Two years ago, a Seattle biotech company made waves by pricing its new prostate cancer drug, Provenge, at $93,000 for a course of treatment — about 30 percent higher than what many analysts had expected.

Today, the company is hardly alone. **Bristol-Myers Squibb, Sanofi and Johnson & Johnson**, among others, have introduced cancer drugs with costs in a similar price range.

Scientific advancements and the rise of the biotechnology industry have enabled the development of highly complex, highly effective and highly targeted drugs — and along with those advances have come very high price tags.

**Michael D. Becker**, founder of the life sciences consultancy **M.D. Becker Partners**, said higher prices shouldn't automatically be characterized as a negative trend.

"It's a really complex issue to say drug prices are high and that's a problem," he said.

At the heart of drug prices are research and development costs, which now can easily span into the 10-year, $1 billion range, Becker said. On top of that, the industry is a high-risk venture, where most products won't make it to market — and those that do often won't recoup their own development costs.

According to the trade group Pharmaceutical Research and Manufacturers of America, or PhRMA, only 20 percent of drugs approved between 1990 and 1994 ended up with sales higher than the industry's average development cost. Drugs typically earn the bulk of their revenue while under patent, and thus shielded from generic competition. Though market exclusivity lengths can vary based on when the patent was filed and whether it was subject to a legal challenge, many of the drugs coming off patent in recent months were first approved by the Food and Drug Administration in the 1990s.

Becker said the general public isn't aware of those facts.
"Overall, the pharmaceutical industry has done a very poor job communicating what goes into developing a drug," he said.

Lujing Wang, who leads the pricing and market access practice at Campbell Alliance, in Parsippany, said setting a price has much to do with the cost of similar drugs already on the market, and with the value proposition for the insurance companies that are going to be paying for the drug.

Wang said many of the drugs that fall into the high-price category are targeted either to conditions with a relatively small patient base, or to a small subset of a larger patient base. That means despite the high price, the per-patient, per-month costs of such drugs across the payer's entire network will be relatively small.

"Most people can tell that the budget impact is very minimal," he said, though "it does meet a very substantial need out there."

Edward Abrahams, president of the Washington, D.C.-based Personalized Medicine Coalition, said new therapies hold the promise of higher success rates and safety rates, thus payers and patients get more value for their health care dollars.

"Overall, costs should decline system-wide because efficiencies will be introduced into the system," he said.

Becker said in the past, a prostate cancer drug might be given to a large swath of the patient population, but only work on about a quarter of the people who take it. Under the emerging paradigm, a patient might be given a dose specially made for them — as in the case of Provenge — or the patient might be given diagnostic tests before treatment to determine whether the drug will work. Thus, the chances of a drug being administered and failing are greatly reduced.

Diagnostic tests can add to the cost of personalized drugs, but Abrahams said testing costs are dropping steadily, too. Sequencing the human genome cost about $300 million in 2001, he said; today, it costs about $1,000.

A PhRMA representative pointed to a study by the Alzheimer's Association that found a treatment that delays Alzheimer's disease by five years could reduce Medicare and Medicaid spending by more than $100 billion annually by 2030.

Abrahams believes personalized medicine is an easy sell once people understand the full picture. Still, he said, the regulatory framework of the nation's health care system isn't particularly helpful.

"The regulatory environment, to put it charitably, is confused, and it needs clarity," he said. "The reimbursement system is not set up to reward value, and reforms could be introduced there to incentivize payment for personalized medicine products."

Kurt Rotthoff, an assistant professor of economics at Seton Hall University's Stillman School of Business, said the current structure also takes patients out of the process of calculating value.

"The current incentive structure is not designed to keep costs reasonable," he said.
A patient typically pays the same co-pay regardless of whether the drug costs $100 or $1,000. "Because I see no difference between the $100 drug and the $1,000 drug, oftentimes, I'll just take the thousand-dollar drug without thinking about it," he said.

Rotthoff said such decisions are difficult and emotional, "but I think most people are educated and can decide if it (a higher-cost drug) is worth it to them."

Wang said many high-priced drugs have significantly smaller profit margins than other drugs, because manufacturing and distribution of the complex drugs costs so much more. He also noted that drug costs make up just 11 percent of the overall health care spending in the United States — far less than many European and Asian countries.

If rising health care costs are to be feared, Wang said, there are better targets than drug companies.

"Look at things on a more holistic basis," he said. "It's more driven by providers, physicians and hospitals."

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