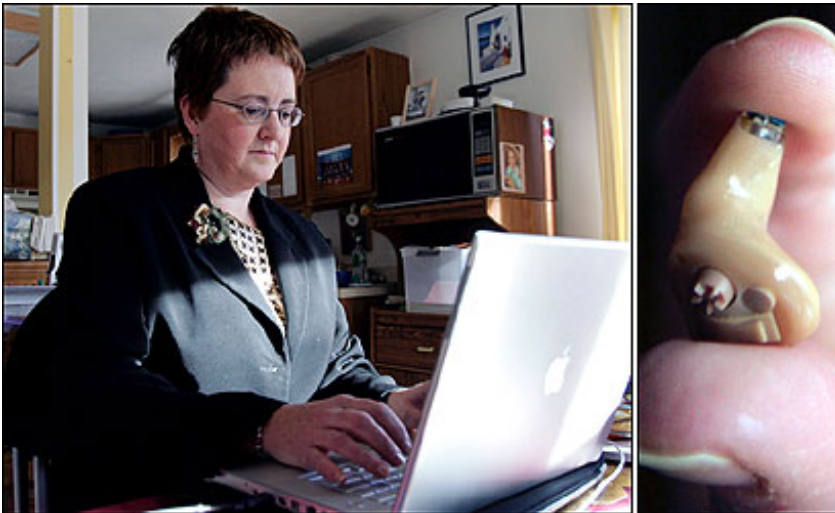


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Lexington firm testing drug to help stuttering

The Boston Globe

Pagoclone began life as anxiety pill



Beth McNeill, an East Bridgewater speech therapist, uses the SpeechEasy fluency device (right) in her ear. (Globe Photo / Robert E. Klein)

By Stephen Heuser, Globe Staff | December 31, 2005

A few years ago, doctors testing an experimental anxiety pill noticed something odd in a 26-year-old woman trying the drug: Her severe lifelong stutter was going away.

Soon after she stopped taking the pills, her stutter returned.

The drug, pagoclone, eventually failed as an anxiety medicine, but a Lexington company is trying to revive it as the first-ever medication aimed at helping people who stutter. In a test on 120 patients across the country, Indevus Pharmaceuticals Inc. hopes to show that the drug's effect on the woman was more than an intriguing surprise.

If the drug succeeds -- a process that would take years, even if the first test goes well -- it would mark a major shift in how stuttering is treated, and validate a growing amount of research suggesting medical causes for a disorder long seen as emotional.

"For years we thought [stuttering] was brought about by bad parenting, or that the individuals are too nervous," said Gerald Maguire, a psychiatrist and researcher into stuttering at the University of California at Irvine who is testing pagoclone on eight patients. "But we're learning now, especially in the last 10 years, that there are specific brain regions that aren't functioning well in people who stutter."

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Stuttering affects 3 million people in the United States, but has been slow to receive the serious medical attention given to brain disorders such as depression or schizophrenia. Speech therapy and devices designed to alleviate stuttering are rarely covered by health insurance. The disorder is even a staple of low comedy, from Porky Pig to former Howard Stern sidekick Stuttering John.

For severe victims, however, stuttering is a dramatic neurological interruption that blocks words with the abruptness of a CD player skipping. Some have so much trouble just articulating their names that their faces distort and their arms flail.

"Many people pick their jobs, or choose their careers, based on their perceived ability to communicate," said Michael Blomgren, a speech researcher at the University of Utah who also stutters. "When I was young I dreamed of becoming a pilot, but the reality is pilots need to communicate in a split-second way with the control tower, and that just wasn't an option for me."

Like many people who stutter, Blomgren enrolled in intensive speech therapy and essentially re-learned how to talk.

Others use a device based on a technique called "altered auditory feedback," which requires them to wear an expensive earpiece that replays their speech.

The idea of drug therapy for stuttering is relatively new. Although doctors don't understand why, certain psychiatric drugs seem to help alleviate stuttering. Maguire, the California researcher who himself stutters, has been taking an antipsychotic called Zyprexa since 1997. "If I weren't on it, this conversation would be taking hours," he said.

But such drugs have serious limitations. Their side effects, including weight gain and sexual dysfunction, can be more debilitating than the original disorder. And their effect on stuttering has not been extensively tested.

Pagoclone, the experimental pill from Indevus, started its life in the 1990s as a potential psychiatric drug. It was licensed to the pharmaceutical giant Pfizer Inc., which tested its effects on both panic and anxiety with mixed results. It had few side effects, but tests didn't show clear improvements either. Pfizer killed the program in 2002, sending Indevus stock into a tailspin.

Indevus officials, however, were intrigued by a striking and unanticipated effect on test patients: Two of them suddenly stopped stuttering.

"It really made us believe that it's worth investing the money to do a proper trial," said Jim Shipley, the company's vice president for medical affairs.

Indevus re-acquired the rights to pagoclone, took out a fresh patent based on its possible use as a treatment for stuttering, and launched a new clinical trial designed to show whether it can help a broader population. They have enrolled about half of the 120 patients they hope to test, and expect to have results by the middle of 2006.

Indevus warns that even if the trial succeeds, a larger trial will need to follow, and approval wouldn't come for at least three years.

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But even if the drug ultimately fails, stuttering researchers believe the effort is worthwhile. "We may have stumbled across the panacea, and if it is, fantastic," said Maguire. "But at least it's going to give us significant insight into the mechanisms of stuttering."

Pagoclon is believed to boost the effects of a brain chemical called GABA, which may indirectly inhibit the release of another chemical, dopamine, which dampens brain function. Studies done by Maguire and others have shown that stutterers' brains have too much dopamine in certain areas, preventing them from functioning properly. Measuring pagoclon's effect on brain chemistry against its effect on stuttering will help researchers determine whether a link exists.

New brain-scanning technologies have offered other clues. Blomgren found that when stutterers speak, both sides of the brain tend to light up with activity, whereas in fluent speakers one side naturally dominates. To him, it suggested the two sides were fighting for control, and words were getting caught in the middle.

"Essentially, there were too many cooks in the kitchen," Blomgren said. "We know it's an oversimplification, but we know a part of this definition holds true."

Treatment from such discoveries is still years away. For now, people who stutter have recourse only to a handful of devices and psychiatric drugs that haven't been specifically approved for stuttering.

The best-known device, the SpeechEasy, fits inside the ear and replays the speaker's voice with a slight delay and pitch shift.

Some users report little effect -- Blomgren said the SpeechEasy made his stuttering worse -- but others have reported dramatic improvement, and it was featured on "Oprah" as a "medical miracle."

Beth McNeill, an East Bridgewater speech therapist who has stuttered severely since a bout of encephalitis at age 10, bought one of the devices in August.

Before she started using it, "two percent of my words were fluent," McNeill said, "and now I can basically stand up and read a report and talk fluently 85 percent of the time."

With little clinical research to prove its effectiveness, SpeechEasy isn't covered by most insurance plans, so patients like McNeill have to pay the full cost of \$4,000 to \$5,000. Manufacturer Janus Development Group has sold only 5,500 units since it was introduced in 2001, according to a company spokesman, but says more tests are underway that may encourage more insurers to pick up the tab.

Indevus hopes to avoid similar problems with pagoclon, which will only be approved by federal regulators if clinical evidence shows clear benefits and low risks. But it will still face hurdles, not least of which is that it must be prescribed by a doctor. Currently, stuttering is nearly always treated by therapists.

Shiple, the Indevus vice president, compares the situation with that faced by antidepressant manufacturers about two decades ago, when few people thought depression could be treated with a drug.

"It's a challenge," he said of pagoclon's development, "but it's been an interesting challenge."

Stephen Heuser can be reached at sheuser@globe.com. ■

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