DEPARTMENT OF HEALTH & HUMAN SERVICES



National Institute of Diabetes and Digestive and Kidney Diseases Bethesda, Maryland 20892

July 23, 2004

Mr. Paul Tubiana P.O. Box 21832 Lee High Valley, Pennsylvania 18802

Dear Mr. Tubiana:

Your e-mail to Representative Bart Stupak was forwarded to Dr. Elias A. Zerhouni, director of the National Institutes of Health (NIH), for response. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the lead NIH Institute for diabetes research, and I have been asked to reply.

First, I would like to thank you for sharing your experiences and insights regarding the diagnosis and treatment of diabetes. Researchers still have a great deal to learn about the natural history of the different types of diabetes and ways to improve the diagnosis and treatment of these diseases.

I am glad that you have found a way to control your sinus infection. Infection is known to precipitate diabetes onset in some people and, often, to worsen blood glucose control while increasing insulin needs in patients with pre-existing diabetes. The precise role of various infectious agents in triggering the onset of diabetes, especially type 1 diabetes, is an area of great interest and study. The National Institute of Diabetes and Digestive and Kidney Diseases, the NIH institute with lead responsibility for diabetes research, is funding a multicenter study called The Environmental Determinants of Diabetes in the Young (TEDDY), which seeks to identify infectious agents, dietary factors, or other environmental factors, that trigger type 1 diabetes in genetically susceptible people. For more information, see http://www.niddk.nih.gov/patient/TEDDY/TEDDY.htm

We are increasingly recognizing that it can be difficult to distinguish type 1 diabetes from type 2, particularly in children. The Search for Diabetes in Youth Study (SEARCH) http://www.niddk.nih.gov/patient/SEARCH/SEARCH.htm, sponsored by the Centers for Disease Control and Prevention (CDC) and co-funded by the NIDDK, will be helpful in developing approaches to distinguish between the two major types of diabetes. This study is carefully characterizing all children with diabetes in six regions of the United States to determine diabetes prevalence in children and to help clarify trends in disease development. These regions are: Hawaii; Seattle, WA; southern California; Colorado/Arizona; South Carolina; and Cincinnati, OH. In the SEARCH study, participants will be tested for diabetes autoantibodies, hemoglobin A1c, fasting glucose and fasting C-peptide, lipids, urine albumin and creatinine. The stimulated C-peptide test is being performed in a subgroup of participants.

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We have learned a lot about the autoimmune events preceding the onset of type 1 diabetes from the Diabetes Prevention Trial-Type 1 (DPT-1), (see http://www.niddk.nih.gov/welcome/releases/6_23_01.htm and http://www.niddk.nih.gov/welcome/releases/6-15-03.htm), the DAISY Study (http://www.uchsc.edu/daisy/), and other studies. In patients with newly diagnosed type 1 diabetes, C peptide levels are often present for the first year or two. With the knowledge gained from earlier studies, researchers continue to working toward the goals of preventing type 1 diabetes and delaying or stopping the immune destruction of beta cells in newly diagnosed patients. The preservation of C peptide as a marker of beta cell function is also a goal of the TrialNet studies. (See NIDDK's announcement of the first two studies being conducted by Type 1 Diabetes TrialNet at http://www.niddk.nih.gov/welcome/releases/06-05-04.htm.)

Researchers participating in the TrialNet studies hope to determine how best to measure C peptide in new onset type 1 diabetes. Autoantibody tests can also be valuable in distinguishing type 1 from type 2 diabetes. It may interest you to know that CDC is conducting a program to improve standardization of measurements of C peptide and antibodies.

Finally, I appreciate your effort to share your ideas about the diagnosis of diabetes and assure you that we are moving ahead as quickly as possible to fund promising research that will answer the questions you raise and improve the prevention, diagnosis, and treatment of diabetes.

Sincerely yours,

Judith Fradkin, M.D.

Director, Division of Diabetes,

Endocrinology and Metabolic Diseases

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