

How much is a life worth?

New cancer drugs offer hope, but the price may be too high for some By Roxanne Patel Shepelavy Self

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Michelle Diekmeyer lay awake in the dark, trying not to panic. It was a struggle she seemed to be losing more and more every sleepless night in July 2005.

Seven months after being diagnosed with stage IIIB inflammatory breast cancer, 37-year-old Diekmeyer had spent nearly 100 days in doctors' offices or the hospital near her Ohio home. She'd had five surgeries, with another scheduled for September; slogged through more than three months of grisly chemotherapy; suffered the indignities of baldness and violent nausea. After all that, she still didn't know if she'd survive the year.

But Diekmeyer had another, more immediate, fear keeping her up nights. Because of mounting medical bills, she was worried she might lose her home. Already, Diekmeyer owed her oncologist more than \$10,000, debt that had escalated since May 2005, when she started taking Herceptin, a cutting-edge cancer formula. Produced by Genentech, a leading manufacturer of biotech drugs in South San Francisco, California, the new medicine was her best — perhaps her only — hope of beating the disease.

It was hope that came with a steep price: Every three weeks after her IV infusion of Herceptin, her insurance company paid her doctor 70 percent of the cost of treatment. The rest — about \$1,500 — was supposed to come from Diekmeyer. But she and her husband, Randall, a networking manager for an architectural engineering firm, had already depleted their modest savings on her medical bills; they'd cut out even small luxuries, like the daily newspaper. Diekmeyer was too sick to go back to her job as a church secretary. And she faced 10 more months of Herceptin and an unknown future of other treatments. Still, Diekmeyer had no choice. She either took the Herceptin or faced an almost certain death.

"How do I put a price on my life?" Diekmeyer wondered, not for the last time. "I can't. I just hope my doctors are patient about my bills. There's nothing else I can do."

Out of reach for many

Fighting cancer has always been one of the most expensive prospects in medicine — in part because the drugs that treat it are among the most costly on the market. But as Diekmeyer discovered, biotechnology treatments such as Herceptin are pushing prices into a whole other realm — one that may be out of reach for many people.

Nearly 15 years ago, Bristol-Myers Squibb faced congressional hearings over plans to charge up to \$6,000 for a six-month treatment of Taxol, then a groundbreaking ovarian cancer drug. Now new biotech cancer drugs routinely cost \$25,000 to \$50,000 a year, with some running close to \$100,000. The cost of cancer-fighting drugs went up 27 percent in 2006, compared with less than 2 percent for other drugs, according to the most recent Medco Drug Trend Report. And many of the new medications are being tested in combination, so patients may be faced with not one but two or even three drugs that cost \$50,000 each. That's the case with ImClone's Erbitux and Genentech's Avastin, two of the priciest commonly used cancer drugs on the market, which are being tested together for colorectal cancer.

Genentech provided \$205 million in free drugs to uninsured patients in 2006, according to Kristina Becker, a company spokeswoman. Other major drugmakers have similar programs. But many patients are like Diekmeyer: insured and reasonably well-off but still struggling to pay their portion of the bills. One in 10 cancer patients is unable to cover basics such as food and housing, according to a survey by the Kaiser Family Foundation in Menlo Park, California; more disturbingly, 1 in 12 people with cancer has delayed or decided against treatment because it was too costly. A recent study from another research group showed the problem is worse for insured women than insured men, in part because they take more prescription drugs.

"It's appalling to me that they can charge these kinds of prices," says Cathryn Miller, 51, a Seattle nurse with metastatic breast cancer.

Miller's insurance company paid nearly \$66,400 a month in the spring of 2006 for a cocktail of Avastin, Herceptin and the chemo drug Abraxane, eating up a big chunk of the \$2 million lifetime cap on her plan. "If I'd had a 20 percent co-pay like a lot of patients I know, I'd be bankrupt now," she says.

The issue affects everyone, even those who are healthy: When insurers begin spending upwards of \$25,000 a year per drug for every cancer patient, the entire health care system is going to feel the strain. Which means all of us are going to feel it in higher premiums, fewer choices and less access to any kind of care.

"Is society willing to bear the cost of these drugs to save the lives of these women?" asks Marisa Weiss, M.D., an oncologist in Narberth, Pennsylvania, and founder of BreastCancer.org. "I say yes. But as a doctor, my responsibility is to my patient sitting in front of me, whose life I'm helping to protect with the best medical care possible."

Medicine is not like other commodities, and those who need it are not like other customers. They are often people desperate for a few more months of life—long enough, they hope, to be around for the treatment that turns out to be a cure. But where do companies draw the line between maintaining a profit that satisfies stockholders and gouging patients who'll pay anything to stay alive? The answer—if there is an answer—is something pharmaceutical companies, patient groups and lawmakers are struggling to find. "It's not like buying a high-priced car," when customers can walk away or shop around if prices are too steep, notes Dee Mahan, director of global initiatives for FamiliesUSA, a patient advocacy group in Washington, D.C. "There should be a level of public trust in the making and marketing of products that could save people's lives. I think we've lost that."

By the time Diekmeyer was diagnosed in January 2005, it was too late to worry about how to pay for treatment. Inflammatory breast cancer usually has no telltale lump, so it is hard to catch, especially in someone as young as Diekmeyer, who wasn't getting mammograms yet. Extremely fast-growing, the cancer had already spread from the tissue of her left breast to some lymph nodes.

"The first thing I heard was that I'd be dead in a year," she recalls. "My husband started sobbing, and I just sat there for an hour, not moving."

Diagnosed on a Monday, she started treatment the following Friday and spent the next two months in and out of the hospital, racked with nausea, pain and fear from both the cancer and the chemotherapy. "It was like weed killer in my veins, so strong it almost killed me," she says. "Sometimes I wondered if it was worth it."

Before she got cancer, Diekmeyer thought she and her husband were doing pretty well. Their combined income, a healthy five figures, was more than enough to cover their mortgage, buy a few niceties and allow them to squirrel away a bit for emergencies. Married seven years, Diekmeyer had been trying to get pregnant for the previous two and had been through two unsuccessful rounds of in vitro fertilization. Otherwise, she didn't worry much about her health care costs.

"We were comfortable but never planned for much beyond our regular bills," she says. "Then everything changed."

Like liquid gold

Diekmeyer was covered under her husband's health insurance, a plan that had always seemed adequate. Now she watched her co-pays for doctor visits, hospital stays, surgeries and drugs add up. The plan only partially paid for many meds, including Zofran, an antinausea drug that Diekmeyer says cost her \$42 a pill. Allotted 12 pills a month by her insurance, she sometimes needed twice that many. "Every time I wanted to stop throwing up I'd think, That's \$42 I'm spending," she recalls.

When Diekmeyer's doctor told her about Herceptin in late April, it was the first piece of good news she'd received all year. Before Herceptin, women like Diekmeyer with HER2-positive breast cancer, an aggressive strain of the disease, had a greater likelihood of recurrence, poor prognosis and decreased survival compared with women who have HER2-negative cancer.

But studies on early-stage breast cancer patients found that those who took Herceptin in addition to chemo were half as likely to have the disease return within four years of surgery. Longer-term results are not yet available, but researchers have hope that Herceptin — an IV infusion administered at a doctor's office — will

prove even more successful in time. To Diekmeyer, it was like liquid gold, especially after she got the first bill and realized that the recommended year of treatment would cost her more than \$25,000 out of pocket. "The first thing we always paid was our mortgage," she says. "I just couldn't stand the thought of being this sick and having nowhere to live."

Biotech companies spend 98 months and \$1.2 billion, on average, to develop a new drug, according to a report from the Tufts Center for the Study of Drug Development in Boston. Herceptin was no different: Genentech invested hundreds of millions of dollars over 25 years researching and testing it. The drug industry — and many patient advocates — see Herceptin as the model for the future of cancer treatment. It was the first of many biotech drugs in the pipeline designed to target a particular gene or protein that makes cancer more deadly for some patients. The eventual goal is to replace chemo altogether with targeted medications having minimal side effects.

"We're not talking about a small difference here," says Lee Blansett, vice president of MattsonJack DaVinci in St. Louis, a consulting firm that helps drug companies look at the implications of pricing. "These are products you can't compare to anything else. They are changing the way cancer is treated."

Herceptin costs so much partly because the market for it is not huge. It helps only 25 percent of new breast cancer patients, the 45,000 women or so who each year test positive for the HER2 protein. And because of the potential for heart damage, it is prescribed for only one year. Some cancer drugs, like those for late-stage lung cancer, are used even less, as, sadly, patients often don't live very long. And drug companies have limited time to profit from new drugs; after their patents expire, other companies can undercut them with generics.

"Pricing these specialized drugs is partly an ethical issue, but it's predominately about economics," says Eric M. Meslin, Ph.D., director of the Indiana University Center for Bioethics in Indianapolis. "Drug development costs money, and drug pricing has to recoup those costs, plus turn a profit for shareholders."

On the other hand, it's not as though drug companies are struggling to turn a profit. As new biotechnology drugs hit the market, drugmakers are seeing profits and stocks soar, so much so that by 2010, analysts predict the worldwide market for cancer-fighting drugs will double to \$50 billion a year. Even years after a medication's development, its price may continue to rise, especially if it is being repurposed for a new use. In 2005, after Genentech announced success in using the colorectal cancer drug Avastin to treat breast and lung cancer, the company also said these patients would need twice the dose — doubling the price tag to \$100,000 per year. After an uproar, the company last fall capped Avastin charges for lung and colorectal cancer at \$55,000 and said it would apply the same cap to breast cancer patients when the FDA officially approves it for that use. Even so, Avastin is poised to become a huge cash cow: The first drug to cut off the blood supply to tumors, it's being tested on 20 cancers, and analysts predict that by 2009, it will bring in \$7 billion in annual sales.

The debate has prompted drugmakers to acknowledge with surprising candor a final reason for the eye-popping price tags: These meds cost a lot because patients are willing to pay a lot for something that works so well. Genentech raised the price of Tarceva, a lung cancer pill, by 30 percent because "it was a more powerful and more active agent" than originally understood, and "so more valuable," an executive told The New York Times last year. "Unfortunately, health care in the United States is still seen as a commodity to be bought and sold," Meslin says. "So it's not surprising that companies will charge what they think the market will bear."

Which returns us to the uncomfortable question: How much is a life worth?

Value is relative

Some patients do refuse expensive medications that would prolong their life by only a few months. But that extra time can also make a huge difference. After being diagnosed with metastatic breast cancer in 2001, 45-year-old Debbie Osborne of Philadelphia underwent a series of biotech therapies, each of which kept her cancer from growing for a few months — often just enough time for another drug to hit the market. Osborne, a mother of three teenagers when she was diagnosed, went through eight drugs and was mostly asymptomatic for nearly four years, long enough to see two sons graduate from high school.

"I know it costs a lot," she said in the summer of 2006. "But it's my life we're talking about." She was in a

clinical trial for a ninth drug when she died that September.

For Osborne, whose insurance covered the drugs, the choice was uncomplicated by financial worries. Many women are not so fortunate, a fact that drugmakers finally seem to realize. Genentech announced its \$55,000 price cap on Avastin two weeks after Amgen announced a similar limit for its new colon cancer drug, Vectibix.

"Everyone's looking at ways of supporting patients so they have access to new drugs," says Blansett, who consults for all the major pharmaceutical makers. "Three years ago, the question was, How high can I price my drug? Now some are asking about the socially responsible and reasonable price."

It's all relative, of course; \$55,000 a year remains daunting, especially when that's only one piece of the treatment puzzle. And that's if the price caps apply to you; in the case of Avastin, breast cancer patients could still pay nearly twice that.

In April, the Senate voted down legislation that would allow Medicare — the nation's biggest insurer — to negotiate with drugmakers to lower prices even more.

"Still, we have to have some sort of drug price control," says Barbara A. Brenner, executive director of the advocacy group Breast Cancer Action in San Francisco. "We can't just tell drug companies we want them to limit their prices. That's like leaving the fox in charge of the henhouse."

Despite Diekmeyer's struggles, the debate over drug prices to her is simply academic. By the end of 2005, she and her husband had exhausted their savings, liquidated a \$5,000 CD and sold a few possessions, including an antique thimble collection, for \$1,000. They cut off cable TV and stopped going out to dinner. Finally, near the end of the year, she had two windfalls: A grandfather died and left her several thousand dollars, and friends at her church threw a fund-raiser that collected \$10,000.

Now, after a year on Herceptin, Diekmeyer is almost paid up. More important, she's cancer-free. "I know the pharmaceutical companies are profiting off my illness," she says. "But I'm so grateful they came up with this drug. How can I also be angry that they're charging so much?"

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