



**State of Florida
Department of Children and Families**

Charlie Crist
Governor

George H. Sheldon
Secretary

July 19, 2010

Ms. Jill Hartzler Warner
Acting Associate Commissioner for Special Medical Programs
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Warner:

Thank you for your response to my letter of May 18, 2010. I sincerely appreciate the information you provided and the effort it took to prepare such a detailed and informative response. I certainly can understand your position concerning the importance of utilizing children in certain clinical trials and recognize the safeguards that the Food and Drug Administration puts into place for clinical trials you regulate.

The State of Florida, however, feels that our responsibility to protect children who are in our care supersedes the benefits of their involvement in such trials. Children who come into our care are often the victims of abuse, neglect, and abandonment. It is therefore imperative that the State do all in its power to stabilize their environment, to protect them from further trauma, and to foster their successful growth into adulthood. The State has, in fact, through its dependency system become the parents of these children, and we must ensure that they are not knowingly placed in harm's way, no matter how well meaning that activity might be.

To that end, we have by administrative procedures prohibited the use of children in State care in clinical trials relating to the development of new psychotropic medications. Additionally, this Department's operating procedure on "Institutional Oversight of Human Subject Research and Institutional Review Board Designation" now specifies: At no time shall a child in the custody of the Department 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. This paragraph does not preclude research that evaluates the consequences of administration of psychotropic medications to children in state care.

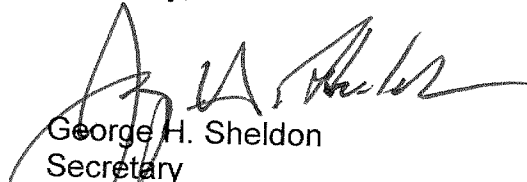
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Mission: Protect the Vulnerable, Promote Strong and Economically Self-Sufficient Families, and Advance Personal and Family Recovery and Resiliency

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Again, thank you for your response to my correspondence. I value the relationship that the Department of Children and Families has with the Department of Health and Human Services and look forward to our on-going communication and involvement.

Sincerely,



George H. Sheldon
Secretary

Co: Secretary Kathleen Sebelius