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July 2, 2002

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, MD 20652
<http://www.fda.gov/dockets/ecomments>

Docket Number: 02N-0152

Dear Sir or Madam:

As a pediatrician and professor of public health, researching health policy, I strongly encourage the FDA to maintain the 1998 Pediatric Rule, as a necessary complement to the Best Pharmaceuticals for Children Act (P.L. 107-109). It would be inefficient and unfair to children to undermine the significant progress in pediatric drug studies and labeling which has been made over the last five years.

The dual approach to obtaining essential pediatric data combines market forces through incentives for voluntary studies of drug safety and dosing by industry (extended in January 2002 in the Best Pharmaceuticals for Children Act [BPCA]); and recognition of market failures through a regulation requiring pediatric studies of new drugs and some already marketed drugs, known as the Pediatric Rule.

The Pediatric Rule ensures that children are no longer a therapeutic afterthought by the pharmaceutical industry. It is an essential and efficient 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, creating equity between adults and children in the development of new drugs.

I believe that all components of the 1998 Pediatric Rule must be preserved.

- Retiring or relaxing any authorities currently in the Pediatric Rule would be to the detriment of children, because the BPCA is time-limited, voluntary and subject to continuation by the Congress. The Pediatric Rule would institutionalize the concern for children.

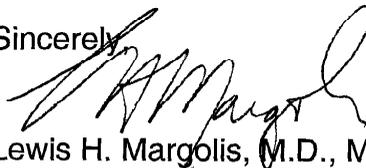
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- The Pediatric Rule should mirror the scope of the BPCA and apply to all labeled and potential indications as well as new indications. If a company submits a supplemental indication to the FDA, it invokes the Pediatric Rule. It is important that appropriate pediatric studies be conducted for that new use; and if the current label lacks appropriate pediatric use information (e.g., for neonates) the FDA should also include in their requirement for pediatric studies of the new indication, any pediatric studies that may be needed for the currently labeled or potential indications.
- It is essential that the Pediatric Rule remain in place because it is the only mechanism that ensures that biological products will be studied and available for children. No provision of BPCA applies specifically to biological products, since the legislation focuses on drugs covered by the Food, Drug and Cosmetic Act (FDCA) and the vast majority of biologics are covered under the Public Health Service Act. Moreover, some of the most innovative new therapies now and in the future are biological products, which are not covered under BPCA.
- Appropriate formulations are an essential component of providing medications for the pediatric population. It is a requisite for studies in infants and younger children to develop age appropriate formulations, if necessary. Failure to require needed formulations for specific age populations negates the intent of the BPCA and the Pediatric Rule.
- BPCA limits its reference to “recommendation” for formulation changes only to studies completed under public contract. This provision was included to acknowledge that once a formulation is developed in the study phase, while it may be necessary to manufacture that formulation, it may not always be possible to scale up the formulation for distribution to the general public.

Thank you for your consideration.

Sincerely,



Lewis H. Margolis, M.D., M.P.H.

