



BAYLOR  
COLLEGE OF  
MEDICINE

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Houston, Texas 77030-3498

July 1, 2002

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

Dear Sirs:

Issues regarding patient safety are before the American public on a daily basis. Continuation of the "Pediatric Rule" (regulations that require drug companies to conduct pediatric studies) is of major importance to our nation's children to ensure the development of pediatric specific safe medications for use in children. It is a foundation for appropriate and necessary medication use in the newborn infant, toddler and child. While "Best Pharmaceuticals for Children Act (BPCA)" moves children further onto safer medical ground, the "Pediatric Rule" must also be in place – the requirement and the incentive.

Examples of where both are needed are as follows:

- The BPCA incentive of additional market exclusivity can only be applied once during the life cycle of a drug. When FDA requests pediatric studies under BPCA, all potential pediatric uses must be anticipated in the request. This request cannot be expanded later if additional studies are needed in very young children or newborns or if a new use is discovered for a drug. Once studies have been completed and the incentive has been granted, there is no obligation on the part of participating companies to generate additional pediatric data. The Pediatric Rule may be invoked in instances where pediatric information is essential but the BPCA is no longer available. Plus, the BPCA sunsets in 2007. If it is not renewed, history suggests that the industry may not see it within their scope or financial best interest to continue to do pediatric drug studies. The Pediatric Rule will allow pediatric studies to continue.
- Because BPCA is voluntary, not all sponsors are interested in complying with the terms. The Pediatric Rule applies to all drugs and biologicals whose intended use in pediatrics is the same as adults and is mandatory, thus ensuring appropriate pediatric information.
- Unfortunately, the BPCA provides incentives to the pharmaceutical industry to study drugs **but does not** address biological products. Significant portions of the medications used in children are biological products. Without the Pediatric Rule there is no mechanism to ensure that pediatric studies are conducted on these important medications.

I hope that you will strongly support the continuation of the "Pediatric Rule" so to enhance the safety of medications given to children.

Sincerely,

  
Michael E. Speer, M.D.  
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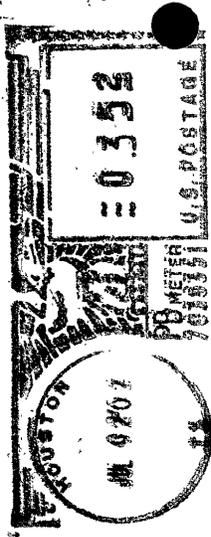
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