JAOA

# federal update

## From the CDC

### Alcohol-related birth defects soar

Fetal alcohol syndrome (FAS) has increased sixfold during a 15-year period, according to figures from the Centers for Disease Control and Prevention (CDC). During 1979 to 1993, the number of such cases rose from 1 per 10,000 births to 6.7 per 10,000 births. A total of 2032 cases of FAS were reported per 9.4 million births during this period.

Whether the reported increase is due to greater diagnostic accuracy or an increase in the number of women who drink during their pregnancy remains uncertain.

One fifth of the women continued to imbibe even after they found out they were pregnant, according to the CDC.

## From the FDA

### Approval of medical devices to be accelerated

In a pilot program, medical devices deemed to pose a low or medium health risk will be tested by private medical groups rather than the US Food and Drug Administration (FDA). The change is intended to cut through the bureaucracy.

In testimony before an April hearing of the Senate Labor and Human Resources Committe, FDA Commissioner David A. Kessler, MD, made assurances that the safety of drugs and medical instruments will not be jeopardized. "We believe many medical devices simply don't pose a sufficient risk to be reviewed by the FDA prior to marketing," he maintained.

The 2-year pilot program will affect 10 additional categories of medical devices. The FDA already has exempted 125 categories from government approval before being marketed. These include syringes, oxygen masks, and certain surgical lasers.

Manufacturers of these devices will pay for the reviews by private medical groups. The pilot program is expected to begin in 1997.

In a related matter, the FDA will allow the exportation of drugs to other countries that have not yet been approved for marketing in the United States but *are* approved in the destination countries.

### New class of asthma drug receives advisory approval

The Pulmonary and Allergy Drugs Advisory Committee to the FDA has recommended approval of Leutrol (zileuton) for the treatment of chronic asthma. Part of a new class of compounds called 5-lipoxygenase inhibitors, zileuton blocks the formation of leukotrienes.

In clinical trials involving more than 2500 patients, the drug was found to decrease the use of other concomitant medications, including inhaled beta-agonists and corticosteroids. Side effects included dyspepsia, abdominal pain, dizziness, and insomnia. ◆