## Drug Firms Studying How Medicines Affect Kids

According to a story by Lisa Richwine of the Reuters news service in the 1960s, several newborn babies died after being given an adult antibiotic that their tiny livers could not break down, proving that, when it comes to medicine, children are not just "little adults."

Despite that lesson four decades ago, pediatricians remain in the dark about how most medicines affect their patients. Only about a fourth of all drugs have been tested in children, leaving doctors at times guessing at the best treatments.

“That has left the medical community that cares for children in a very difficult situation,” said Dr. Ralph Kauffman of Children’s Mercy Hospital in Kansas City. “We either have to deny children useful medicines or we have to give them medicines without adequate prescribing information.”

But new data is coming in thanks to incentives begun two years ago, which have sent companies scrambling to do pediatric studies.

“The interest in developing the type of trials that need to be done has been pretty phenomenal,” Dr. Dianne Murphy, associate director of pediatrics at the US Food and Drug Administration drug evaluation center, said.

“The important thing is you can’t just do any study. FDA determines if there is to be a public health benefit.”

So far, drugmakers have proposed about 200 pediatric studies for medications for AIDS, allergies, asthma, depression and nearly every other ailment that afflicts children. The research could involve more than 20,000 children, from newborns to adolescents. By contrast, only 11 studies on children were done from 1991 to 1997, she said.

And starting this month, a federal rule gives the FDA power to require pediatric studies for drugs that might benefit children. Regulators want to know what doses work best for children and whether some drugs might produce unexpected reactions when they interact with kids’ immature organs and different bodily systems.

Doing research with children is not easy. Companies used to working with adult volunteers need to find researchers with the expertise to help run pediatric studies and address their unique challenges.

For years, people worried that using children as guinea pigs was unethical. But Dr. Robert Ward, professor of pediatrics at the University of Utah, said he views that as largely settled.

“We are treating children with less than optimal information about effectiveness, dosing and safety. You just have to ask yourself: What is more unethical? To treat a child in that situation or to treat a child in part of a controlled clinical trial?” Ward said.

Doctors still must work to convince parents to expose their children to unknown risks and subject the kids to blood and other tests they normally may not need. The pool for recruits is small because there are fewer sick children than adults.

In addition, getting children to cooperate can be tough.

Younger ones may have trouble swallowing pills or may not take a medicine because it tastes bad. In those cases, researchers need to develop kid-friendly formulations. Equipment must be scaled down and tests redesigned to analyze smaller samples.

“You can’t draw a bucket of blood from babies,” Kauffman noted.

And how do you ask very young children to describe pain? Researchers need to find new measurements of whether medicines are working. Also, to minimize any fear of going to see a doctor, some research centers are being revamped with bright colors, games and activities to make the experience fun.