Improving Medical Products for Children:

Q & A with Dianne Murphy, M.D.

Dianne Murphy, M.D., is Director of FDA's Office of Pediatric Therapeutics. Dr. Murphy graduated from the Medical College of Virginia and completed her residency in Pediatrics at the University of Virginia, in Charlottesville, Virginia.

Q. What is the significance of Child Health Day?

A. Child Health Day is celebrated on the first Monday in October every year. This year it's observed on October 1, 2007, and FDA is partnering with the Health Resources and Services Administration and the American Academy of Pediatrics to focus national attention on various issues, including mental health, healthy weight, nutrition, and injury prevention. One of FDA's top priorities is giving pediatricians and parents the same level of tested and researched information on drugs used to treat children that is required for drugs used to treat adults. This effort ensures children are not denied therapies because we do not know how to properly dose or use them.

Q. What are the main areas of responsibility for FDA's Office of Pediatric Therapeutics?

A. FDA's Office of Pediatric Therapeutics (OPT) coordinates all FDA activities that may affect children. The main areas of focus for the office are safety, scientific, and ethical issues that arise during pediatric clinical trials or after a product has been approved for use in children.

We provide consults and advice to all FDA centers on pediatric issues, and we also serve as the agency's pediatric liaison with organizations and agencies outside of FDA, such as the American Academy of Pediatrics, the Elizabeth Glaser Pediatric AIDS Foundation, the National Institutes of Health, and the European Medicines Agency. We are increasingly moving into the international

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It's important to use the measuring device that comes with a child's medicine. If you don't have a medicine device for measuring liquid, ask for one at the pharmacy.

arena so we are working on issues related to pediatric clinical trials with our colleagues in Europe.

Q. What are some examples of how you work with different FDA Centers?

A. We have a very vigorous safety program with FDA's Center for Drug Evaluation and Research. We provide public reviews and discussion of adverse events that are occurring when children take medicines that have been studied under certain programs. The Center for Devices and Radiological Health and OPT have been working together in the area of obesity, and all the Centers work with us on ethical issues involving children. We have been working with FDA's Center for Food Safety and Applied Nutrition on such topics as the use of additives in infant formula. With FDA's Center for Biologics Evaluation and Research, we have had some particularly challenging ethical issues related to gene therapy for children.

Q. Why is conducting medical product research in children so important?

A. All of FDA's initiatives around pediatrics have aimed to get products that are used in children studied in children. Most of our work so far has focused on drugs, but activity is picking up in the area of medical devices.

Children are vulnerable, developing organisms that can go from 7 lbs to about 150 lbs during their maturation. They have to be studied if we are to give them safe and effective treatments. With drugs, it's not just about children being smaller. Their organs are developing and they are experiencing changes that affect how a drug is metabolized. Guessing at the dose doesn't work. Underdosing means we are denying them effective therapy. Overdosing means we are subjecting children to the risk of adverse events and if they occur, effectively removing that therapeutic option for the child. Similarly, with medical devices, children tend to be more active than adults and their body structure is changing as they grow. All of these needs should be considered when developing new medical products.

Improving the way children are studied is the only way we can improve treatments. What we don't want is to deny children lifesaving medical treatment because we don't have enough information. We have to be at the table for children because they can't do it for themselves.

Q. What are the challenges in conducting research in children?

A. The number of children in clinical trials is generally smaller than those for adults. It's also harder to do these trials. You need child-friendly environments, from age-appropriate equipment to pediatric specialists who are sensitive to a child's needs and fears. There are also more ethical issues for children. Children can't give consent the way adults can because consent implies full understanding of potential risks. Adults are able to weigh the risks and benefits and make a decision. FDA works to help others understand the special ethical issues involved in pediatric research.

Q. In your opinion, where have we made the most progress?

A. We've made enormous progress in understanding dosing, which is making for safer and more effectiveness treatments. We've reinforced the fact that you just can't halve an adult dose and give it to a child without knowing what effect that will have. We've learned that drugs are handled differently at different ages.

There were some areas that weren't getting studied until new initiatives came along to support the research. These include the selective serotonin reuptake inhibitors for depression and other pediatric psychiatric disorders, and cardiorenal and endocrine drugs, which are being used in children more and more because of childhood obesity.

Congress has helped increase studies for children by passing legislation that gives companies financial incentives to conduct pediatric studies and to require them to study a product they are developing for adults if the disease also occurs in children. This has allowed us to build a foundation for pediatric research and discover remarkable, science-based facts that we didn't know before. We have found that certain drugs produce more side effects for the nervous system in children than adults. For example, research has shown that drugs that you would not expect to have effects on behavior because the drug is treating an infection, acne, or a bladder problem, are sometimes causing adverse effects in children and may affect behavior. We are able to use this kind of information to change labeling.

Q. What precautions should parents take when giving medication to children?

A. Parents should read medicine labels carefully, the correct measuring device, and follow directions. Always measure doses carefully; too much medicine can be harmful. Ask your child's pediatrician if you have questions about giving medicine and ask the doctor or nurse to go over the best way to measure the correct amount of medicine. Remember that it's always better to double check if you are unsure. FDA

For more information, visit the Web site of the Office of Pediatric Therapeutics
www.fda.gov/oc/opt/default.htm