

TITLE

**Lessons from the
Failed Inhaled
Insulins**

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The inhalable insulin was available from September 2006 to October 2007 in the United States. It was a novel method of delivering insulin for treatment of diabetes and raised so many hopes for millions of diabetic patients to be able to walk away from the daily painful chore of injecting insulin. But, then during October 2007, Pfizer announced that it would be discontinuing the production and sale of Exubera due to poor sales. There were many reasons for the poor acceptance among physicians and patients resulting in poor sales. There were many hidden issues as well for this failure.

Hopes lingered as other inhaled insulins were under approval process. But, early this year, during January, when the MannKind Corporation, failed to win approval from Food and Drug Administration to market its inhaled insulin called Afrezza, for diabetes many hopes were dashed. The Company has led investigational product called the Technosphere Insulin System. The Food and Drug Administration had found the workup insufficient and asked for more studies of the device in patients with Type 1 and Type 2 diabetes. MannKind contentions failed to satisfy the agency's requirements.

There are many lessons to be learned from this turn of events for researchers and pharmaceutical industry, as well as for physicians and the patients.

Biography

Vinod Nikhra, M.D. is Fellow of International Medical Sciences Academy and Fellow of Royal Society of Medicine. He is trained in endocrinology and clinical nephrology. He has authored 4 books and contributed more than 30 papers in reputed journals and has been a reviewer for International Journal of Obesity (the Nature group) and Family Practice (the Oxford group). He is a senior consultant physician and on teaching faculty at Hindu Rao Hospital, Delhi, India. He can be found on www.vinodnikhra.com and www.nikhrafoundation.in.