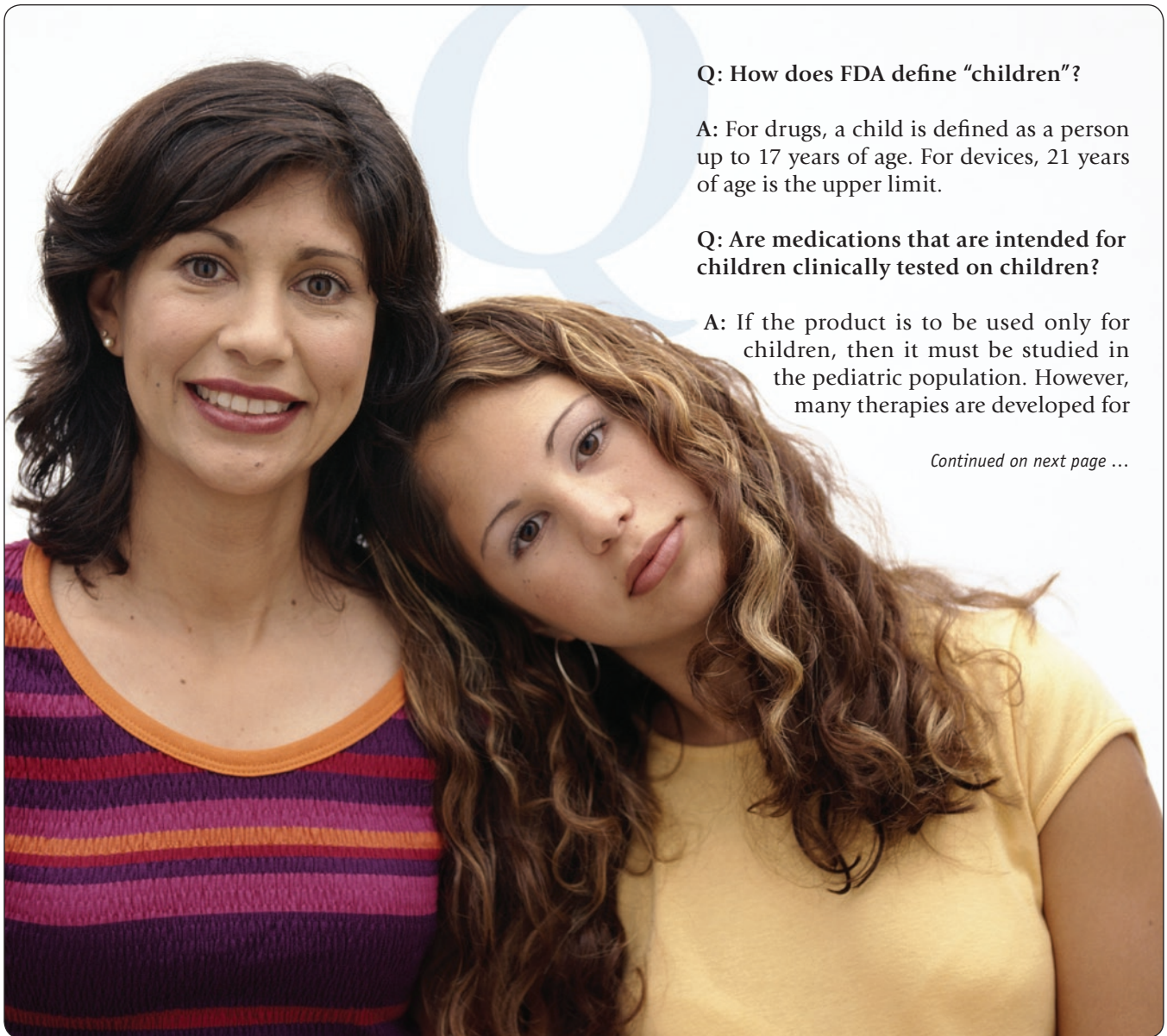


# Giving Medication to Children:

Q & A with Dianne Murphy, M.D.

**D**ianne 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. She has been with FDA since 1998.



**Q: How does FDA define “children”?**

**A:** For drugs, a child is defined as a person up to 17 years of age. For devices, 21 years of age is the upper limit.

**Q: Are medications that are intended for children clinically tested on children?**

**A:** If the product is to be used only for children, then it must be studied in the pediatric population. However, many therapies are developed for

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## *Many therapies are developed for adults and then used in children without having been studied in children.*

adults and then used in children without having been studied in children. Therefore, most marketed products that are mostly used in adults have not been studied in children—even though they may be used by doctors to treat children.

There has been improvement in this area in regard to prescription drugs. As of 2008, an estimated 50 to 60 percent of prescription drugs used to treat children have been studied in some part of the pediatric population. Still, the likelihood that a medicine has actually been studied in neonates—children less than a month old—is close to zero.

So nearly a decade into the 21st Century, most medicines intended for children, including many over-the-counter (OTC) products, haven't been clinically studied in children—and certainly not in all age populations that comprise the branch of medicine known as "pediatrics."

**Q: How can parents find out if a medication has been tested for its effects on children?**

**A:** With prescription medications, there is a "Pediatric" section in the labeling that states whether the medication has been studied for its effects on children. The label will also tell you what ages have been studied.

Most OTC products other than those for fever or pain have not actually been studied in children for effectiveness, safety, or dosing. They were approved for marketing many decades ago under a process where an expert

panel looked at the evidence, including literature, and decided if a product should continue to be sold OTC.

Most of the time, these panels did not have pediatric studies and were mostly using information collected in adults to determine if the product could be used in children.

**Q: What are the challenges with testing medications in children?**

**A:** There have been numerous challenges to studying drugs in children involving ethical, scientific, and commercial considerations.

There are extra protections for children enrolled in clinical trials because they cannot give consent and there must be compelling reasons why a trial should be conducted in the pediatric population.

Pediatric trials are in general more difficult to carry out because you must have special facilities, laboratory and radiological services, and staff who know how to work with children and their families.

Also, the market for pediatric products is small compared to the adult market because children are generally healthy and are a smaller part of the population. The high cost and difficulties associated with these trials are not attractive to sponsors who make these products.

**Q: Should OTC medications be given to a child?**

**A:** Parents need to weigh the benefit of treating the child's symptoms

against the risk of any adverse effects of the drugs. For the common cold, for example, the symptoms will run their course. Remember, OTC cough and cold products do not treat the underlying cause of the problem. They treat the symptoms.

Read the labels to make sure the product is appropriate for your child's age. Just because a product's box says that it is intended for children does not mean it is intended for children of all ages.

Also, be sure that you understand the possible side effects so you can be aware that it may not be the disease that is causing a symptom.

**Q: What should parents keep in mind when giving medication to children?**

**A:** Know that children can have different adverse reactions to a drug than adults. So for a product that has not been studied in children, it is possible for an adverse effect to occur that may not be listed on the drug's label.

Children are more sensitive than adults to many drugs. For example, antihistamines and alcohol—common ingredients in cold medications—can have adverse effects at lower doses on young patients, causing excitability or excessive drowsiness. Some drugs, like aspirin, can cause serious illness or even death in children with chickenpox or flu symptoms.

Also, realize that some diseases may be expressed differently in children than in adults, and some drugs

don't work for kids even though they have been proven to work in adults.

All of these factors underscore the importance of speaking to your health care professionals, and asking questions about the medicines that you are buying OTC or that are being prescribed for your child.

**Q: What are active ingredients, and why should parents be familiar with them?**

A: A product is made up of many components. Some of these are "inactive" and just help make it taste better or dissolve better. Unless it is a combination product, usually there is only one "active" ingredient in a medication that makes it pharmaceutically active—that is, it is what causes the medicine to be effective against the disease or condition.

Many products, including products that treat different conditions, use the same active ingredients or the same class of active ingredients. For example, products to treat allergies may have the same active ingredient as some cough and cold products. So it is possible to overdose with a certain active ingredient if you are not careful.

You should not decide what OTC medications to take or to give a child based merely on what the large print on a product's box says. You must look for the active ingredient.

If parents or caretakers really want to know if a product has been studied in the age population that their child belongs to, they really should become familiar with the pediatric section of the label for that product, and learn to compare active ingredients for OTC products.

Also, don't rely just on advertisements for information when it comes to giving medication to children. Remember, many products have not been studied in children or not in all pediatric populations. Don't hesitate to ask questions of health care professionals, including the pharmacist.

**Q: How can parents make sure they give proper dosages of a medication to a child?**

A: The main rule is: Use only as directed.

Use the measuring devices that come with the products, and use these devices as instructed. Never use home utensils such as spoons or other devices that have not been designed to measure medicine, and never have a child drink directly from a medicine bottle.

With measuring devices, pay attention to the small details. It can be easy to misread a measurement or a marking. You don't want to give your child a tablespoon when you're supposed to give him a teaspoon, or give her 5 milliliters (mls) when you're supposed to give her 0.5 mls. Mistakes like this can be deadly.

**Q: What has FDA recommended regarding OTC cough and cold medicines and young children?**

A: FDA recommends that OTC cough and cold medicines not be used to treat infants and children less than 2 years of age. Giving these products to these children can cause serious and potentially life-threatening side effects.

The serious adverse events reported with cough and cold products include death, convulsions, rapid heart rates, and decreased levels of consciousness.

Many drug manufacturers have preemptively and voluntarily withdrawn cough and cold medicines that were being sold for use in this age group. That action was strongly supported by FDA.

If you are concerned about making your child feel more comfortable, talk with your doctor about what approaches to take. If your child's cold symptoms do not improve or get worse, contact your doctor. A persistent cough may signal a more serious condition such as bronchitis or asthma.

**Q: Can parents give OTC cough and cold products to older children?**

A: FDA knows of reports of serious side effects from OTC cough and cold medicines in children 2 to 11 years of age, but we haven't completed our review of information about the safety of these products in children of this age. [FDA](#)

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This article appears on FDA's Consumer Update page ([www.fda.gov/ForConsumers/ConsumerUpdates/default.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm)) which features the latest on all FDA-regulated products.

**For More Information**

Using Over-the-Counter Cough and Cold Products in Children  
[www.fda.gov/ForConsumers/ConsumerUpdates/ucm048515.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048515.htm)

OTC Cough and Cold Products: Not For Infants and Children Under 2 Years of Age  
[www.fda.gov/ForConsumers/ConsumerUpdates/ucm048682.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048682.htm)

Should Your Child Be in a Clinical Trial?  
[www.fda.gov/ForConsumers/ConsumerUpdates/ucm048699](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048699)