

# Three Minute Read™

Insights from the Healing American Healthcare Coalition™

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**From the Editor:** TMR begins its fourth year of publishing with FDA and Covid updates, and ending with some of healthcare's struggles to recover from the pandemic. To read the full article, click on its headline.

[Congressional Inquiry into Alzheimer's Drug Faults Its Maker and FDA](#), by Pam Belluck, New York Times, 12/29/22



**TMR Topline** – The FDA's approval process for Aduhelm was "rife with irregularities," according to a congressional investigation that "raise serious concerns about FDA's lapses in protocol." Aduhelm was approved in June 2021 despite its uncertain benefits and risks of brain swelling and bleeding. The FDA's advisory committee overwhelmingly voted against the approval. The FDA's own internal inquiry resulted in four recommendations to prevent future problems. The report also describes Biogen's intent to set "an unjustifiably high price" of \$56,000 a year for Aduhelm because it wanted a history-making "block-buster." The company planned to spend more than 2-1/2 times what it cost to develop Aduhelm on marketing it.

[FDA approves Alzheimer's drug that appears to modestly slow disease](#), by Jon Hamilton, NPR, 1/6/23



**TMR Topline** – The FDA has [approved](#) a drug, lecanemab, that may help people in the early stages of Alzheimer's maintain their mental abilities. Developed by Eisai in conjunction with its partner Biogen, it will be marketed as Leqembi and priced at \$26,500 a

year. Like Aduhelm, side effects include brain swelling and bleeding. In a [study](#) of 1,800 people with early Alzheimer's, those who got Leqembi for 18 months experienced 27 percent less decline in memory and thinking. To qualify for treatment, people need to be tested to confirm that they are in the early stages of dementia and that their brains contain the amyloid deposits that are a hallmark of Alzheimer's.



[The FDA. Now Says It Plainly: Morning-After Pills Are Not Abortion Pills](#), by Pam Belluck, New York Times, 12/23/22

**TMR Topline** – It took ten years, but the FDA finally revised the leaflets inserted in Plan B One-Step packaging to clarify that the medication "works before release of an egg from the ovary," meaning that it acts before fertilization, not after. The package insert also says the pill "will not work if you're already pregnant, and will not affect an existing pregnancy." In 2013, [European health authorities](#) revised the label of a pill identical to Plan B to say that it "cannot stop a fertilized egg from attaching to the womb." The FDA received the application to revise the wording in 2018. Anti-abortion groups have been asserting incorrectly that Plan B can cause an abortion.

**TMR's Take:** Don't expect to see Leqembi widely available soon. Eisai has applied for full approval, but its application likely will receive added scrutiny given Biogen's attempt to rapidly get approval for Aduhelm. While it may not take the ten years it took for the FDA to clarify that Plan B is a contraceptive, not an abortifacient, nimble bureaucracy remains an oxymoron.



[New Covid omicron subvariant XBB.1.5 is 'spreading like wildfire' in US: Health experts reveal why](#), by Angelica

Stabile, Fox News, 1/5/23

**TMR Topline** – The immuno-evasive XBB.1.5 omicron

subvariant is spreading rapidly across the US, accounting for 41% of confirmed Covid-19 cases according to the CDC. It's highly contagious and less susceptible to natural immunity or vaccines than earlier mutations. NYU Langone Medical Center's Dr. Mark Siegel explained it's more contagious because of its ability to grip tightly onto a host: "The spike proteins are like suction cups. Viruses always want to be more and more transmissible and infect more hosts. So, the more it can get a grip ... the more easily it transmits from cell to cell." He added that so far there's "no evidence" that XBB.1.5 is more virulent.

commonly used by the CDC. A Pew Research Center [report](#) found 57% of U.S. adults believe "false and misleading information about the coronavirus and vaccines has contributed a lot to problems the country" has faced during the pandemic. Phil Maytubby, deputy CEO of the Oklahoma City health department said the primary tactic among those trying to sow distrust about vaccinations has been to cast doubt — about everything from the science to their safety. "In that aspect, they've been pretty successful. Misinformation has changed everything."



[China defends its Covid response after WHO, Biden concerns](#), by Eduardo Baptista and Brenda Goh, Reuters, 1/5/23

**TMR Topline** – After the WHO's Emergencies Director, Dr. Michael Ryan, said that China was underreporting Covid-19 data and President Biden voiced concern about China's handling of a Covid outbreak that is [filling hospitals](#), foreign ministry spokesperson Mao Ning said "China's epidemic situation is controllable." Chinese officials and experts also [outlined the latest situation](#) in an online meeting with the WHO. China narrowly defines Covid deaths, counting only deaths caused by pneumonia and respiratory failure in patients who had the virus.



[Nonprofit healthcare will likely take years to recover, S&P says](#), by Nick Thomas, Becker's Hospital Review, 1/3/23

**TMR Topline** – In a December report, S&P Global Ratings downgraded its nonprofit healthcare sector view to negative stating, "Meaningful improvement will likely take multiple years." While weaker cash flow and the need for capital spending amid higher construction costs restricts reserves, the main obstacle facing healthcare systems will be sustained labor costs, S&P said. Moody's and Fitch Ratings issued similar warnings last month.



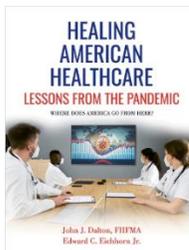
[Public Health Agencies Try to Restore Trust as They Fight Misinformation](#), by Lauren Sausser, Kaiser Health News, 1/4/23

**TMR Topline** – The more than 3,000 US public health agencies face difficult challenges resulting from years of underfunding pre-pandemic, including misinformation and growing parental skepticism about vaccine effectiveness. [KHN and the Associated Press](#) found local health department spending dropped by 18% per capita from 2010 to 2020, losing more than 40,000 jobs. During Covid's early days, many local health departments [used fax machines](#) to report Covid case counts. According to the [CDC](#), flu vaccine coverage among children was 3.7% lower than the December 2020 and 18% lower among pregnant women. A [KFF survey](#) found 35% of American parents oppose mandatory vaccination for measles, mumps, and rubella for children before starting school, up from 23% in 2019. A [JAMA](#) study found Covid-related language often was more complex than an 8th-grade reading level and harder to understand than the language



[Congress Overrides Some – But Not All – Medicare Physician Payment Cuts](#), by Jessica L. Bailey-Wheaton, Esq., Health Capital Topics, December 2022

**TMR Topline** – The \$1.7 trillion spending bill to fund the federal government through 9/30/23 included partial relief from the threat of a 4.48% Medicare funding cut. Instead, physicians will see a 2.5% payment cut in 2023, and a 1.25% cut in 2024. The spending bill also extends current Medicare telehealth flexibilities to 12/31/24. States will be allowed to review Medicaid rolls and remove ineligible enrollees starting 4/1/23. AMA President Dr. Jack Resneck, Jr. expressed disappointment with the cuts, noting that some practices may stop enrolling new Medicare patients due to this legislation.



**TMR's Take:** Want to learn the lessons that China ignored? Order "Lessons from the Pandemic," the Coalition's new book, available in both soft-cover and eBook versions. Click [here](#) to buy it at a discounted price with coupon Printbook or ebook at checkout.