

Gone is the insulin bong as Pfizer announces they have spent 2.8 billion on the marketing and development of the first inhaled insulin, but have received just 12 million in sales in 2007. This will be a great opportunity to educate those patients using Exubera.

[Pfizer](#) said last Thursday, that it would stop selling [Exubera](#), its inhaled insulin, less than two years after introducing the drug. Despite Pfizer's heavy promotion, Exubera's sales were minuscule, with prescriptions amounting to less than 1 percent of the insulin market.

Jeff Kindler, chairman and chief executive officer of Pfizer, said "we made an important decision regarding Exubera, a product for which we initially had high expectations. Despite our best efforts, Exubera has failed to gain the acceptance of patients and physicians. We have therefore concluded that further investment in this product is unwarranted."

Kindler said the company would work with physicians to "transition Exubera patients to other treatment options in the next three months. We remain committed to investing significant resources in the development of new and innovative medicines to manage diabetes, including monitoring inhalation technologies and other innovative delivery systems for insulin and other medicines."

The inhaled insulin was approved less than two years ago, but that approval followed a long and rocky development process. Although clinical trials had demonstrated Exubera to have efficacy similar to that of short-acting insulins, but without the needle stick, a host of concerns had cropped up, including worries about pulmonary toxicities, and questions about Exubera's ability to achieve a reduction in glycosylated hemoglobin (HbA1c) levels to below 7%, the accepted gold standard.

Over the years, the developmental challenge had been to reduce insulin to particles of just the right size to be inhaled by the lung and then absorbed into the bloodstream. Too small, and the particles would be exhaled. Too large, and the particles would be filtered out.

In its approval statement, the FDA noted that the safety and efficacy of Exubera have been studied in approximately 2,500 adult patients with type 1 and type 2 diabetes.

Exubera's end is another black eye for Pfizer, the world's biggest drug company, which has sustained a series of recent reversals. The abrupt discontinuation also calls into question whether inhaled insulin — once viewed as a potential multibillion-dollar market worldwide — will ever be able to compete with conventional injectable insulin as a treatment for [diabetes](#).

Several companies, including [Eli Lilly](#), are investing in expensive programs to develop inhaled insulin. But Pfizer said it would not try to develop a replacement for Exubera, ending its inhaled insulin research after more than a decade of work.

Many diabetes experts and longtime skeptics about Exubera, said that the problems that bedeviled Exubera would probably plague other inhaled insulin treatments under development.

In a statement, Pfizer said it would work with physicians to move all patients off Exubera within three months.. "Despite our best efforts, Exubera has failed to gain the acceptance of patients and physicians," Jeffrey B. Kindler, Pfizer's chairman, said in a statement.

When federal regulators approved Exubera in January 2006, analysts and Pfizer predicted that the drug would become a blockbuster, easily topping \$1 billion in sales annually. Pfizer

was so bullish on Exubera's prospects that just a few days before the approval, the company paid \$1.4 billion to [Sanofi-Aventis](#), the French drug maker, to buy out Sanofi's share of Exubera.

Even a few months ago, with Exubera's sales lagging badly, Pfizer insisted that it still believed that the drug could reach blockbuster status. And for much of this year, Pfizer has heavily promoted Exubera to physicians and patients. But Exubera was not able to overcome questions about its safety, efficacy, convenience and cost.

Clinical trials showed that Exubera marginally decreased patients' breathing ability, although Pfizer said the declines reversed if patients stopped taking the drug. Further, regulators required that patients take a lung function test before starting on Exubera, and another test after taking it for six months. The tests were an inconvenience for patients and for busy doctors.

Physicians also said that they worried about the possibility that patients would receive more — or less — insulin than they expected because of the natural day-to-day variability of lung function. Too little insulin can lead to uncontrolled high blood sugar, while too much can produce hypoglycemic shock.

In addition, the needles that are used to inject insulin have shrunk over the last two decades, making injections less painful. The size of the Exubera inhaler, variously described as looking like a tennis can or a bong for smoking marijuana, was also an obstacle.

Finally, insurance companies were reluctant to pay for Exubera, or the required lung function tests, since Exubera does not control blood sugar better than ordinary insulin. Exubera has cost about \$5 a day, compared with \$2 to \$3 a day for injectable insulin.

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