

To: Cathy Groupe, Center for Drug Evaluation and Research, FDA, at groupec@cder.fda.gov.

As the committee considers inhaled insulin, I would like to offer some observations. I am a Clinical Nurse Specialist and Certified Diabetes Educator with more than 25 years of experience. I am also a person with type 2 diabetes and I use insulin.

The goal of diabetes care is control. The American Association of Clinical Endocrinologists defines control as having an average HbA1C of 6.5%. This is the benchmark that has been shown to deliver near normal outcomes regarding complications of diabetes and also, provides a high quality of life.

As the committee knows, the current standard of care insulin regimen features long-acting insulin to manage basal insulin levels accompanied by bolus doses to cover meal related glucose excursions. Inhaled insulin, based on the data shared with the diabetes community to date, seems to address only the bolus side of the regimen, and people with diabetes will continue to inject their basal insulin. If the message associated with inhaled insulin heard by people with diabetes is that they no longer a need needles, it will be a great disservice.

People need to understand that the only people who are afraid of insulin injections are those who have never given one. The emotional fear of shots is different from the reality. The reality is that insulin injections don't hurt. While it may be hard to convince the general public of this, as a diabetes educator, helping people with diabetes to adopt an insulin regimen that controls their condition is a daily role I play and one that is easy to fulfill when people are able to overcome their misperceptions.

The question the committee should consider is whether inhaled insulin helps people with diabetes to control their disease to the levels set as the standard by the diabetes community. Avoiding shots is not the reason to approve this product, and we should not compromise the goals of care because of the myth associated with insulin injections.