

American Academy of Child and Adolescent Psychiatry

**Statement for the
Senate Health Education, Labor and Pensions Committee Hearing on
The Best Pharmaceuticals for Children Act of 2001
May 8, 2001**

**American Academy of Child and Adolescent Psychiatry
3615 Wisconsin Avenue, N.W.
Washington, D.C. 20016
202. 966.7300
202. 966.1944
www.aacap.org**

Introduction

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 7 – 12 million American youth under 18 years of age who are affected by emotional, behavioral, developmental and mental 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 AACAP would like to thank the sponsors of the “Best Pharmaceuticals for Children Act,” Senator Chris Dodd (D-CT) and Senator Mike DeWine (R-OH). We applaud their continued commitment to pediatric research.

The Surgeon General’s 2000 report on children’s mental health estimated that 20% of American children and adolescent have a diagnosable mental or emotional illness. Of this number, fewer than one in five children receive treatment. Anxiety disorders and depression are the most common mental illnesses occurring in children and adolescents. Barriers to treatment are lack of affordability, lack of availability of specialists, including child and adolescent psychiatrists, and stigma. The stigma carried by mental illnesses is often worse in children than in adults. Parents often worry that medications will stigmatize their child. 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.

Recommendations for Reauthorization

The AACAP supports the renewal of the pediatric exclusivity provision of the FDA Modernization and Accountability Act (FDAMA). We believe that the pediatric studies

provision has advanced therapeutics for infants, children and adolescents. Prior to enactment of the pediatric exclusivity incentive in 1997, 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 substantial 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 and medication usage for children and adolescents cannot be extrapolated from adult trials with an assurance of effectiveness and safety.

The pediatric studies program has dramatically increased the amount of pediatric drug information available to physicians. Since the law was passed, FDA has granted 28 products exclusivity and 18 products have new labeling that provides dosage, safety and adverse event information to assist physicians in treating children and adolescents with the correct dose and in avoiding potential toxicities. Clinical trials are underway to establish more clearly which medications are most helpful for specific disorders and presenting problems. Clinical practice and experience, as well as research studies, help physicians determine which medications are most effective for a particular child. There are currently 15 new medications in trials that can treat mental illnesses in children and adolescents. Medications that became available for the treatment of mental illnesses in children and adolescents include Ritalin, used to treat attention deficit/hyperactivity disorder and Luvox and Prozac, both used to treat depression.

Strengthening the Law Through New Provisions

The AACAP believes there are several proposals that can further enhance the therapeutic benefits of the pediatric studies program. We applaud Sens. Dodd and DeWine for developing legislation to strengthening the pediatric studies program by addressing the problem of the lack of pediatric clinical trials in off-patent medications. Off-patent use of medications is legal and is an accepted part of medical practice, but it should not have to be standard operating procedure.

We strongly support options that will expedite labeling changes. Currently, labeling changes take from 12 – 18 months. We are hopeful that this process can be completed within 12 months.

Wider dissemination of information from pediatric trials is key to improving physicians knowledge of medications. Label information and package inserts provide critical information to physicians but more findings gleaned directly from the trials would be beneficial for physician review.

The neonate population (0- 1 month olds) is an important but difficult group to study in pediatric trials. Neonates are an especially vulnerable population, but their delicate condition should not preclude pediatric studies to determine what medications will best treat them.

Finally, the AACAP supports the establishment of an Office of Children’s Therapeutic Research within the Food and Drug Administration. The FDA has implemented the pediatric studies provision despite limited resources. We believe FDA staff specifically assigned to assess the effectiveness of pediatric studies and perform oversight, review scientific data, negotiate labels would further strengthen and expand the pediatric studies program. The AACAP urges Congress to provide the appropriate funds and resources to FDA to create an office of Children’s Therapeutic Research.

Summary

The AACAP appreciates this opportunity to submit a statement for the record on its support for extending the pediatric studies law and the related labeling and information dissemination additions to the law.

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