

AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY

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July 8, 2002

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(HFA-305)

Food and Drug Administration

5630 Fishers Lane - Room 1061

Rockville, MD 20652

Docket Number: 02N-0152

Dear Sir or Madam:

On behalf of the American Academy of Child and Adolescent Psychiatry (AACAP), 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). The AACAP supports the full preservation of all components of this dual approach to ensuring that pediatric clinical trials are conducted on all medications used by physicians, including child and adolescent psychiatrists, to treat children and adolescents.

The American Academy of Child and Adolescent Psychiatry (AACAP) is a medical membership association established by child and adolescent psychiatrists in 1954. Now over 6,700 members strong, the AACAP is the leading national medical association dedicated to treating and improving the quality of life for the estimated 14 million American youth under 18 years of age who are affected by emotional, behavioral, and developmental disorders. AACAP supports research, continuing medical education and access to quality care. Child and adolescent psychiatrists are physicians fully trained in psychopharmacology. Medications are used by child and adolescent psychiatrists as one part of a comprehensive treatment plan, which includes ongoing medical assessment, and individual and family therapy for treating psychiatric disorders in children and adolescents.

The Surgeon General's 2000 report on children's mental health estimated that 20% of American children and adolescents have a diagnosable mental or emotional illness. Of this number, fewer than one in five receive treatment. Barriers to treatment are a lack of affordability, lack of availability of specialists, including child and adolescent psychiatrists, and stigma. Anxiety disorders and depression are the most common mental illnesses occurring in children and adolescents. The growing numbers of children and adolescents with mental illnesses underscore the importance of increased study of children's mental illnesses and the critical need for more effective treatment options, including new medications.

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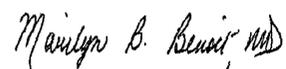
Psychotropic medications can be an effective part of the treatment for several psychiatric disorders of childhood and adolescence including ADHD, bi-polar disorder and anxiety disorder. The physical and developmental differences between children and adults require that medications used to treat adults also be tested for use by children. Prior to the Pediatric Rule and the Best Pharmaceuticals for Children Act (BPCA), psychotropic medications had not been well studied in children and adolescents, in part because studies in this age group are difficult to do and there was no incentive for the industry to conduct them. The increasing use of psychotropic medications by physicians, despite the lack of clinical trials to test safety and efficacy, was creating a public health dilemma as medication usage for children and adolescents cannot be extrapolated from adult trials with an assurance of effectiveness and safety. Thanks to the enactment of the Pediatric Rule in 1997 and the BPCA, many more pediatric clinical trails are underway that will yield important information about medications used to treat the mental illnesses of children and adolescents.

The AACAP strongly supported last year's reauthorization of the BPCA. While this program has been extremely successful in increasing the numbers of pediatric clinical trials, the program is voluntary and cannot be relied on exclusively to generate clinical trials on all drugs used for children and adolescents, including those on and off patent. The BCPCA is also time-limited and subject to future reauthorizations by Congress, which indicates a degree of uncertainty. The Pediatric Rule fills in the gaps of the BPCA by requiring that all new drugs be studied for pediatric use at the time a drug comes to market unless the FDA grants a waiver. Suspending or relaxing any requirements of the Pediatric Rule would be detrimental to the health of children and adolescents.

The AACAP has several recommendations for the strengthening of the Pediatric Rule. One is a clarification that the Pediatric Rule applies to all labeled and potential indications, and, in addition, to supplemental indications. It is important that appropriate pediatric studies be conducted for any new uses; and if the current label lacks necessary pediatric use information, 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 pediatric indications. Another recommendation is to ensure that age appropriate formulations are generated as required under the Pediatric Rule. Indications may vary for children and adolescents of different age groups, thus age appropriate indications are necessary to ensure safety and efficacy in prescribing medications. A final recommendation is broader dissemination of information gained from pediatric clinical trails. Label information and package inserts provide critical information to physicians, but more findings gleaned directly from studies would improve physician knowledge of medications.

The Pediatric Rule and the BPCA together now ensure that medical treatment planning for children and adolescents is safe and effective. The AACAP urges the FDA to maintain and strengthen this comprehensive approach to improving therapeutics for this population. Please contact Nuala S. Moore, AACAP Asst. Director of Government Affairs, at 202. 966. 7300, ext. 126, if you have any questions or would like more information about the medications used by child and adolescent psychiatrists to treat children and adolescents with mental illnesses. Thank you for your consideration.

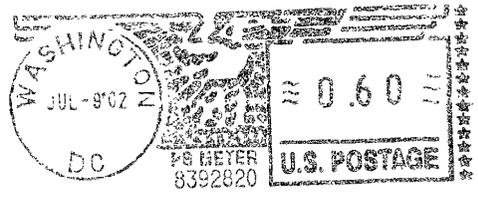
Sincerely,



Marilyn B. Benoit, M.D.
President

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