

## POLICY & PRACTICE

### FDA to Regulate Tobacco at Last?

It seemed like back to the future in Washington on Feb. 15, when Sen. Edward M. Kennedy (D-Mass.) presided at a press briefing to announce a proposal that would give the Food and Drug Administration the authority to regulate cigarettes as a drug delivery device. In the mid-1990s, Dr. David Kessler, then FDA commissioner, made a bid to do just that, but lost in a battle that ended at the Supreme Court. Since that time, congressional bids to extend FDA's purview have failed. Sen. Kennedy declared that 2007 is the lucky year. "The likelihood of passage is extremely high," he said of his bill, which according to cosponsor Sen. John Cornyn (R-Tex.) already has 30 allies, 11 of them Republicans. Rep. Henry Waxman (D-Calif.), introducing the House companion bill, agreed that "this is the year it will become law," noting that 100 of his colleagues are ready to sign on. The bill would give FDA more power to restrict tobacco ads and sales to children in particular, require reduction of nicotine levels, and necessitate bigger and more informative warnings on tobacco products. FDA could not ban nicotine-containing products.

### Parents Need Help With Safety LATCH

The National Highway Traffic Safety Administration held a summit in early February urging child safety seat and automobile makers, retailers and consumer groups to make it easier for parents to install the seats in vehicles. "Our children are precious and parents and caregivers must have the information they need to properly install their car seats," said NHTSA Administrator Nicole R. Nason in a statement. In December, a NHTSA survey found that 40% of parents relied on seat belts when installing a car seat, instead of new safety technology, known as Lower Anchors and Tethers for Children (LATCH). The technology is standard in vehicles made since 2002. Only 55% of parents surveyed used the top tether.

### Lead Testing Measure Proposed

The National Committee for Quality Assurance is proposing a new quality measure for 2008 that calls for children under age 2 years who are enrolled in Medicaid managed care plans to be tested for exposure to lead. "Lead poisoning can have a devastating impact on child development. Screening is simple and inexpensive. There's no reason for this not to be part of routine well-child care for those at risk," Dr. Greg Pawlson, NCQA executive vice president, said in a statement. The proposed Health Plan Employer Data and Information Set (HEDIS) measure would be aimed at helping to detect elevated levels of lead exposure among the 310,000 children that are presumed to be at risk for lead poisoning. In addition to the health implications, studies estimate that children with high levels of lead in their blood incur an average of \$1,300 in avoidable medical costs, according to NCQA. The final HEDIS standards will be released this summer. In the first year that a HEDIS measure is rolled out, data are collected, reported, and audited, but the results are not publicly reported.

### Bill Addresses Custody of Mentally Ill

New federal legislation aims to help parents obtain mental health treatment for their children without losing custody. The bill (H.R. 687/S. 382), which was introduced in both the House and the Senate, would authorize \$100 million in family support grants to states that chose to end the practice of forcing parents to relinquish custody of mentally ill children to state agencies to receive mental health services. The legislation was prompted by an April 2003 report from the Government Accountability Office, which found that more than 12,000

children from 19 states were placed in the juvenile justice system to receive mental health treatment in 2001. The grants created by the legislation could be used to improve access to mental health and other family support services or to create statewide care coordination program. "It is simply unconscionable that families are forced to choose between custody of their children and the mental health services they desperately need," Rep. Jim Ramstad (R-Minn.), one of the sponsors of the legislation, said in a statement.

### Katrina's Long-Term Emotional Impact

Mississippi children and families displaced

by Hurricane Katrina continue to have emotional problems, according to a report from Columbia University and the Children's Health Fund. The researchers interviewed 576 adults from randomly selected households displaced by the hurricane and found that more than half of the parents reported that at least one child in the family had experienced emotional or behavioral issues following Katrina, but only 29% had sought some form of professional help. The findings mirror the results of a similar survey of Louisiana families released last year by Columbia University and the Children's Health Fund.

—Alicia Ault

## Oddly enough, the way they describe their GERD may be why it's often overlooked.



- #1 prescribed acid-suppressing agent by PGEs\*<sup>2</sup>
- Only FDA-approved PPI for kids as young as 12 months<sup>3,8</sup>
- Available as capsules and strawberry-flavored PREVACID for Oral Suspension or PREVACID SoluTab



### Important safety and other information

- The safety and effectiveness of PREVACID have been established in patients 12 months to 17 years of age for the short-term treatment of symptomatic GERD and erosive esophagitis.
- PREVACID use in this population is supported by evidence from adequate and well-controlled studies in adults along with additional clinical and PK/PD studies performed in pediatric patients. The pediatric studies were uncontrolled, open-label studies performed in 66 patients aged 1 to 11 years old and 87 patients aged 12 to 17 years old. The safety and effectiveness of PREVACID have not been established in patients <1 year of age.
- The most frequently reported adverse events in patients aged 1 to 11 years were constipation (5%) and headache (3%).

In patients aged 12 to 17 years, the most frequently reported adverse events were headache (7%), abdominal pain (5%), nausea (3%), and dizziness (3%). The adverse event profile in children and adolescents resembled that of adults taking PREVACID, where the most common adverse events were diarrhea (3.8%), abdominal pain (2.1%), and nausea (1.3%). Symptomatic response to therapy does not preclude the presence of gastric malignancy. PREVACID formulations are contraindicated in patients with known hypersensitivity to any component of the formulation.

Individual results may vary.

See adjacent page for brief summary of prescribing information.

\*Based on IMS Health Xponent® data, December 2005.

Visit [www.prevakidsHCP.com](http://www.prevakidsHCP.com) for more information.

References 1. Rudolph CD, Mazur LJ, Liptak GS, et al. *J Pediatr Gastroenterol Nutr.* 2001;32(suppl 2):S1-S31. 2. Data on file, TAP Pharmaceutical Products Inc. 3. PREVACID Complete Prescribing Information. 4. Aciphex® (rabeprazole sodium) Complete Prescribing Information. 5. Nexium® (esomeprazole magnesium) Complete Prescribing Information. 6. Prilosec® (omeprazole) Complete Prescribing Information. 7. Protonix® (pantoprazole sodium) Complete Prescribing Information. 8. Zegerid™ (omeprazole) Complete Prescribing Information.

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