



FEATURE

The secret recipe behind the launch price of a drug

By **Lisa LaMotta** • Aug. 14, 2017

Plenty of people have been talking about drug pricing, from the president to the media and pharmaceutical CEOs, but few talk about how companies determine these incredibly specific, and often incredible, price tags.

It raises many eyebrows when a company chooses to charge \$750,000 a year for a drug. But even for those drugs with more down-to-earth prices, have you ever questioned how a drugmaker could come up with a wholesale acquisition cost (WAC) of, say, \$9,548 per month?

While it may seem that pharma companies are "sticking their fingers in the air to check the wind," Sanofi's Head of Policy Cybele Bjorklund asserted to BioPharma Dive that pricing is anything but arbitrary. It's a bit of science, a dash of art and more than a few secret ingredients.

Sanofi is just one of the many companies that has come out and taken a proactive, transparent stance on drug pricing. Bjorklund, who joined Sanofi only several months ago after a previously life in Washington policy making, was an integral part of establishing the French drugmaker's new pricing principles.

These principles have committed the company to being more transparent about drug prices, limiting the increases in prices on older drugs to match the national health expenditures (NHE) growth projection and providing a clear rationale for how drugs are priced at launch — all things the industry as a whole has been loathe to do.

While pricing principles like these are a step in the right direction, the ingredients baked into drug pricing are gathered much earlier in the process.

Mix in market research

The process all begins with market research, a term that encompasses a wide variety of techniques that pharma companies use to determine at which price point to launch their drug onto the market.

One of these many market research techniques includes mapping out both the current commercial landscape as well as the competitive pipeline.

"We look at the treatment landscape — what else is available or anticipated at the time of launch? This to me, put more simplistically, means are we a first-in-class or are we a "me-too" or even somewhere along the line of the continuum of care," said Bjorklund.

The presence of older, low-cost treatments or newer alternatives on the market for a certain disease is major factor in how a drug can be priced. Take the cholesterol market, for instance. Statins have been some of the best-selling drugs in the world for decades. These drugs work reasonably well and can be used in a majority of patients. They are also largely available as generics and don't put a hurt on people's wallets.

Enter: PCSK9 inhibitors. This new class of drugs provided a huge step up in innovation, as well as arguably better efficacy. But due to the availability and effectiveness of statins, the market simply hasn't been willing to bear their \$14,000-plus price tags, and these drugs have failed to gain much commercial traction.

Looking at the pipeline is important too. A battle is currently playing out in the migraine space as four drugs from a new class called CGRP inhibitors are making their way through the development and regulatory framework.

All four of these drugs have the potential to hit the U.S. market over the next two to three years, making pricing a tricky prospect for developers. While Amgen and Novartis' Aimovig (erenumab) is likely to be first of these drugs approved, the companies will have to be particularly careful how they price the drug, which could be undercut by a lower cost (and equally effective) offering within months of approval. They will also have to be careful about not pricing the drug too low, leaving money on the table.

This competitive landscape research, as well as tapping other stakeholders like patients, doctors and payers all begins around the start of Phase 2 testing — though it can vary depending on therapeutic area. By this time, companies typically know if they have a compound that should work and are ready to evaluate the value proposition.

This includes patient focus groups to see what the needs of patients are that have not been met — perhaps there are therapies that only address some symptoms of a disease but not others, or maybe current therapies have terrible side effects. Maybe patients just need a more convenient way to take a drug, or maybe there aren't any treatments at all. These are all the sorts of questions that pharma companies want to know the answers to when thinking of a drug's added value.

Companies also begin engaging primary care doctors and specialists, inquiring about their current prescribing practices, asking about the most common complaints of patients and trying to find where treatment gaps are.

These are all necessary steps to determine what the differentiated value of a product will be — something that is particularly important to payers.

Sometimes companies get it wrong. Over a decade ago, Pfizer Inc. brought an inhalable insulin to market, dubbed Exubera. The pharma giant believed it had a blockbuster on its hands, and was thrilled to beat out competition from both tiny biotechs and other big pharmas.

But their excitement was short-lived. While type 2 diabetes patients aren't especially eager about the daily injections needed to administer insulin, the mode of administration isn't actually at the top of the list of complaints for these patients. Exubera flopped and Pfizer pulled it from the market after just 11 months of sales, admitting defeat.

Take the temperature of payers

The role of payers like insurance companies and pharmacy benefit managers (PBMs) has become increasingly important in recent years. Payers have largely become the gatekeepers to the market and their decisions to cover a drug on their formulary or include it as a preferred product can mean the difference between a blockbuster and a never-was.

For example, Novo Nordisk A/S has seen the market share of its blockbuster GLP-1 antagonist Victoza (liraglutide) drop by nearly 20% in recent quarters as major PBMs have opted to include a competitor from Eli Lilly & Co. instead.

For this reason, conversations with payers begin at the same time as those with patients and doctors. Payers often have their own panels of experts that will weigh in for pharmaceutical companies.

There is even an industry standard form that payers require to help them evaluate the value of a drug as well. The form — called the Academy of Managed Care Pharmacy Form for Formulary Submissions — is over 95 pages and addresses everything from clinical benefits to economic benefits to the place of therapy in treatment (as well as a variety of other concerns). It is not an easy form to fill out and often requires a team of people to complete.

But there are other factors that go into pricing as well — the things that Bjorklund refers to as the "unique factors bucket." This includes potential post-marketing regulatory commitments like large, costly cardiovascular outcomes trials or other things like special training for physicians.

Don't mistake salt for sugar

One major misnomer about how drug prices are set at launch may actually be the fault of the industry. The industry line — from companies to lobbying groups — is that the cost of innovation is high and therefore drug prices need to be at a level to pay for the expense of research and development.

But pharmaceuticals aren't like most other goods. Prices aren't set based on what it cost to actually "make" the product. You, as a consumer, aren't paying to help a pharma company directly recoup its cost of development.

Drugs often take more than a decade to go from concept to patient, a path typically termed as "bench to bedside." During that time, a product is likely to change hands a number of times, going from the lab bench of a researcher at a university to preclinical testing at a biotech to development at a big pharma and potentially even commercialization by another partner. All of this time and changing ownership makes determining the actual cost of developing a single drug nearly impossible to determine.

When the industry says they need drug prices to be high to pay for the cost of development, they really mean to support the *future* cost of innovation and drugs that may come to market years or even decades later.

The other major misconception when it comes to drug prices is that the price pharmaceutical companies set is the price patients pay for a drug — this is just not the case.

The wholesale acquisition cost, or WAC, is what pharma companies spend all this time and market research toiling over. But negotiations with payers apply often multiple layers of discounts to this price. Insurance co-pays further muddy the pricing waters.

So next time you read about the \$9,500 drug, remember that there was a team of people who spent years trying to get the recipe just right.