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Biotech Psoriasis Drugs Hit a Cost Ceiling



Dr. Mark G. Lebwohl examining Tiffany Ishak, 20, of Brooklyn.

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Are biotechnology companies reaching the limits of how much they can charge for their drugs? One sign of that is the sluggish sales of drugs for psoriasis.



When the biotech industry began rolling out psoriasis drugs a few years ago, experts heralded the new medications as safer, more effective treatments for the skin disease. And the companies — [Amgen](#), [Genentech](#) and [Biogen Idec](#), arguably the industry's best-known firms — forecast a repeat of the success they have had with similarly priced drugs for rheumatoid [arthritis](#), [multiple sclerosis](#) and [cancer](#).

But they may have overestimated the medical establishment's willingness to spend \$10,000 to \$35,000 a year on treatments for psoriasis, a condition that is often, though incorrectly, perceived as merely a cosmetic problem.

Many insurers are insisting that psoriasis patients try older, cheaper therapies first before approving reimbursement of a biotech drug, frustrating some doctors and patients.

Dr. Mark G. Lebwohl, chairman of dermatology at Mount Sinai School of Medicine and a consultant to many of the drug developers, said he grew so frustrated he had sought help from the New York attorney general's office on a number of occasions to persuade insurance companies to pay for the drugs. The tactic usually worked, he said.

Price is not the only barrier. Dermatologists, many of whom prefer doing lucrative Botox procedures to treating psoriasis, worry about the side effects of the drugs, not to mention the vexation of trying to help patients seek insurance reimbursement. "In today's market I can see four acne patients in the time I see one patient on biologics," said Dr. William Abramovits, a professor of dermatology at [Baylor University Medical Center](#) in Dallas, referring to the biotech psoriasis drugs, which he prescribes despite the obstacles.

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Even many patients seem to have little enthusiasm for the drugs, which users typically take by injecting themselves as often as twice a week.

"Have drugs, need patients," said Dr. Craig Leonardi, a St. Louis dermatologist who is a consultant to many of the drug developers.

Amgen, which sells the field's leader, Enbrel, estimates there are 1.1 million Americans with severe enough psoriasis to warrant one of the biotechnology drugs, which are called biologics because they are manufactured in cultures of living cells. But the company estimates that only about 60,000 people are using one of the drugs.

Psoriasis can be far more than the bad case of dandruff that might come to mind for people old enough to recall a vintage shampoo commercial that lamented "the heartbreak of psoriasis."

An autoimmune disease, in which the body's defenses mistakenly attack the skin, psoriasis is marked by red, scaly patches that can be itchy or painful. And because of its potential impact on a patient's social or sexual life, psoriasis can cause severe emotional distress. In some cases the condition is linked to a joint disease known as psoriatic arthritis.

The sluggish sales of the biotech drugs have already started taking a toll on their makers.

Biogen Idec, which introduced the first biologic for psoriasis in 2003, has already given up, divesting its drug to Astellas Pharma, a Japanese pharmaceutical company. The drug, Amevive, had sales of only \$48.5 million in 2005.

Raptiva from Genentech, which was approved later in 2003, had \$90 million in sales last year, up 14 percent from 2005. That makes the drug a laggard by that company's standards. Its new eye drug, Lucentis, for instance, had \$153 million in sales in just its first three months on the market.

Raptiva's sluggish sales have also dashed the hopes of Xoma, a small company that helped develop the drug and had hoped to become profitable from its share of the proceeds.

Both Amevive and Raptiva lost out to Enbrel, which many doctors perceive as more effective. But even Enbrel is "not meeting expectations, despite considerable effort," George Morrow, an executive vice president at Amgen, told analysts recently.

Enbrel sales in North America did rise 10 percent in the first nine months of last year, to \$2.1 billion. But that is down from 35 percent growth in 2005 and is likely to leave 2006 sales less than \$3 billion, a figure Amgen had originally expected to reach by 2005.

[Wyeth](#) helps market the drug in North America and handles overseas sales by itself.

One reason for the slowdown is that Enbrel is losing market share for its main use — as a treatment for rheumatoid arthritis, a different autoimmune disease, which accounts for as much as 70 percent of its sales. But another factor is slow growth of the psoriasis market, which accounts for much of the rest.

Amgen is trying to underline the seriousness of the disease with television commercials using the theme "Enough is enough."

The ads do not mention Enbrel by name. A previous commercial that did was withdrawn in 2005 after the [Food and Drug Administration](#) warned that the ad — which featured actors with perfect skin frolicking on the beach — exaggerated the drug's effectiveness and underplayed its risks.

Adhering to voluntary industry guidelines, Amgen is discussing with the F.D.A. proposed new ads that mention Enbrel.

Manufacturers say they remain enthusiastic, though. And indeed, the market is getting more crowded.

A [Johnson & Johnson](#) drug, Remicade, already used for rheumatoid arthritis and Crohn's disease, won approval for psoriasis in September. Humira, from [Abbott Laboratories](#), is approved for psoriatic arthritis and is now being tested for psoriasis itself.

Several doctors said those two new drugs appeared more effective than Enbrel at clearing skin. But they also have sterner warnings about side effects, though all three drugs have similar risks. Because they block part of the immune system, the drugs leave patients more vulnerable to infections and possibly some types of cancer.

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The other, older drugs to treat moderate to severe psoriasis include the generic immune suppressors methotrexate and cyclosporine. But methotrexate, which can cost as little as \$600 a year, can damage the liver, and cyclosporine, which costs a few thousand dollars a year, can harm the kidneys.

Another option is phototherapy, in which the skin is exposed to ultraviolet light. While effective, it can require three visits a week to a doctor's office, often for about three to four months a year, sometimes longer.

Factoring in the cost of the biologics and their success rate in clearing skin, researchers at [Wake Forest University](#) and elsewhere found the drugs to be the least cost-effective. They cost from \$24,000 to \$45,000 a year for every patient who achieves a 75 percent reduction in psoriasis severity.

Achieving similar reductions with methotrexate costs less than \$2,500 a year and with phototherapy, \$3,000 to \$7,500. The study was sponsored by Connetics, a maker of an older psoriasis drug.

Insurers are usually requiring "step therapy," in which patients must try the less expensive therapies first.

Bill Fatland is one of the patients unhappy with that approach. Mr. Fatland, 56, who has had psoriasis for more than 30 years, said he had used various creams, but avoided drugs like methotrexate, fearing their side effects. His psoriasis was never under satisfactory control.

About three years ago Mr. Fatland, a retired teacher who lives in Tigard, Ore., tried Enbrel in a clinical trial. "It was like a miracle," he said. "Pretty much looking at me, you wouldn't know I had psoriasis anymore."

But when the trial ended, his insurer, Regence Blue Cross Blue Shield of Oregon, declined to cover the drug unless he tried cheaper therapies first. Over the next two years, Mr. Fatland tried phototherapy twice and methotrexate, but they caused rashes. Only after many appeals, he said, did the insurer approve Enbrel.

Even when biologics are reimbursed, though, the co-payment can be high. Vicky Wheeler, an administrator at a consulting firm in Burlingame, Calif., said her [Health Net](#) insurance paid for Enbrel in 2005 without requiring any co-payment.

But last year the policy switched to a 30 percent co-payment for self-injected drugs, and she began paying nearly \$400 a month. As a result, she and her doctor cut her dose in half, which they had been considering doing anyway. And she found a charity that provided \$1,400 of her annual co-payments.

Hoping to ease reimbursement, the National Psoriasis Foundation, a patient advocacy group, and the American Academy of Dermatology, a professional society, held a "summit on psoriasis" for insurers in Philadelphia on Nov. 9.

But for all the efforts by the drug makers, many dermatologists are still not comfortable using any drug other than a topical cream. And some patients might not realize new treatments are available, or do not seek them out, said Liz Horn, director of research for the psoriasis foundation.

"Some patients," Ms. Horn said, "have just sort of accepted that they will have psoriasis and this is what it's going to be like."