

POLICY & PRACTICE

FDA Would Expand Promotion

The Food and Drug Administration last month proposed draft guidance that would allow drug and medical device makers to distribute medical or scientific journal articles and reference publications that involve unapproved uses of FDA-approved drugs and medical devices. Drug and device makers had been allowed to disseminate such materials under guidelines set by the FDA, but that authority expired in September 2006.

The FDA's new "Good Reprint Practices" draft guidance states that the article or reference should be published by an organization that has an editorial board and fully discloses conflicts of interest. In addition, articles should be peer reviewed, and manufacturers should not distribute special supplements or publications funded by product manufacturers, or articles not supported by credible medical evidence.

Rep. Henry Waxman (D-Calif.), chairman of the House Committee on Oversight and Government Reform, blasted the FDA for its proposal, which he said in a statement "is great news for the drug industry but terrible for the public health. It caters to the industry's desire to market [its] products without adequate testing or review. The FDA should suspend its pro-

posal to weaken the law until Congress can ensure that the new policies will protect the American people."

Products Threaten Tobacco Progress

An "insidious" new generation of tobacco products is threatening efforts to reduce tobacco use in the United States, warned a new report from a coalition of public health organizations. The report, funded by the Robert Wood Johnson Foundation and produced by a coalition that includes the American Cancer Society, the American Heart Association, the American Lung Association, and the Campaign for Tobacco-Free Kids, describes how tobacco manufacturers are finding new ways to gain new users, especially children, and to discourage quitting. For example, cigarettes, smokeless tobacco, and cigars have been introduced in an array of candy, fruit, and alcohol flavors, and new smokeless products have been marketed as ways to help smokers sustain their addiction in the growing number of places where they cannot smoke, the report said. New products and marketing have been aimed at women, girls, and other populations. For example, R.J. Reynolds' Camel cigarettes now are available in pink, according to the report, and smokeless tobacco now comes in teabaglike pouches and even in

dissolvable, candylike tablets. "Until Congress grants the FDA authority over tobacco products, America's kids and consumers will remain guinea pigs in the tobacco industry's never-ending experiments to sell more of its deadly and addictive products," William Corr, executive director of the Campaign for Tobacco-Free Kids, said in a statement.

ADA: Amalgam Fillings Safe

Dental amalgam tooth fillings do not adversely affect children's brain development and neurologic status, researchers reported in the February issue of *The Journal of the American Dental Association*. The authors of the report studied the possible neurologic effects of dental amalgam, which contains elemental mercury combined with other metals such as copper, silver, tin, and zinc. Beginning in 1997, the team followed 507 Portuguese children aged 8-12 years who received either amalgam or resin-based composite fillings, conducting clinical neurologic exams to assess two types of neurologic signs: hard (indicating damage to specific neural structures), and soft (subtle signs of central nervous system dysfunction that likely point to immature sensory-motor skills rather than to any structural damage in the brain). The researchers also evaluated the children for presence of tremor. After 7 years, the two groups of children did not

differ in any of the measures. "Even at the levels of amalgam exposure in this study (a mean of 7.7-10.7 amalgam surfaces per subject), [we] conclude that exposure to mercury from dental amalgam does not adversely affect neurological status," the authors wrote.

Early Intervention in Autism Tested

Researchers at the University of Washington, Seattle, are investigating the benefits of early parental intervention with young siblings of children who have autism spectrum disorders, in effect testing whether extra interaction between these babies and young toddlers and their parents can prevent or reduce the delays in social interaction associated with such disorders.

The study will test such techniques as coos, lilting speech, eye contact and other interactions delivered by parents. The \$11.3 million research project is expected to include 200 6-month-old babies from the Seattle area who have older siblings already diagnosed with autism or another autism spectrum disorder. Parents will receive developmental evaluations along with advice regarding appropriate services, and those families assigned to the intervention group will receive parent training, and, if appropriate, more intensive intervention for their infants.

—Jane Anderson

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