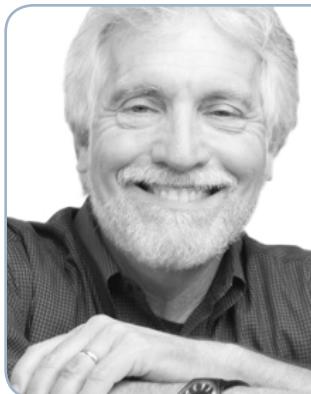


# INHALED INSULIN: HIGHWAY TO HEAVEN OR ROAD TO RUIN?



DR. JIM FINK, Senior Fellow Clinical Aerosol Product Development, **Dance Biopharm**

A highly trained clinician and researcher, Dr. Jim Fink has spent the past 25 years of his career focused on understanding the design of aerosol devices and how patients interface with them. In his capacity as Fellow of Aerosol Science at Aerogen (later Nektar), Fink developed efficient liquid aerosol delivery systems for adults, children, and infants, in critical care and ambulatory contexts, with multiple patents both in the US and abroad. Dr. Fink is a Registered Respiratory Therapist with a Ph.D. in Pharmaceutical Innovation from Bradford University, UK and a Fellow of both the American Association of Respiratory Care (FAARC) and the College of Chest Physicians (FCCP). An internationally recognized researcher and lecturer, Fink has authored 3 textbooks and more than 120 chapters and peer-reviewed papers. Dr. Fink serves on the editorial board for the Journal of Aerosol Medicine and is adjunct Professor for the Respiratory Therapy Program at Georgia State University in Atlanta GA, and faculty at Rush Medical School in Chicago.

## Why did you choose vibrating mesh technology for the delivery device?

One of the reasons that we used the mesh technology is that it has been shown to be very efficient with small doses. When you use the vibrating mesh and an individual drop reaches the aerosol generator mesh, that single drop is nebulised, and it produces the same efficiency and same particle size characteristics as you would have in a larger volume of ½ ml or even 3-4 ml. This means that drop by drop nebulisation is a key feature. The Aerogen technology has also been around for over a decade worldwide and is used in critical care devices. They have produced more than a million devices a year, so it has really become a stable process which means that we didn't have to go through a steep learning curve in that aspect of the device.

## Why should marketing of inhaled insulin extend to primary care providers?

This is simply because primary care providers are the people who see the patients. Generally, the majority are the Type 2 patients who are seen while they are pre-diabetic. They are counselled to get some exercise and make lifestyle changes and then they are started on some orals. When they have failed their first oral they go on to the next oral and there's such an extended period before they reach the endocrinologist. The primary care providers have a much closer feel for how these patients respond to their early diagnosis of diabetes and of their concerns and problems in adhering to the prescription and their reluctance to go on to injections. They are a much broader group of people who have contact with the inhaled diabetic. Endocrinologists do an excellent job but for years they have been using injections and they have patients who are reluctant at first to have accepted injections but don't really have much alternative. They are probably, as a group, less excited about giving people and inhaled alternative.

## What are the risks of contamination of the device?

Many devices have reservoirs that contain all the liquid and that liquid is generally below the mouth piece. This allows any bacteria or saliva that enters the mouthpiece to drain into

reservoir. The vibrating mesh is unique because it provides a barrier of sorts in the reservoir and this is above the mouth piece, so we believe that there is less risk of contamination from the patient. To test this, we took five different biologicals and sprayed them individually into a mouth piece (100 mcL sprays). We then continued to spray the aerosol and collected it to see if it had become contaminated. Sure enough we had zero contamination. This meant that coughing into the mouthpiece, which we were trying to simulate didn't in fact contaminate the device. So, our recommendation is that you do not need to wash the device after every dose, you could rinse and air dry it at the end of the day ready for the next one.

## What do you think the future holds for inhaled insulin and its research, what is left for the future?

It's safe to say that there is no drug research war more intense than inhaled insulin. There are over 12 different people doing extensive studies and phase 2 & 3 trials, but I think that the biggest barrier that we have now to inhaled insulin is the failed marketing in the past two cases. This means that it's very difficult to get investors and the financial community to see past that. Should we be able to get past that, I'm sure that some day we will have a range of effective devices for long term inhalation of insulin. I'm sure that injections are probably appropriate for most people with insulin, but for people who have put off taken the injections when the others have failed, that is where all the damage happens, and it can go on for 10 years. So, I think that inhaled insulin is not a technological barrier anymore and there are several ways to give it.

This is an excerpt from the free webinar, 'Inhaled Insulin: Highway To Heaven Or Road To Ruin?'

The full recording is available on our website at: [www.drugdelivery-congress.com/free-webinar-recordings](http://www.drugdelivery-congress.com/free-webinar-recordings)

