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July 2, 2002

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20652

IARSHA D. RAPPLEY, MD
Associate Professor,
and Interim Chair

Docket Number: 02N-0152

Dear Sir or Madam:

As a pediatrician who cares for infants and children every day, I welcome the opportunity to comment on the relationship between the 1998 Pediatric Rule and the Best Pharmaceuticals for Children Act (P.L. 107-109). As a member of the American Academy of Pediatrics (AAP), I know that the AAP has advocated for appropriately tested and labeled medications for infants, children and adolescents for over 40 years. Securing safe and appropriate drugs for use by children has had a long and laborious history. Significant progress toward pediatric drug studies and labeling has been made over the last five years.

A dual approach to obtaining essential pediatric data was instituted in the late 1990's. This approach combines: 1) incentives for voluntary studies of drug safety and dosing by industry (extended in January 2002 in the Best Pharmaceuticals for Children Act [BPCA]); and 2) a regulation requiring pediatric studies of new drugs and some already marketed drugs, known as the Pediatric Rule.

In March 2002 the FDA proposed to suspend the Pediatric Rule. While this proposal was reversed, this action indicates that children are at risk of losing the ground we have fought so hard to secure for them.

The Pediatric Rule ensures that children are no longer a therapeutic afterthought by the pharmaceutical industry. It is an essential and successful tool in ensuring that children have the quality and quantity of drugs they need. All new drugs must be studied for pediatric use at the time a drug comes to market unless the FDA grants a waiver. This makes medications for children a certainty, not an option and puts children on a level playing field with adults for the first time.

02N-0152

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DEPARTMENT OF
**PEDIATRICS/HUMAN
DEVELOPMENT**

Michigan State University
B240 LIFE SCIENCES
East Lansing, MI
48824-1317
517/353-5042
FAX: 517/353-8464

My own patients and my practice benefit greatly from studies safety and efficacy profiles for psychotropic medications. Many of these are a direct result of the Pediatric Rule.

I believe that all components of the 1998 Pediatric Rule must be preserved. It is a comprehensive approach to securing pediatric studies. FDA has not yet invoked all the provisions of the Pediatric Rule; however, together they weave a safety net for children to ensure that children have appropriate drugs available for their use.

Thank you for your consideration of these comments.

A handwritten signature in black ink, appearing to read "Marsha D. Rappley". The signature is fluid and cursive, with a large initial "M" and a stylized "R".

Marsha D. Rappley, M.D.
Associate Professor and Interim Chair

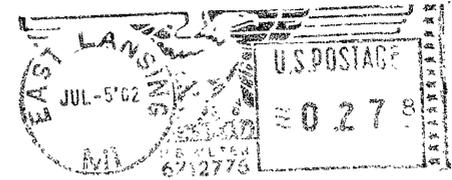
MDR/ljk

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