Jill Escher
Escher Fund for Autism
[redacted]

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

May 20, 2013

Re: Request for Emergency Action on Citizen Petition to Revoke Approval for Diclegis and Revise Pregnancy Drug Labeling Rules FDA-2013-P-0522/CP1, filed 4/30/2013

To the Commissioner of the Food and Drug Administration:

The undersigned has submitted a petition to revoke approval for the drug Diclegis pending fetal germline impact assessment, and to issue additional pregnancy label warnings for all drugs regarding potential for fetal germ cell perturbation.

As you are aware, prescriptions for Diclegis are scheduled to commence in June, less than two weeks away. The urgency of the present situation must be acknowledged: unless the FDA suspends its approval, revises the pregnancy label status of Diclegis to "C," or takes other reasonable action, the agency and the drugmaker will be falsely informing millions of pregnant women of the risk-free status of this drug, and exposing millions of fetuses to potential germline (sperm and egg) epigenetic damage.

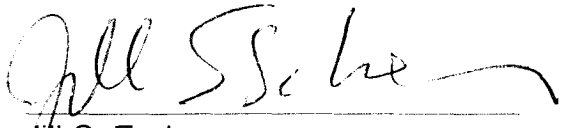
While the FDA's historic and persistent obliviousness to fetal germline impacts of prenatal pharmaceuticals is of course a tremendously catastrophic oversight, past ignorance and recklessness should in no way justify current actions, particularly in light of what science of the past decade has taught us about germline susceptibily. The FDA has the discretion -- and indeed, the Congressionally mandated duty, should safety issues surface -- to change its course today. It can begin by taking immediate action on Diclegis, to insure the public is fully informed of risks.

Nothing can possibly be more urgent than safeguarding the integrity of human germline, during its most vulnerable period, from insult by synthetic chemicals which can easily cause molecular derangements and genetic destabilization.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

I wish to thank the FDA staff for its consideration of this emergency request.

Very truly yours,



Jill G. Escher
[redacted]

cc via email:
Nancy Hayes, Acting Director, Office of Regulatory Policy, Center for Drug Evaluation and Research
Hylton V. Joffe, M.D., M.M.Sc., Director

The Escher Family
[redacted]

OAKLAND CA 945

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