

DIABETES AND ENDOCRINE ASSOCIATES

E.N. Gold, M.D. DANIEL EINHORN, M.D. CHRIS SADLER, PA-C RAYMOND I. FINK, M.D.

BOARD CERTIFIED ENDOCRINOLOGY & METABOLISM, INTERNAL MEDICINE

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Docket # 2004-0086 Joint Symposium on Diabetes

Dear Distinguished Panel:

I commend you for your desire to improve the development and availability of treatments for persons with diabetes and for acknowledging that the prevention and treatment of diabetes must be a priority. The personal and fiscal impact is too great and can only be controlled through new technologies and management.

My involvement, over the past 20 years, in the area of diabetes has taken me from direct inpatient care and education to the area of clinical research. I have been involved in the conduction of clinical trials for the past 15 years and the advancements in devices, as well as in the pharmaceutical arena, have been astounding, but much more is needed! The process for R&D-to-market is too lengthy and the cost to the patient is too great, both in terms of management of the disease and fiscal impact.

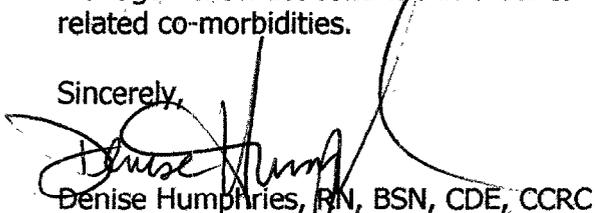
I have been directly involved in clinical trials with diabetes and its related complications, and the co-morbidities associated with diabetes are devastating, especially that of macro-vascular disease. New treatments must be made accessible through research and then a means to control the cost to the patient must occur.

Many patients, due to a lack of, or inadequate insurance coverage cannot afford the tremendous expense required to manage their diabetes and related diseases. Clinical research often serves to provide the needed diabetes management, medications and treatments that would otherwise go unaddressed.

My experience has shown me that clinical trials are a positive experience for the participant. Not only because they are receiving the medications and supplies they need, but because they are getting supervised and personalized diabetes management. This is reassuring and helps them to stay focused in their management.

Research serves to bridge the complex management that is involved with diabetes care and treatment. Clinical research in new diabetes related therapies and management must continue in order to keep pace with this progressive disorder and related co-morbidities.

Sincerely,


Denise Humphries, RN, BSN, CDE, CCRC

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