

Dear Drs. Cross and Garfield

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

First and foremost, despite all of the advancements in diabetes care such as pumps, analogs, and meters, diabetes care at the community level remains quite poor. Even for those people with access to all of 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 developed a feel for Pramlintide, as I was an investigator in a clinical trial for subjects with type 1 diabetes. I kept on hearing a consistent theme from these patients of 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 throughout the day including hypoglycemia. During the extension period of the study, the vast majority 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 be exemplified in a traditional randomized, double blinded, placebo controlled clinical trial. A classic example is that of home glucose monitoring. In addition, our country has tunnel vision in that a drug is judged on its ability to drop the A1c and is blinded to the many other important aspects that a therapeutic agent for diabetes can offer.

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

My motives for taking the time to write this letter are selfish in nature. Pramlintide is now a vital part of my daily routine for over two years and quite frankly, I truly rely on this hormone to help me take control of 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, who may benefit from Pramlintide therapy. Diabetes is with my patients and me 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, 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,

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Of Your Diabetes 501(c)3