

AMERICAN SOCIETY FOR  
CLINICAL PHARMACOLOGY AND THERAPEUTICS



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

Docket Number: 02N-0152

Dear Sir or Madam:

As an organization working to ensure better health care for our citizens, we welcome the opportunity to comment on the relationship between the 1998 Pediatric Rule and the Best Pharmaceuticals for Children Act (P.L. 107-109). Securing safe and appropriate drugs for use by children is essential to the health of our citizens and is a goal of the American Society for Clinical Pharmacology and Therapeutics (ASCPT).

The Pediatric Rule has been an essential and successful tool for ensuring that children have the quality and quantity of drugs they need. This approach combined: 1) incentives for voluntary studies of drug safety and dosing by industry (codified in January 2002 in the Best Pharmaceuticals for Children Act [BPCA]); and 2) the requirement for pediatric studies of new drugs and some already marketed drugs. Significant increases in the number of drugs studied in children and labeled for pediatrics have been made over the last five years as a result of the Pediatric Rule. This makes medications for children a certainty, not an option, and puts children on a level playing field with adults for the first time.

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We believe that all components of the 1998 Pediatric Rule must be preserved: both the incentive and requirement for pediatric studies have been crucial to its success. 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.

Sincerely,



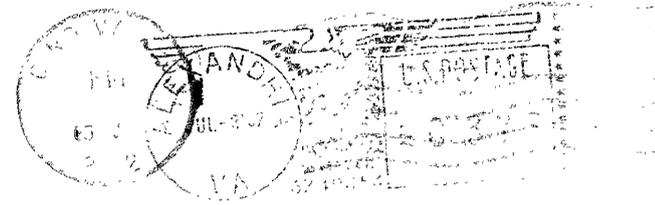
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