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## United States Senate

Washington, DC 20510-3802

November 2, 2006

Mr. Paul Tubiana P.O. Box 21832 Lehigh Valley, PA 18002-1832

Dear Mr. Tubiana:

Per your request, I have enclosed information for your benefit.

I hope you will find this information helpful. If you should have any additional questions regarding this or any other matter, please don't hesitate to contact my Allentown Office.

Alle Part

Arlen Specter



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service National Institutes of Health

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

October 31, 2006

Mr. Paul Tubiana P.O. Box 21832 Lehigh Valley, PA 18002-1832

Dear Mr. Tubiana:

Your letters to Senator Rick Santorum and Senator Arlen Specter about the use of C-peptide testing in the diagnosis of childhood diabetes has been forwarded to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which leads the National Institutes of Health (NIH) research effort in diabetes.

The measurement of C-peptide, which indicates how much insulin the pancreas is producing, is not consistently informative because significant levels of C-peptide can be present when type 1 diabetes is diagnosed and can persist for years. In other words, the absence of C-peptide suggests a diagnosis of type 1 diabetes, but patients with measurable C-peptide levels may have either type 1 or type 2 diabetes. For this reason and because the C-peptide assay has not been standardized yet, the test is not widely used except in research centers. The Centers for Disease Control and Prevention (CDC) and NIDDK are funding an effort to standardize and optimize the laboratory assay for C-peptide as well as the measurement of specific autoantibodies. Knowing the blood levels of these autoantibodies is very helpful in predicting and diagnosing immune mediated, or type 1, diabetes.

Researchers recognize that it can sometimes be difficult to distinguish type 1 diabetes from type 2, particularly in children. They 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. The Search for Diabetes in Youth Study (SEARCH) <a href="http://www.niddk.nih.gov/patient/SEARCH/SEARCH.htm">http://www.niddk.nih.gov/patient/SEARCH/SEARCH.htm</a>, sponsored by the CDC and co-funded by the NIDDK, is investigating the best methods for diagnosing the different forms of diabetes in children, including cases with characteristics of both type 1 and type 2 diabetes. Participants in the SEARCH study are being tested for diabetes autoantibodies, hemoglobin A1c, fasting glucose and fasting C-peptide, lipids, urine albumin and creatinine.

Several NIDDK-funded studies including Type 1 Diabetes TrialNet <a href="http://www.nih.gov/news/pr/jun2006/niddk-09.htm">http://www.nih.gov/news/pr/jun2006/niddk-09.htm</a> are probing the autoimmune events preceding the onset of type 1 diabetes. With the knowledge gained from earlier studies, researchers are working toward the goals of preventing type 1 diabetes and delaying or stopping the immune destruction of beta cells in newly diagnosed patients.

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Thank you for sharing your concerns about the diagnosis of diabetes. I assure you that the NIH is 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,

Joan Chamberlain

Office of Communication and Public Liaison National Institute of Diabetes and Digestive and Kidney Diseases National Institutes of Health