



CHILDREN'S HEALTH CARE JUL -9 910 306
OF PORT HURON, P.C.

July 2, 2002

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

RE: Docket Number: 02N-0152

To Whom It May Concern:

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.

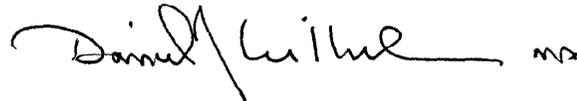
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The Pediatric Rule ensures that children are no longer a therapeutic afterthought by the pharmaceutical industry. It is an essential and successful tool in ensuring that children have the quality and quantity of drugs they need. All new drugs must 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.

Sincerely yours,

A handwritten signature in black ink that reads "Daniel J. Wilhelm, M.D." with a stylized flourish at the end.

Daniel J. Wilhelm, M.D.

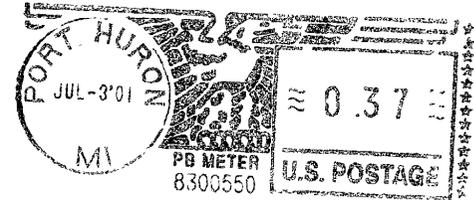
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