News From the Food and Drug Administration

Vaccine Approved in Pregnancy to Protect Young Infants
The FDA recently approved the use of Boostrix (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine, adsorbed [Tdap] vaccine) for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age.

This is the first time the FDA has approved the use of a vaccine during pregnancy to protect infants who are too young to be vaccinated themselves.

The vaccine was previously approved for use during pregnancy to protect the person receiving the injection. Since 2012, the US Centers for Disease Control and Prevention has recommended that all pregnant individuals receive a Tdap vaccine during their third trimester.

"Babies are at highest risk for getting pertussis and having serious complications from it," Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, said in a statement. Most serious pertussis cases, hospitalizations, and deaths occur among infants younger than 2 months, according to the FDA.

The FDA's determination of effectiveness relied on a reanalysis of data from an observational case-control study involving 108 young infants who had contracted pertussis and 183 who hadn't. Four mothers of infants in the first group and 18 in the second group had been vaccinated during the third trimester. A preliminary estimate of 78% effectiveness was consistent with that found in other published observational studies, according to the FDA.

The vaccine's safety during the third trimester was evaluated in a placebo-controlled randomized clinical trial with approximately 680 pregnant individuals; half received the vaccine and half received the saline placebo injection. After childbirth, the placebo group also received the vaccine.

The rates of adverse effects reported by trial participants who received the vaccine during the third trimester were similar to those reported by participants who received it after delivery. No vaccine-related adverse effects on pregnancy or the fetus or newborn were seen.

The vaccine used in the trial was a non-US formulation that contains the same components as the US version but with more aluminum, the FDA noted.

Tackling Young People's e-Cigarette Use
More than 2.5 million US middle and high school students report current e-cigarette use, according to data from the 2022 National Youth Tobacco Survey (NYTS) recently released by the FDA and the US Centers for Disease Control and Prevention.

The online survey, conducted in January through May, found that 3.3% of middle school students and 14.1% of high school students reported they had used e-cigarettes, also known as vaping, within the previous 30 days. Among the e-cigarette users, nearly 85% reported using flavored e-cigarettes, and 27.6% reported using e-cigarettes daily. The ability to compare 2022 findings with those from previous NYTS waves is limited because of methodological changes in recent years, according to the FDA.

The most commonly used device type was disposables, with Puff Bar, Vuse, and Hyde reported as the 3 most commonly used brands, the FDA said.

The FDA also announced taking steps against 2 of those brands. It issued a warning letter to EVO Brands LLC and PVG2 LLC, doing business as Puff Bar, for receiving and delivering e-cigarettes in the US that are nontobacco nicotine products without a marketing authorization order. A new federal law, effective April 14, 2022, clarifies that the FDA has the authority to regulate products containing nicotine from any source, whether from tobacco or not.

In addition, the FDA ordered Magellan Technology to stop selling and distributing 32 Hyde e-cigarettes because the company did not demonstrate that the fruit-flavored products would provide a benefit to adult users that would outweigh risks to youths. As with the Puff Bar e-cigarettes, none of the Hyde e-cigarettes has received marketing authorization orders from the FDA, so selling or distributing them is illegal.

"FDA is actively working to identify violations and to swiftly seek corrective actions, particularly for products popular among youth," Brian King, PhD, MPH, director of the FDA's Center for Tobacco Products, said in a statement.

New Funding for Research Into Rare Diseases Treatments
The FDA's Orphan Products Grants Program recently awarded $38 million in funding over the next 4 years to advance the development of medical products to treat rare diseases.

"One of the greatest obstacles facing individuals who suffer from rare diseases is the limited treatment options currently available," FDA Commissioner Robert Califf, MD, said in a statement. Since the

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Orphan Products Grants Program was created in 1983, it has facilitated the approval of more than 80 rare disease products, Califf added.

Eleven of the new grants are for clinical trials supporting the development of rare disease treatments; 7 of the 11 fund studies of rare cancers, mostly of the brain and peripheral nerves. Eight grants, totaling more than $11 million, support natural history studies, several of which seek to characterize subgroups within a disease and to identify novel clinical outcome measures and biomarkers. Three of the natural history studies are related to rare neurodegenerative diseases, including 1 for amyotrophic lateral sclerosis (ALS) that is partially funded by the National Institutes of Health (NIH).

Two new contracts, related to rare neurodegenerative diseases, were also awarded. One, co-funded by the FDA and the NIH, involves a study to determine whether a physical assessment of patients with ALS can be conducted remotely instead of in a health care professional’s office. The second contract is for an analysis of patient preference information studies focused on brain-computer interface devices that could enable people who are no longer able to speak or move to interact with their families and health care professionals. –Rita Rubin, MA

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