

Ads, not research, create some best-selling drugs

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An overhead light drawing attention to his face, actor Danny Glover starts to cry, dropping his head into one hand - and then, he abruptly switches over to deep belly laughs, before resuming a straight face. "When I act, if I do this it's totally in my control," he says, getting to the point: "But for someone with pseudobulbar affect, choosing to cry or laugh may not be your decision."

The 60-second TV advertisement, which ran widely late last year, concerns a neurological condition known by the acronym PBA, characterized by inappropriate, uncontrolled outbursts of laughing or crying. Though no [drug](#) is mentioned, the advertisement is sponsored by Avanir Pharmaceuticals, an Aliso Viejo, Calif., firm that launched Nuedexta, an expensive medicine that targets the disorder. The ad ends by referring people to a website and toll-free number for more information.

PBA is real, affecting mostly people with neurological conditions such as multiple sclerosis, a recent stroke or Lou Gehrig's disease. It runs the spectrum from mild to severe impairment. Because the definition of the condition is ambiguous, estimates of its prevalence vary widely. Some clinicians say PBA is relatively uncommon among their [patients](#), while Avanir sets the number at nearly 2 million.

But the ad campaign has helped fuel the controversy over how direct-to-consumer advertising - typified by ads that call on viewers to "ask your doctor" about a possible treatment - takes niche medicine and promotes

its use for a broad range of patients and fosters the use of pricey prescription products when cheaper ones might suffice.

"I suspect this disease is being redefined to include overly emotional people" through advertising, said Adriane Fugh-Berman, a doctor who teaches at Georgetown University Medical Center and has investigated pharmaceutical marketing practices. The United States is one of two countries that allow advertising of prescription drugs.

Not so, the company said in a written statement outlining that its efforts are "focused on raising awareness about PBA to help people better understand the symptoms of a condition that is often overlooked, misunderstood and misdiagnosed."

The case of Nuedexta is notable because of its price, more than \$700 a month for a supply of the twice-a-day pills. The drug is a combination of two low-cost ingredients - an over-the-counter cough medicine and a generic heart drug - that, purchased separately, would run roughly \$20 a month based on online cost estimators. The comparison is apples to oranges because the dosage of the heart drug is so much lower in Nuedexta than is generally available on its own by prescription. Experts say a do-it-yourself treatment would be difficult and potentially dangerous for a consumer to try to concoct. "You'd have to get the exact doses right, and that would be tricky," said Dr. Aiesha Ahmed, a neurologist at Penn State Hershey Medical Center who has researched the prevalence of PBA and its treatment options.

The pill doesn't cure PBA but must be taken for the rest of a patient's life to help reduce the laughing or crying episodes. While it's the only Food and Drug Administration-approved drug specifically for PBA, doctors have successfully treated the condition with several alternatives costing far less - all antidepressants.

"The cost for mixing two old drugs together is unconscionable," said Jerry Avorn, professor of medicine at Harvard Medical School and chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital.

The strategic marketing of Nuedexta is part of a broader trend in which even small pharmaceutical firms turn to high-cost advertising to encourage use of their products. Pharmaceutical industry spending on direct-to-consumer television ads has been on the rise - up 62 percent since 2012 to an estimated \$6.4 billion in 2016 - even as TV advertising for other product types remained flat, according to Kantar Media, a consulting firm that tracks multimedia advertising. By last year, drug ads were the sixth-most-common category of television advertisement - behind such things as cars and restaurants - up from 12th just five years ago.

A number of the ads, like Nuedexta's, promote medication for relatively unusual conditions, such as a sleep disorder that affects only people who are blind; or more common conditions, such as opioid-induced constipation.

Drugmakers defend the slew of advertisements as educating patients who may not understand they have a disease or that their symptoms can be treated. The uncontrolled laughing or crying of PBA "is quite debilitating," and Nuedexta provides substantial relief for many, said Avanir's chief medical officer, Rick Malamut, a neurologist who recently joined the company.

Avanir declined to say how much it is spending to market Nuedexta. In justifying the price, Malamut said the company had invested hundreds of millions of dollars over 10 years on research before winning FDA approval in 2010. More is now being spent to research whether it - or other Avanir products - could help with other neurological conditions.

"We understand the cost of medication is burdensome for people without (insurance) coverage," he said. The company offers financial assistance to help such patients, he said.

Some experts say the cost isn't worth it: "If it were your loved one, there would probably be a value to prevent these episodes," said Mark Pauly, a health economist at the Wharton School of the University of Pennsylvania, of the outbreaks of laughter and crying. But, he said, "As a hardhearted economist, I have to ask if it's worth \$700 a month."

Still, the market has proved lucrative. Nuedexta's sales have risen from about \$37 million in 2012 to \$218 million last year, according to EvaluatePharma, which tracks pharmaceutical industry pricing and markets.

The story of Nuedexta began with Richard Smith, a neurologist whose Center for Neurologic Study was looking to develop a new treatment for Lou Gehrig's disease, also known as ALS. In the early 2000s, Smith combined dextromethorphan - the main ingredient in cough syrups such as Robitussin - with quinidine, a drug used to treat irregular heart rhythms. The heart drug helps boost and maintain levels of the dextromethorphan in the bloodstream.

What his research team observed in preliminary studies was that patients "almost immediately started reporting an effect on PBA," Smith said in an interview. The drug was eventually sold to Avanir. In October 2006, the FDA responded that the drug looked approvable, but investigators had "fundamental questions about both the effectiveness and safety of the product."

The company then lowered the dose of the [heart drug](#) and performed another clinical trial, which found that the drug cut in half the number of episodes of uncontrolled laughing or crying by patients who took it

rather than a placebo. It was not compared with other treatments already in use and the patients in the study had either MS or ALS. It won FDA approval.

Early on, Avanir executives were clear that they had big ambitions for the new product. In 2013, CEO Keith Katkin touted the drug as a "pipeline in a pill" to investors, predicting it could eventually be used to treat conditions such as pain related to MS and agitation in patients with dementia.

During and after approval of the drug, Avanir provided educational talks for doctors aimed at raising the profile of the little-known condition and expanding the use of their drug.

It made a pitch to consumers with a 2013 ad campaign online and on television that directed viewers to a website. The campaign produced "an overwhelming" response, with "350,000 new unique visitors to the website or calls to the hotline," Keith A. Katkin, the chief executive at the time, told investors that year.

That potential - along with other drugs in Avanir's research labs - helped prompt Japan-based Otsuka Holdings to purchase Avanir in 2014 for \$3.5 billion.

But after marketing surveys found that, still, only about one-third of potential patients and primary care doctors who treat such patients knew about PBA, Avanir decided to enlist Glover's celebrity power, said Lauren D'Angelo, senior director of marketing for Avanir.

The ad featuring Glover, who doesn't have PBA or any personal link to it, was on cable and national news programs sporadically in 2015 and through the end of December the following year. Glover's publicist didn't offer any additional comment for this story.

The ad is "non-branded" - meaning the drug is not mentioned - and therefore isn't required by the FDA to list side effects and risks. Instead, it simply suggests patients ask their doctor about treatment or go a website to find out more about PBA. Awareness among primary care doctors rose to 72 percent and 52 percent among patients.

"It was an extremely successful campaign," D'Angelo said. "We drove a lot of patients into doctors' offices. The challenge was they did not ask for Nuedexta by name." For sales, that was a problem. Instead of getting Nuedexta, some patients were incorrectly diagnosed or prescribed an antidepressant, she said.

So, in 2017, the drugmaker started a new advertising campaign.

This one, which is currently running on prime-time TV, features a man inexplicably bursting into tears at a child's birthday party. It intends to move potential customers beyond "could you have PBA?" to "ask your doctor for Nuedexta."

"We are mimicking what we want them to do, to ask about PBA and ask about Nuedexta," D'Angelo said.

And there's good reason for this kind of messaging. A 2016 poll conducted by Medscape, an online physician education website, found that 62 percent of physicians said they would or might prescribe an innocuous, even placebo treatment to a patient who didn't need it but demanded it.

Some neurologists like the drug. Kenneth Heilman, a professor of neurology at the University of Florida School of Medicine and a fellow of the American Academy of Neurology says Nuedexta "seems to control PBA symptoms very well." He also doesn't object to the advertising campaign, since it might be useful in alerting family

physicians who don't know about the disorder.

But PBA can be difficult to diagnose, because symptoms - crying and emotional volatility - can be attributed to other conditions, such as depression. Inappropriate laughter or tears are relatively common in dementia, referred to merely as "emotional lability" in many other countries, but may not be a problem that needs treatment. Many experts worry that "patient awareness" and pressing doctors to write prescriptions will lead to overuse.

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