosimilars in ways that are untrue.’’

Gottlieb did not name specific companies or groups. But an alliance of makers of the highly profitable advanced drug therapies issued some of the most glaring warnings about government-approved copies of their products: They could “put you in the emergency room.’’ They may carry “additional risks.’’ The “potential problems involve efficacy, safety.’’

Gottlieb indicated the FDA may take action if it determines a company is deliberately misleading the public about the safety of biologic copies, by issuing warning letters to the drugmakers involved.

Such messages about unbranded biologics “raise public health concerns,’’ he said. “They could negatively impact a patient’s judgment about an otherwise safe and effective product.’’

At stake are savings to the U.S. health-care system that have been estimated at $54 billion to more than $200 billion over 10 years.

Policymakers say getting the costs of biologics under control is vital to curbing U.S. health-care spending; it is estimated that 70 percent of growth in prescription drug costs between 2010 to 2015 was fueled by biologics, with drugs such as AbbVie’s Humira leading the way.

The copies are projected to be priced 10 percent to 51 percent less, according to a study by the nonprofit Rand Corp.

Although they have been available in Europe for years, driving down costs for consumers across the Atlantic, unbranded versions of biologic drugs are still relatively new in the United States. The European Medicines Agency has approved more than 40 biologic copy drugs. The first U.S. version was approved by the FDA in 2015, and just 16 have been approved so far, according to the FDA website.

Unbranded biologics are different from typical generic medicine. Instead of a combination of chemicals, biologic drugs are grown in vats from living proteins. The complexity makes it impossible for a generic manufacturer to make a replica of the brand medicine; production results in small variations.

Those molecular-level variations give brand companies and allied groups an opening to sow doubt about effectiveness or safety.

“This is a field in which the marketers are having a field day,’’ said Corey Cutler, an oncologist at Dana-Farber Cancer Institute in Boston, who has consulted for generic manufacturers. The complexity makes it harder for the FDA and unbranded biologic manufacturers to soothe concerns. “It’s just hard to understand,’’ Cutler said.

The FDA approves the unbranded biologic copies by analyzing their structure and reviewing data from limited human tests. Drugs that make it through this process, according to the FDA, contain “no clinically meaningful differences in safety, purity, and potency.’’

Yet companies and industry-funded groups are citing the potential for problems, even as they claim to support development of unbranded biologic drugs as a way of reining in U.S. drug costs. The campaign of confusing, mixed messages has been underway for years but is attracting greater attention as market competition edges closer to reality.

Included in the effort are the Biotechnology Innovation Organization (BIO), the industry trade group that spends well over $10 million a year lobbying the federal government; as well as two of the largest brand manufacturers of biotech drugs, Amgen and Roche’s Genentech division, which make top-selling drugs for cancer and rheumatoid arthritis.

The three have been financial backers and are prime “member partners’’ of the nonprofit Alliance for Safe Biologic Medicines, which is itself part of a broad network of industry-funded groups trying to curb the spread of unbranded biologics.

Raising safety concerns is a key part of the strategy. In an interview, an official with the Alliance for Safe Biologic Medicines raised the specter of a historic tragedy in global drug safety.

The U.S. medical community should proceed cautiously with moving patients to unbranded biologics “so we don’t end up with another thalidomide’’ or “all the other things that happen when safety isn’t considered,’’ said Philip Schneider, chairman of the alliance’s international advisory board and a former associate dean of pharmacy at the University of Arizona.

Thalidomide use by pregnant women globally from the late 1950s until 1961 led to tens of thousands of deformities in children before the drug was blocked from markets; the scandal led to stronger FDA drug-testing requirements.

There has been no suggestion of any such health effects through the use of unbranded biologics, in the United States or Europe.

Warnings about hazards also are contained on the Alliance for Safe Biologic Medicines website. In a video posted on the site, Schneider declares briefly that generic versions of biotech drugs are “safe and effective’’ but goes on to say, with much greater emphasis: “They may or may not produce the same effects, or they may carry additional risks.’’

A patient advocate affiliated with the Alliance for Safe Biologic Medicines is featured in another of the group’s videos, making the point that safety is a paramount concern. But then the advocate, lupus patient Kathleen Arntsen, says this about the possibility of a patient switching from one drug to another:

“It disrupts your continuity of care. You could end up in an emergency room, or being hospitalized, or trying other, less efficient treatments. All that can exacerbate or flare your disease, bring it out of remission.’’

In an interview with The Post, Arntsen said she based that statement on her own experience being switched from one anti-malarial drug to another nearly 20 years ago. Arntsen denied that she intended to question the safety of biologic copies.

Her real point, she said, is that only doctors and patients should decide what drug to use, not insurance companies.

“Don’t rock my boat. Don’t disrupt my care,’’ she said. “Don’t get between me and my educated providers.’’

The Alliance for Safe Biologic Medicines is run by executive director Michael Reilly, a former associate deputy secretary in the Department of Health and Human Services during the administration of President George W. Bush.

Reilly insisted his organization is not attempting to scare doctors or patients. “ASBM has been extremely supportive from our beginning of biosimilars and the need for them,’’ Reilly said.

But in a column published in the Vancouver Sun in 2017, Reilly argued that switching to an unbranded biologic “may produce a different effect’’ than the original drug. He also amplified physician concerns that “the different medications may cause adverse effects in patients.’’

His group’s cautions dovetail with advocacy by another industry-funded nonprofit, the Institute for Patient Access, which rails against “cost-motivated treatment changes.”

“There’s just not robust information out there that gives physicians the assurances they need,’’ Reilly said. “These are not generics. They are a different product. They are never identical.’’

Reilly said BIO, Amgen, Genentech and other alliance members did not participate in producing his group’s videos, which he said were made in September. BIO, which Reilly said gave his alliance a combined $85,000 in 2011 and 2013, said it supports development of unbranded biologic drugs — but has misgivings about their use in certain circumstances.

“We do agree that there are safety concerns when a patient who is stable on a biologic medicine is forced to switch (often because their insurance company changes their formulary) to a different medicine,’’ BIO said in an email to The Post.

The warfare is dividing big industry players.

Johnson & Johnson is facing a lawsuit from Pfizer for allegedly offering rebates on its drugs to convince insurance companies to give its anti-inflammatory biologic Remicade preferential treatment.

AbbVie, whose anti-inflammatory drug Humira is the biggest seller in the world by revenue, is facing questions from Congress about alleged anti-competitive practices. Critics say the company has created “patent thickets” around its drug that discourage generic competition. The drug manufacturer also has cut deals with the makers of biologic copies to keep them off the market until 2023.

In a petition to the FDA in August, Pfizer accused Amgen, Genentech and Johnson & Johnson’s Janssen Biotech unit of misleading doctors and patients.

Pfizer said “false and misleading information that casts doubt about the safety and efficacy of biosimilars in the minds of patients and prescribers” has shaken market confidence in the United States.

Pfizer cited a Genentech website called “Examine Biosimilars’’ where videos raise questions about the FDA’s use of “extrapolation’’ to approve a biologic copy for multiple illnesses, and “cut and paste’’ information on the drug label insert.

Pfizer also claimed the branded companies are seeking to unfairly exploit a separate “interchangeability’’ standard in the FDA rules for biologic copies, to suggest copycat drugs approved thus far are not as good.

These points may seem subtle to most consumers, but for the target audience of doctors and patients with complex diseases like rheumatoid arthritis and cancer, they could have a big impact.

Amgen, Genentech and Johnson & Johnson denied they misled anyone about biologic copies. They cast their activities as education efforts.

“Genentech is committed to providing health care professionals with accurate, fair and balanced information on both biologic and biosimilar medicines,’’ the company said in a statement.

Amgen pointed out that it is developing its own line of biologic copies. What’s more, its Neupogen drug to boost white blood cells in chemotherapy patients, which was the target of the first unbranded biologic

approved by the FDA in 2015, has lost considerable market share in the last several years, Amgen noted, evidence that competition will ultimately work.

Even so, it indicated it will continue to raise concerns.

“Scientific education about what they are and what they aren’t is critically important to instill confidence in the marketplace,’’ said Scott Foraker, vice president and general manager of Amgen’s unbranded biologics business. “There is an unanswered question when you switch from one biosimilar to another. That’s an unanswered question scientifically.’’

Correction: *An earlier version of this article misspelled Kathleen Arntsen's last name.*

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Chris Rowland joined The Washington Post business team in 2018 after serving as the Washington bureau chief for the Boston Globe, leading coverage of two presidential elections