



**TESTIMONY OF DR. HARRY L. GEWANTER
ON BEHALF OF THE AMERICAN ACADEMY OF
PEDIATRICS**

**THE FOOD AND DRUG ADMINISTRATION
ARTHRITIS ADVISORY COMMITTEE**

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Good Morning. I am Dr. Harry L. Gewanter and am honored to speak to you today on behalf of the American Academy of Pediatrics. The Academy represents over 60,000 pediatricians whose mission is the attainment of optimal physical, mental, and social health and well being for all infants, children, adolescents, and young adults. I am a pediatrician and pediatric rheumatologist from Richmond, Virginia and am privileged to serve on the Executive Committee of the Academy's Section on Rheumatology.

The Academy does not and will not support the approval or denial of any specific medication for use in children. However, on behalf of the children we serve, especially those with juvenile rheumatoid arthritis (JRA), we do wish to emphasize a number of issues for you to consider in your deliberations.

Children are not small adults. While an obvious statement, this is often forgotten in the world of health policy discussions. Children are growing and developing human beings and their response to medications may be significantly different from that of adults. A simple example is the "delivery system" of all medications that will be administered to children. While issues such as palatability, pill size, etc., are not usually a large consideration in adults, they can be absolutely crucial in determining whether the pediatric patient will actually receive the prescribed drug. The potential benefits and risks of **any** medication may be different in children and adults and we urge you to keep this concept in the forefront throughout your discussions.

There are limited therapeutic options for children with juvenile rheumatoid arthritis. Even with the magnificent recent advances in the treatment of juvenile rheumatoid arthritis, we still have relatively few therapeutic agents available. Further, we know from the over 25 years of

pediatric trials and clinical use of Nonsteroidal Antiinflammatory Drugs (NSAIDs) that this class is generally safe and effective within the pediatric population. We also know that there is a wide range of individual responsiveness within the class. From a practical standpoint, that means we can usually find an effective NSAID for any particular child, but this choice must be individualized. It may take a number of trials before we can find the right NSAID for that child. We believe it important that pediatricians have the option of as many safe and effective NSAIDs as possible so that we may better reduce the pain and inflammation of our patients with juvenile rheumatoid arthritis.

No one can tell the future. Another obvious statement, but one that bears repeating. We are gathered in an attempt to predict the future consequences of today's decisions. No one has that ability and we can only make our best judgments based upon the admittedly incomplete data available. Regardless of whether you choose to approve or deny the application today, we need further ongoing monitoring of this and all pediatric medications so we may improve the care of the children we serve.

On behalf of the American Academy of Pediatrics, thank you for your time and the opportunity to speak today. We know that you will do your best to improve the lives of the thousands of children with juvenile rheumatoid arthritis.