

# FDA panel backs first non-drug asthma treatment

October 29 2009, By MATTHEW PERRONE , AP Business Writer

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(AP) -- Federal health advisers on Wednesday said a novel technology from a small medical technology firm should be approved as the first non-drug treatment for asthma.

The Food and Drug Administration's panel of respiratory device experts voted 6-1 that Asthmatx's Alair System be approved under certain conditions, including long-term safety monitoring of patients.

The FDA is not required to follow the group's advice, though it usually does.

The company's procedure, called bronchial thermoplasty, uses extreme heat to burn away [lung tissue](#) that makes it difficult to breath and causes coughing spasms and wheezing. The heat is delivered via a catheter that emits radiofrequency waves, similar to microwaves used to cook food. The procedure would be performed by respiratory specialists known as pulmonologists over the course of three, half-hour sessions.

While roughly 20 million people in the U.S. suffer from [asthma](#), thermoplasty would only be appropriate for about 2 million adults with severe asthma who don't get relief from existing drugs, according to Asthmatx.

Chief Executive Glen French said he was very pleased with the positive review from the panel.

"It's a very interesting and stressful process and we're happy to have it behind us," French said in a phone interview with The Associated Press. He added that the company hopes to launch the technology in the U.S. in the first half of next year. The company already has approval to market Alair in Europe, but has held off due to the logistics of launching a device in multiple countries.

"Our biggest opportunity and the location in which we can most efficiently market the product is in the U.S.," French said.

Asthma medications were among the top-selling drugs in the U.S. last year, with sales of more than \$4.8 billion, according to health care data firm IMS Health.

FDA's expert panel recommended the company keep a registry to track the safety of patients who have undergone the procedure. The group also said the procedure should only be performed at facilities that can handle respiratory complications.

The Alair System is Sunnyvale, Calif.-based Asthmatx's only product. The privately-held company planned to make an initial public offering in 2006, but ultimately backed away from the plan.

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