

August 20, 2005

TO: Endocrine and Metabolic Drugs Advisory Committee
Food and Drug Administration

RE: Written Public Comment Regarding Inhaled Insulin
EMDAC Meeting, September 8, 2005

The mission of my practice is to help children and adolescents with type 1 diabetes achieve good regulation of their condition during childhood with the intent to keep them healthy throughout their adult years. I am pleased that inhaled insulin is being reviewed as another modality to use to treat people with diabetes, but I am concerned that the Advisory Committee understands how important injection therapy will continue to be for children and adolescent with diabetes.

While the *thought* of an insulin injection may be unpleasant, every day I see children who give themselves multiple daily insulin injections – injections that rarely cause pain. Today's needles are so small and so short that the only people who think that insulin needles hurt repeatedly are those who have not ever tried an injection.

In order for inhaled insulin to be advisable for children, it must measure up to the already known dependability of injected insulin regarding efficacy, safety, and ease of use. We must know that inhaled insulin will work well in children with asthma and respiratory infections. We must know that it will not damage lungs when inhaled for decades. We must know that it will allow children to have the flexibility in dosing that they currently have with injections and pumps.

Syringes and insulin pumps are essential and effective tools for delivering insulin. We must ensure that these technologies are not perceived as outdated modalities. We rely on these tools and will continue to consider them central to diabetes control.

Thank you for your consideration.