# POLICY & PRACTICE

## Mandating HPV Vaccination

Under a proposal gaining momentum in Michigan, vaccination against human papillomavirus (HPV) would be required for all girls entering the sixth grade beginning next school year. Two pieces of legislation introduced in the Michigan state senate last month would require the HPV vaccine to be added to the roster of required immunizations for the state's public and private schools. While the vaccine would be required, parents could choose to opt out for medical, religious, or philosophical reasons. If this legislation is passed by the legislature and signed by the governor, Michigan would be the first state to require the HPV vaccine for school entry, according to state Sen. Beverly Hammerstrom, a Republican, who introduced the bills. "Recent studies have shown that cervical cancer may be one of the few cancers that is actually preventable. This new vaccine will serve as our most effective tool in the fight against cervical cancer," she said in a statement. "For the first time in history, we have an opportunity to finally eliminate this deadly disease." The bills have the support of all of the women in the Michigan senate, according to Sen. Hammerstrom. The FDA approved one HPV vaccine (Gardasil) for girls and women aged 9-26 in June. Also in June, the Advisory Committee on Immunization Practices, which advises officials at the Centers for Disease Control and Prevention, recommended routine vaccination in girls 11-12 years old and permissive use in individuals aged 9-26.

## Exclusivity Data Not Reaching Doctors

Results from a huge number of trials undertaken specifically to investigate dosing, safety, or efficacy of pharmaceuticals in children are not reaching clinicians, researchers from the FDA and the Duke Clinical Research Institute reported. They examined studies conducted from 1998 to 2004 by manufacturers seeking patent extensions under the FDA's pediatric exclusivity rule. During that time, 253 studies were submitted to the FDA—125 evaluating efficacy, 51 on multidose pharmacokinetics, 34 on single-dose pharmacokinetics, and 43 on safety. For half (127), the results indicated a label change, but only 113 were published. Studies that showed efficacy or had results that gave rise to a positive labeling change were more likely to be published, wrote the authors in the Sept. 13 issue of the Journal of the American Medical Association. Of 100 trials associated with a key labeling change—that is, one that would show substantive dosing changes, new safety information, or lack of efficacy in phase III—only 37 were published. While the pediatric exclusivity rule has promoted new research, "the research has not been consistently disseminated into the peer-reviewed medical literature"—a crucial step to educating and notifying the prescriber, said the authors.

## Gaps in Mental Health Knowledge

Clinicians now have better information on the short-term efficacy of medications for children with mental illnesses and behavioral problems, but there is a need for more evidence on the long-term impact and safety of these therapies, according to a report from the American Psychological Association. More research also needs to be conducted in practice settings to show the benefits of therapies under real-life conditions, the report said. The report, which was produced by the APsA Working Group on Psychotropic Medications for Children and Adolescents, provides a review of the current literature on the use, sequencing, and integration of psychotropic medications and psychosocial interventions in children and adolescents. The group found that evidence for treatment efficacy is "uneven" across disorders, with most of the research attention focused on childhood ADHD, adolescent depression, and anxiety disorders. But there is less information on treatment efficacy available for some of the most severe conditions, including bipolar disorder and schizophrenia, the report noted.

## FDA Brings on New Ethicist

Dr. Robert M. Nelson, who has served as the chairman of the Food and Drug Administration's Pediatric Advisory Committee for the last 2 years, is joining the agency full-time as an ethicist in the Office of Pediatric Therapeutics. Dr. Nelson is an associate professor of anesthesiology and critical care at the Children's Hospital of Philadelphia; he will keep his faculty appointments at the University of Pennsylvania, Philadelphia. Dr. Nelson is also a former chairman of the American Academy of Pediatrics' Committee on Bioethics. At the Office of Therapeutics, he will guide the agency on issues related to pediatric clinical trials and products that may have an impact on children. "His expertise and experience further bolster our ability to ensure the highest level of scientific and ethical rigor in pediatric clinical research," said FDA acting commissioner Dr. Andrew von Eschenbach in a statement.

**—From staff reports**



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