THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS

AAP News

DEDICATED TO THE HEALTH OF ALL CHILDREN

Volume 34 • Number 11
November 2013
www.aapnews.org

Washington Report

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DEPARTMENT OF FEDERAL AFFAIRS
AMERICAN ACADEMY OF PEDIATRICS

AAP outlines agenda with FDA, marks milestone for pediatric drug use

Regulating flavored tobacco products, improving the labeling of medications used for children and limiting the marketing of caffeinated beverages to youth are part of the ambitious agenda the Academy is undertaking with the Food and Drug Administration (FDA).

As with a number of federal agencies, the FDA's child health agenda is wide-reaching. However, the agency is unusual in that it is advancing so many pediatric priorities simultaneously. Following is a review of the Academy's FDA agenda as well as its strategy to elevate the needs of children.

500 drug labels revised with pediatric information

Recently, the FDA reached the historic milestone of 500 drug labels being revised with pediatric information (see article on page 21).

These label changes were made possible by laws championed by the Academy: the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) passed in 1997 and 2003, respectively, and made permanent through reauthorization last year. Prior to their passage, most medicines used to treat children had been tested for safety and efficacy only in adults.

"Children are not just small adults; they may need a different dose of a medication than an adult, may require safety precautions or may benefit from a different use of the drug altogether," said AAP President Thomas K. McInerny, M.D., FAAP. "We now have 500 drug labels that include just this type of information for children, which has not only revolutionized pediatric practice, but has also helped provide children with access to safe and effective medicines labeled especially for them."

Drugs studied under BPCA and PREA treat a range of diseases, including HIV/AIDS, cancer, diabetes, allergy and asthma. The laws also have helped reduce off-label use of drugs in children from approximately 80% to about 50%.

In addition to ensuring that drugs are labeled appropriately for children, the Academy has led efforts to limit shortages of medications used in pediatric populations.

Tobacco prevention

The Academy recently partnered with the American Lung Association and 14 other medical and public health groups to send a letter to President Obama urging his support for FDA authority to regulate all tobacco products, including e-cigarettes and cigars.

The FDA prohibited the sale of candy-flavored cigarettes four years ago. However, it does not have authority over cigars and e-cigarettes, which can be marketed to attract young people by using flavors like cotton candy, grape and strawberry. (See Parent Plus on page 24.)

Dr. McInerny and American Lung Association President Harold Wimmer co-wrote an op-ed piece in the *Chicago Tribune* calling on the administration to give the FDA oversight over these products.

Menthol cigarettes, which also are exempt from the ban on candy-flavored cigarettes, are another area of focus for the Academy. Last summer, the FDA published a report finding that menthol in cigarettes increases adolescent smoking initiation, makes nicotine addiction stronger and inhibits smoking cessation. For the first time, the agency went on record in concluding that "menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes."

The Academy will submit comments this month in response to the FDA's request for feedback on whether it should prohibit menthol cigarettes.

"For years, pediatricians have called for the elimination of all flavored tobacco products, including menthol," said Dr. McInerny. "We know that candy and other flavors make tobacco products more attractive to children, and it's time to stop manufacturing products that we know will lead many of today's children to nicotine addiction, unnecessary illness and premature death."

Arsenic in food products

The Academy is monitoring the FDA's ongoing evaluation of arsenic levels in food products and is educating the public on the agency's findings.

The FDA recently proposed an "action level" of 10 parts per billion for inorganic arsenic in apple juice, the same level set by the Environmental Protection Agency for drinking water. An action level provides industry with guidance and is used by the FDA when it considers taking action if a product exceeds the threshold.

The Academy issued a statement indicating that while apple juice is safe overall, parents should limit how much of any type of juice their children drink because the beverages contain high levels of sugar.

A recent FDA analysis of arsenic in rice and rice products found that overall levels are safe in terms of short-term consumption, with variable levels in different products. The agency is conducting a risk assessment based on long-term exposure. The Academy issued a statement suggesting that parents include a variety of grains in their children's diet.

The Academy will continue to work with the FDA and other federal agencies to limit the use of arsenical compounds in food and beverages.

Energy drinks

Marcie Schneider, M.D., FAAP, a former member of the AAP Committee on Nutrition and a lead author of the AAP clinical report on sports and energy drinks, testified last summer before a Senate committee about the safety of energy drinks and marketing of these products to children. Dr. Schneider emphasized AAP recommendations of increased public awareness, media literacy, labeling changes, research and governmental policies to reduce the amount of caffeine in energy drinks.

Senators echoed the AAP recommendation that energy drinks are not appropriate for children and adolescents, and questioned industry executives about their marketing to children under the age of 12.

Energy drinks can contain three to five times more caffeine than a cup of coffee. However, the FDA's ability regulate the amount of caffeine is limited because some drinks are sold as dietary supplements. The FDA is investigating the health effects of energy drinks, which may mean changes to the energy drink industry. The Academy is monitoring this issue.

Food safety

The FDA Food Safety Modernization Act, signed into law by President Obama in January 2011, initiated sweeping changes to the food safety system. This year, three of the law's major provisions were released as proposed rules to improve preventive controls in food facilities and to ensure the safety of fresh produce and imported foods. However, implementation of the law remains behind schedule, adequate funding is uncertain and some members of Congress are offering legislative proposals that would undermine its continued implementation.

The Academy organized a letter last year from pediatricians to President Obama urging rapid implementation and full funding of the act. It also facilitated publication of letters to the editor emphasizing the vulnerability of children to foodborne illness, and will submit comments to the FDA on the importance of these rules to public and child health.

Judicious use of antibiotics

Through comments to the FDA, letters to President Obama, meetings with key agency staff and work with coalition partners, the Academy continues to urge the FDA to finalize a pair of proposals that would reduce nontherapeutic use of antibiotics in animals used for food (see related article on page 11).

The Academy co-chairs a working group of more than 40 medical, public health and consumer organizations committed to addressing antibiotic overuse in animal agriculture to better assess its relationship to antibiotic-resistant disease in humans. The Academy also co-hosted the second Supermoms Against Superbugs event in Washington, D.C., to raise awareness of antimicrobial resistance and the need for improved federal oversight of antibiotics in animal agriculture. The event featured more than 50 caregivers, farmers, chefs, veterinarians, pediatricians and other advocates concerned about antibiotic resistance.