May 18, 2010

The Honorable Margaret Hamburg, M.D.
Commissioner of Food and Drugs
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

As you may be aware, the State of Florida has been focusing on the use of psychotropic medications to treat children in the custody of the State for behavioral issues. Our most recent concern followed the April 2009 death of 7-year-old Gabriel Myers who apparently hanged himself while undergoing treatment with three such medications. The report of a Work Group established immediately following his death issued 147 findings and recommended 90 specific systemic improvements to allow us to better protect and treat our children. I would call your attention to the website established for the Gabriel Myers Work Group (www.dcf.state.fl.us/admin/gmworkgroup) for their report and documentation of their deliberations.

A specific concern focused on the use of children in clinical trials. The Work Group has recommended that a child in the custody of the State never be allowed to participate in a clinical trial that is designed to develop new psychotropic medications or evaluate the suitability of providing medications previously approved for adults to children.

Several recent warning letters issued by the FDA to both pharmaceutical firms, such as Pfizer, and individual psychiatric researchers, including Dr. Sohail Punjwani, have raised concerns about the protocols and safeguards surrounding the obtaining of informed consent in these trials. To ensure the safety of those children in State care, I would ask the Food and Drug Administration to determine if any Florida foster children may have been used in the past in clinical trials. I would be particularly interested in information...
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relating to the use of foster children in the clinical investigations conducted by Dr. Punjwani and for which he was issued a warning letter from the FDA on February 4, 2010. Staff of this Department will be available to assist you in determining if any children used in these trials or investigative procedures are in fact within State care.

Thank you for your assistance in this vital matter. I will look forward to discussing it at your convenience.

Sincerely,

George H. Sheldon
Secretary