



DEPARTMENT OF MEDICINE
SCHOOL OF MEDICINE

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May 13, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0086

Dear Drs. Cross and Garfield

The purpose of my letter is to support the approval of Pramlintide based on personal and professional experience. I am writing to you not only as a person who has lived with type 1 diabetes for over 33 years (since age 15), but also as a diabetologist on faculty at the University of California San Diego and Veterans Affairs Medical Center.

First and foremost, despite advancements such as pumps, analogs, and meters, diabetes care at the community level remains quite poor. Even for people with access to all the tools and experts, normalization or near normalization of the A1c is difficult, limited by hypoglycemia and weight gain. In addition, many of those with a normal A1c have severe problems with wide and unpredictable glucose swings throughout the day and night. I believe that although Pramlintide does not solve all of the above problems, it is an important piece in the puzzle of successful diabetes management.

I first learned about Pramlintide as an investigator in a clinical trial for subjects with type 1 diabetes. A consistent theme for these patients was a reduced need for Lispro or Aspart, sustained weight loss, improved post-prandial glucose values and after an adjustment period, reduced fluctuations of the glucose values (including hypoglycemia) throughout the day. During the extension period of the study, the vast majority of subjects volunteered to continue therapy with Pramlintide. Many of their experiences were reflected in the published results from this and other studies on Pramlintide; however, these benefits are difficult to demonstrate in traditional randomized, double blinded, placebo controlled clinical trials. Home glucose monitoring is a classic example. In addition, drug researchers frequently exhibit tunnel vision, focusing solely on whether a drug has the ability to lower A1c and ignoring consideration of the many other important aspects a therapeutic diabetes agent may offer.

Pramlintide is an analog of a hormone found naturally in the beta cell co-secreted with insulin. Its role is not fully elucidated but it clearly works to limit glucose appearance by balancing the glucose disappearance actions of insulin. It logically follows that when Pramlintide is administered with insulin, hypoglycemia will occur if insulin is not adjusted downward. I have learned from my own experience and from my patients that once the correct balance is obtained between Pramlintide and insulin dosages, postprandial glucose values are improved and the rate of delayed hypoglycemia is reduced.

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My motives for writing this letter are selfish in nature. Pramlintide has been a vital part of my daily routine for over two years and quite frankly, I truly rely on this hormone in controlling my diabetes. I am also writing to you on behalf of my patients and the many people in this country searching and reaching out for help, and who may benefit from Pramlintide therapy. Diabetes is a constant presence 24 hours a day, 365 days a year with no holidays. Every day is a new and different day with unpredictable swings in glucose levels despite all attempts to do things "right." Please understand that any tool, big or small, with the potential to help the growing number of people with diabetes live more normal lives is valuable and very much needed. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Edelman', written in a cursive style.

Steven Edelman, MD
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