

Top news stories from AMA Morning Rounds®: Week of Oct. 25, 2021

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Benefits of Pfizer/BioNTech COVID-19 vaccine outweigh risks in children ages 5 to 11, FDA review finds

The Washington Post (10/22, A1, Johnson, McGinley) reported that the Pfizer-BioNTech COVID-19 “vaccine appears poised to become available to children 5 to 11 years old within weeks, after” an FDA “review found the benefits of the shot outweigh the risks in most scenarios.” The agency’s review “found that for four scenarios that were weighed, ‘the benefits of the Pfizer-BioNTech COVID-19 Vaccine 2-dose primary series clearly outweigh the risks.’” In one scenario, however, “when the virus was at its lowest levels, there could be more hospitalizations related to a rare heart side effect [myocarditis] associated with the vaccine than the number of hospitalizations prevented from COVID-19, the illness caused by the virus.”

NIH to invest \$70M to increase availability of rapid at-home COVID-19 tests

The Washington Post (10/25, Abutaleb) reports, “The Biden administration announced additional steps on Monday to increase the availability of rapid at-home coronavirus tests and bring down their cost” through a \$70 million National Institutes of Health investment “to help manufacturers navigate the Food and Drug Administration’s regulatory process.” The NIH “aims to speed up the authorization process for new tests by helping manufacturers produce the data regulators need.”

The Wall Street Journal (10/25, Abbott, Subscription Publication) reports rapid coronavirus tests have been difficult to find on e-commerce sites and pharmacy shelves since late summer.

According to Reuters (10/25, Roy), “The FDA is also streamlining its regulatory pathway for manufacturers developing over-the-counter at-home tests.” Separately, the FDA “said it has issued emergency use authorization to another rapid antigen test developed by Celltrion Diatrust, bringing the total number of rapid, at-home tests available to the public to 10.”

FDA panel backs Pfizer-BioNTech COVID-19 vaccine for children ages 5 to 11

The New York Times (10/26, LaFraniere, Weiland) reports, “An independent committee of experts advising the Food and Drug Administration met on Tuesday and voted to recommend authorizing the Pfizer-BioNTech coronavirus vaccine for children 5 to 11 years old, opening the way to inoculating 28 million children in the United States.” If both the FDA and CDC “rule in favor, the children could become eligible for shots in the first week of November.” The Times adds, “An evaluation of data released by regulators on Friday from a clinical trial showed that Pfizer’s vaccine was very effective at preventing symptomatic COVID-19 in children in that age range, and that the vaccine’s benefits outweighed the risk of rare side effects.”

The Washington Post (10/26, McGinley, Shepherd) reports the FDA “concluded the benefits outweighed the risks in almost all scenarios, except possibly when there are very low levels of viral transmission.” But even then, the agency “said, the benefits might exceed the risks because vaccine-related myocarditis cases have tended to be mild, while COVID can lead to serious illness and death.”

The Wall Street Journal (10/26, A1, Hopkins, Subscription Publication) reports that if authorized, young children will receive the two-dose vaccine three weeks apart, with each shot containing only one-third of the dosage used to vaccinate adolescents and adults.

FDA adds boxed warning on breast implants, requires physicians to disclose risks

The New York Times (10/27, Rabin) reports, “Federal regulators on Wednesday placed so-called black box warnings on breast implant packaging and told manufacturers to sell the devices only to health providers who review the potential risks with patients before surgery.” These warnings and “a new checklist that advises patients of the risks and side effects state that breast implants have been linked to a cancer of the immune system and to a host of other chronic medical conditions, including autoimmune diseases, joint pain, mental confusion, muscle aches and chronic fatigue.”

The Washington Post (10/27, Shepherd) reports, “The new requirements follow years of complaints from tens of thousands of women who received breast implants and later suffered from brain fog, fatigue and other health issues, collectively known as ‘breast implant illness.’” Many “activists have long sought an informed consent process for patients so they have a clear understanding of the risks and benefits before they opt for surgery.”

The AP (10/27, Perrone) reports, “The Food and Drug Administration announced the new regulations mainly aimed at implant manufacturers, who are also being required to add a boxed warning message—the most serious type—to their written patient materials.” The agency “had originally proposed the rules as voluntary measures in 2019, but Wednesday’s action makes them legal requirements for breast implant makers, including leading manufacturers like Johnson & Johnson’s Mentor unit and Allergan.”

Heart groups release guidelines designed to help clinicians evaluate source and symptoms of chest pain while improving patient outcomes, reducing health care costs

Cardiovascular Business (10/28, Vecchione) reports, “The American Heart Association (AHA) and American College of Cardiology (ACC) have unveiled new guidelines designed to help clinicians evaluate the source and symptoms of chest pain while improving patient outcomes and reducing health care costs.” The guidelines were published in the Journal of the American College of Cardiology.

TCTMD (10/28, O’Riordan) reports, “The guidelines incorporate the use of contemporary imaging modalities, including cardiac computed tomography angiography (CCTA) and coronary artery calcium (CAC) scores, and emphasize the intensification of preventive therapies.” TCTMD adds, “Importantly, the guidelines also urge the more selective use of imaging and detail the factors to take into consideration when deciding between CCTA and stress testing.”

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