FDA: Children Are Not Little Adults

Hello. Welcome to this week's version of Andy's Take. I am Dr. Murray Lumpkin. I am a pediatrician and serve you and the FDA as the FDA Deputy Commissioner for International and Special Programs. Dr. von Eschenbach is away this week, and I am delighted to have the chance to talk with you a few minutes about FDA's efforts to help assure the safest possible use of medicines in our children.

Did you know that, until recently, approximately 75% of medicines used in children did not have prescribing information on how to use these medicines safely in children? FDA efforts to implement special pediatric legislation over the past decade has led to a significant amount of new, science-based, ethically-obtained information that helps parents and physicians to more safely and more effectively use medicines in our children.

My Take is that:
Children are not simply "little adults." Their reactions to medications can be very different from adults, and simply cutting down an adult dose and giving that to a child just doesn't work – in fact, it can be very dangerous.

Our children deserve better. In the mid-1990's the American Academy of Pediatrics, FDA, and others began pushing for new legislation to correct this situation. Congress responded by passing crucial legislation that has led to a significant increase in data that should help parents and physicians use medicines more wisely in children.

New pediatric information has now been developed for over 200 drug products. New or enhanced pediatric safety information is available for 48 drugs commonly used in children. New, more accurate pediatric dosing information is now available for around 150 drug products, and over 20 new formulations have been developed specifically for children that allow parents to give a more accurate dose. This is all a tremendous step forward.

But developing the data is not enough. It is critically important that parents and physicians have access to this information. One way this information is made available is at our public Pediatric Advisory Committee meetings where national experts discuss information. This information is also on our FDA website: *http://www.fda.gov.* Simply click on the "Pediatrics" icon.

The health of children is also a concern internationally. FDA and its European counterpart are collaborating intensively to help ensure that strong, science-based data are developed to guide the safe use of medicines in children on both sides of the Atlantic.

Here in the US, we are now also using this successful pediatrics medicines model to expand efforts to other FDA-regulated products. Legislation passed last fall expands this work to pediatric medical devices and pediatric biological products.

FDA remains firmly dedicated to actively facilitating and fostering the development of sound data to guide the safest and most effective use of medicines and medical devices in our children. Children are not little adults. They are not second-class citizens. They are not guinea pigs. They are our most precious gift. Children deserve medical care based on the best data science can give us. That's my take today on FDA and its role in protecting and promoting the health of our next generation. FDA

About Andy's Take

Through this communications column on the FDA Web site, Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., will discuss weekly FDA issues of interest to the American consumer and occasionally preview upcoming FDA issues and events.

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