FDA Endocrinologic and Metabolic Drugs Advisory Committee
Public Comment Statement
September 8, 2005

Presenter: Marc Sandberg, MD
Medical Director
Diabetes Health Center
Hunterdon Medical Center
marcira@comcast.net

Statement:

My name is Marc Sandberg. I am an endocrinologist and serve as the medical director for the Diabetes Health Center at Hunterdon Medical Center in New Jersey. I would like to disclose to the committee that I have no current financial relationship with the drug sponsor and am here presenting my comments on my own expense. I do have experience working on the early clinical studies of Exubera when I was a staff physician at the Ochsner Clinic in New Orleans from 1996 to 2001.

The following are considerations that should be examined as the committee considers providing guidance to the FDA on the approval of Exubera. My perspective is based on 10 years of experience as a clinical endocrinologist as well as involvement in the early clinical trials of inhaled insulin.

Inhaled insulin will need to be given for many years, and we do not know the long-term effects on lung tissue. People with major organ system disease, a history of epilepsy, asthma, other respiratory diseases, as well as smokers were excluded from the main Exubera studies. These perspective patients are included in a large segment of our diabetic population whom may be considered for inhaled insulin. Some Exubera studies have shown that there are changes in lung function. Further, we know that diseases, for example asthma, respiratory infections, smoking and chronic obstructive pulmonary disease, may change lung function. How will this affect inhaled insulin absorption and will there be related variations in absorption across patient types based on their baseline lung function?

The inhaled insulin device requires a very different administration technique than syringes. Many patients may be excluded because of this, especially since, unlike syringes, another person cannot administer the inhaled insulin for the patient. The administration needs to be exact, and we need be sure that patients are getting the right dose. When we give a patient 8 units injected sub-q, we have good confidence in what dose we are delivering.

For an individual dose, patients have to give themselves one shot of insulin with the appropriate number of units insulin injected. Inhaled insulin may have a limited dose selection and may require multiple administrations to achieve different dose selections.

This is a paradigm change in how patients administer insulin from both a mechanism as well as dose perspective.

We also know that inhaled insulin only addresses the bolus insulin, not the basal insulin. Quite possibly patients will be adding inhaled insulin to continued use of syringes. Many patients will not be able to throw away their insulin needles. Conversely, we may see patients who are currently managed by one shot of a long-acting insulin per day moving to multiple puffs of inhaled insulin per day.

The consideration of a new form for the delivery of insulin needs to be fully evaluated so that the diabetes community is able to best determine the right patients that might benefit from inhaled insulin. We will also need the resources to provide education and guidance to ensure that our patients are able to use this new tool correctly.

Thank you for your consideration.