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Making "Miracle" Drugs Affordable

Some might think it will take a miracle to make "miracle" drugs accessible to those with the direst of diseases, but others are putting their faith in Congress and pharmaceuticals to lower the cost of these so-called biologics.

BY ANA RADELAT
July 2009

In her battle with rheumatoid arthritis, Yvonne Bacarisse has had her hips, knees, and bones in her feet replaced; her wrists fused; operations on her left elbow; and cervical fusion of two neck vertebrae. But the 74-year-old Cuban American won a victory over her disease a few years ago when she was prescribed Enbrel, a then-revolutionary drug that belongs to a class of pharmaceuticals known as biologics.

At least 400,000 U.S. Hispanics suffer from rheumatoid arthritis, and most are 50 or older, according to the Centers for Disease Control and Prevention. Biologics—made through the use of living organisms—can help many people who suffer from this and other diseases. Unfortunately, their high cost can keep such life-changing drugs out of reach or place the ill and their families in an economic bind. A year's worth of breast cancer-fighting Herceptin, a biologic, for example, averages $42,000. And Cerezyme, which is used to treat a rare disorder known as Gaucher disease, costs around $175,000 a year.

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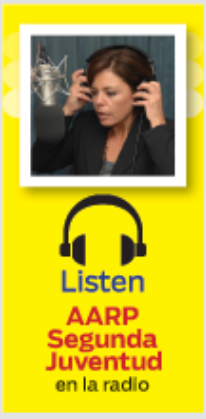

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The scenario could be changing. President Barack Obama and some members of Congress are backing an effort to speed production of cheaper, generic-type drugs called biosimilars. They argue that biosimilars would hold down the nation's spiraling health care costs and help those who struggle to buy needed medicine.

Enbrel blocked Bacarisse's immune system from attacking her joints, giving her greater mobility and relief from pain. "My doctors said the sickness got the worst of me 20 years too soon," Bacarisse says. "[Taking Enbrel from the start] could have saved me a lot of pain and deformity. All other medications were only slightly palliative but not effective in either slowing down or halting the progression of the rheumatoid arthritis."

Some of the first biological agents were vaccines and blood plasma. Today's biologics are much more sophisticated, like Enbrel, and treat a wide range of illnesses that include cancer, Crohn's disease, and some 20 other chronic conditions. Biological drugs are becoming increasingly popular and could account for half the new drugs approved in 2012 by the Food and Drug Administration, according to Kathleen Jaeger, president and CEO of the Generic Pharmaceutical Association.

Nearly all major drug companies, and many smaller ones, are researching and testing new biologics, hoping to put them on the market in the next few years to treat more illnesses. But producing a biological drug is much more complicated than producing a pill. That's because biologics are developed through advance technology called "genetic modification" and can search out, usually with pinpoint accuracy, diseased organs and cells that need treatment. Drug makers say the enormous cost to research and develop these drugs—usually administered by injection or intravenous infusion at a hospital or doctor's office—makes them so expensive.

One biologic still in the experimental stage would treat heart disease, which affects about a million, mostly older, Latinos, according to the National Institutes of Health. Another biologic, now in clinical studies, would treat Alzheimer's by attacking the root cause of the disease. If successful, the medical breakthrough could help the estimated 200,000 Latinos suffering from the mind-robbing illness.

Who's Going to Pay?

Medicare and private insurance paid for most of the cost of Bacarisse's Enbrel, which in her case averages about $19,000 a year. Others aren't as fortunate. Insurance companies sometimes balk at paying for biologics, arguing that their use to fight certain diseases is experimental. And many patients have trouble even keeping up with copayments, which can exceed $100 per dose.

The high costs of copays are a concern for Aimee Busquet. As a result of arthritis, her hips, right shoulder, and both jaws are all replacement parts. She got them before she was prescribed Enbrel and then another biological drug called Remicade.

The drugs have done "a remarkable job," she says, in fighting her arthritis. But the $350 a month in copayments strains the family budget and could prove unaffordable if she or her husband were to lose their job. "We call it 'the car payment,' because the cost of my medicines would pay for a new car," says the Atlanta resident who is of Cuban descent.

At age 45, Busquet doesn't qualify for Medicare, but, for those who do, Medicare's prescription drug benefit program covers most biologics. That good news, however, is usually countered by the "doughnut hole," an inherent problem for many people using the program. Under Medicare's


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prescription drug benefit, patients whose medicines cost more than $2,700 in the course of a year—a target hit quickly by those on pricey biologics—must pay the entire cost for their drugs until the cost exceeds $6,153. At that time, Medicare recipients are automatically eligible for what is called "catastrophic" drug coverage and will have 95 percent of their drug costs paid for the remainder of the year.

Programs That Can Help

What happens to those who are uninsured? Most are completely priced out of the biologic drug market. That scenario could also be changing.

Drug manufacturers say they've made efforts to make these drugs affordable. And they recently agreed to lower the cost of their products by $80 billion over ten years by giving those in the doughnut hole discounts of 50 percent for brand-name medicines, including biologics. But the agreement to discount drugs will only go into effect—in July 2010—if Congress approves sweeping health care reform. And there is still no agreement in Congress to accept such a deal.

Pharmaceutical companies also offer patient assistance programs by covering copayments and, in some cases, dispensing the drug for free or at a discount. Doctors often help their patients register for these programs. But since the biologics are often administered in doctors' offices and covered under Medicare Part B, federal law prohibits drug discounts to many Medicare patients. Other drug companies don't have approval to dispense their products at a discount under Medicare Part D, the plan's prescription drug program.

But some foundations, including the Gaithersburg, Maryland-based HealthWell Foundation, don't face those restrictions on helping Medicare patients. Since its inception in 2003, HealthWell has helped more 59,000 patients suffering 20 chronic or life-threatening diseases. The foundation helps low- and moderate-income patients on Medicare, Medicaid, or private insurance with copayments and other expenses, including insurance premiums for those who are at risk of losing their coverage due to cost concerns. A large percentage of those seeking help are Medicare-eligible patients, according to a foundation official.

Other Medicare patients can get help for their biological medicines through pharmacy discount programs. CVS Caremark, for example, does this for eligible applicants. Genentech, which makes Herceptin and cancer-fighting Avastin, often helps patients if their insurer declines to pay for one of their drugs. Genentech spokesman Ed Lang says his company has given away more than $1.3 billion worth of drugs since 1985. In fact, most pharmaceutical companies, including Abbott Laboratories, Amgen, AstraZeneca, Bristol-Myers Squibb, and Wyeth, have patient assistance programs.

But some say the price of biological drugs still needs to come down. A stumbling block: current federal law that allows for cheaper, generic copies of popular medicines does not apply to biologicals.

U.S. Rep. Henry Waxman, the California Democrat who heads the House Energy and Commerce Committee, and New York Democratic Sen. Charles Schumer recently introduced bills that would speed FDA approval of biosimilars and curb the exclusive marketing period biological drug makers now enjoy. But the Senate's Health, Education, Labor, and Pensions

Committee (HELP) in mid-July agreed to a 12-year exclusivity period for biologics. AARP supports a much shorter timeframe—possibly between five and seven years—for exclusive marketing before biosimilars could be sold, arguing that it would allow consumers earlier access to such lifesaving drugs.

But Lang says it will take years of scientific research to safely produce a biosimilar. "Biosimilars will never be identical to the original, so even little changes in how the drug is made can change how the drug acts inside a person's body," he says.

And Ken Johnson, senior vice president of Pharmaceutical Research and Manufacturers of America (PhRMA), the umbrella group that represents the country's drug makers, says drug companies producing biological therapies need at least 14 years of data protection and robust patent protections—incentives that foster the innovation that produces lifesaving therapies.

Waxman rejects that argument. "Lifesaving drugs are useless if no one can afford them," the congressman said during a June 2009 hearing on the matter.

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