Feds to Study Health Effects of BPA

BY ELIZABETH MECHCATIE

The potential health effects of exposure to bisphenol A, the chemical compound used in baby bottles and many different food and beverage packages, will be studied in short- and long-term trials in animals and humans, William Corr, deputy secretary of the Department of Health and Human Services, announced during a briefing.

More than $30 million will be provided by the National Institute of Environmental Health Sciences for studies to be conducted by the Food and Drug Administration, the National Institutes of Health, and other institutions. Results are expected in 18-24 months, he said.

In the meantime, HHS has issued recommendations for consumers on simple steps they can take now to reduce infants' exposure to BPA, including discarding scratched baby bottles and infant "sippie" cups and being careful about how breast milk or formula is heated, he said.

The recommendations, with information on what is currently understood about the effects of BPA on health, are posted on the HHS Web site (www.hhs.gov/safety/bpa).

BPA is a component of the epoxy resin that lines many food containers, as well as plastic used in a range of products that includes baby bottles and water bottles. Small amounts of BPA have been detected in canned liquid infant formula, but powdered formula generally does not have detectable levels, said the HHS.

During the briefing, Linda Birnbaum, Ph.D., director of the National Institute of Environmental Health Sciences and director of the National Toxicology Program (NTP), said that a "growing body of evidence" indicates that BPA exposure may be harmful to humans, but more data are needed on the potential health effects, which might involve behavior, obesity, reproductive disorders, diabetes, cardiovascular disease, asthma, and cancer.

FDA commissioner Dr. Margaret Hamburg said at the briefing that the FDA's assessment of the potential risks of BPA exposure is now in line with the NTP's assessment that there is a basis for "some concern." In an August 2008 draft assessment of the health risks of BPA, the FDA said that, based on a review of toxicology research and other information, exposure to BPA-containing materials is safe. However, the NTP followed with a report that concluded there was a basis for "some concern" about the potential health effects of BPA. The FDA's change in position was a result of the agency's evaluation of data that became available since the NTP report was released, Dr. Hamburg said.

A 'growing body of evidence' indicates that BPA exposure may be harmful, but more data are needed on potential health effects, which might involve a wide range of medical disorders.

The recommendations for parents include the advice to follow guidelines for feeding infants, which includes breastfeeding for at least 12 months. If breastfeeding is not an option, iron-fortified formula is the safest and most nutritious alternative, and although trace amounts of BPA have been detected in canned formula, good nutrition "outweighs any potential risks of BPA," Mr. Corr said.

The recommendations also advise letting boiled water cool to a lukewarm temperature before mixing it with powdered formula, avoiding heating baby bottles in a microwave, allowing bottles to cool to room temperature before adding infant formula, and avoiding putting boiling or very hot water, formula, or any other liquids in bottles that contain BPA.

According to the HHS information sheet, the six major manufacturers of baby bottles and infant feeding cups—which represent over 90% of the U.S. market—have not manufactured these products with BPA for the U.S. market since January 2009. ■

Awardee to Develop FDA Safety System

The Food and Drug Administration announced that it has chosen Harvard Pilgrim Health Care Inc. to design a pilot of a new safety monitoring system.

The agency said that the program, called the Sentinel System, will help it keep closer tabs on safety problems because it will analyze information collected during routine health care. The system will allow the agency to collect data on drugs and devices at the source—from medical records. For instance, if the agency knew that a device or drug had been linked to cardiac side effects, FDA safety officers could query the Sentinel System to see if such problems had arisen.

Congress required the FDA to develop such a safety system as part of the Food and Drug Administration Amendments Act of 2007. It was also recommended by the Institute of Medicine in a 2006 report on drug safety.

"Once operational, the Sentinel System will help us find answers to important drug safety questions, leading to stronger safeguards for public health, while still protecting the privacy and security of individual health information," said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, in a statement.

—Alicia Ault

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