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DISTRICT 27

Arizona House of Representatives
Phoenix, Arizona 85007

August 21, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20857

Dear Director:

It has come to my attention that the FDA is in the process of reviewing certain ethical standards in medical research, specifically research protocols for testing drugs on children. There apparently are waiver approvals pending for children defined as "neglected" or "abused" without an adjudication of dependency occurring.

If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part.... provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, statutes, and condition.

The above proposed language is very alarming to the basic constitutional rights of parents and their children, ethical and medical standards, and common sense. I would wholly object to the approval of such a deviation from right and proper standards and ask that a full investigation be implemented regarding the DHHS' intention of their horrendous approval.

Children are not to be used as guinea pigs for the private sector research through agencies that supposedly have their best interest at heart.

This approach surely breeds further contempt for an already faulty child welfare system as well as encourages further outrage as credibility diminishes further.

Sincerely,

A handwritten signature in cursive script that reads "Laura Knaperk".

LAURA KNAPERK
State Representative

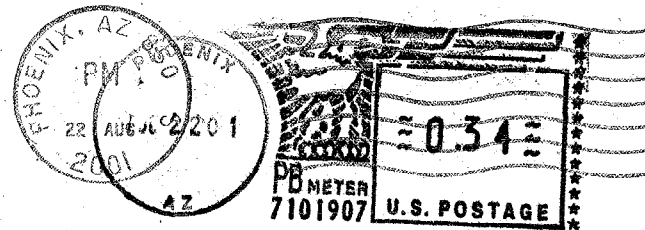
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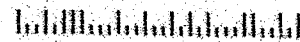
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Representative Laura Knaperek
House of Representatives

STATE OF ARIZONA
HOUSE WING, CAPITOL BUILDING
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