

Three Minute Read™

Insights from the Healing American Healthcare Coalition™

July 2021-3



From the Editor: While the Delta variant surges among the unvaccinated, much of the news deals with drugs: the controversial FDA approval of Aduhelm, the record deaths from drug abuse and the opioid abuse settlements. To access each article, just click on the headline.



[Hospitals in low-vaccination states struggle as COVID-19 surges](#), by Steven Ross Johnson, Modern Healthcare, 7/13/21

TMR Topline™ - States with the highest seven-day average

increases in cases also have some of the country's lowest vaccination rates. CoxHealth is one of the health systems at the forefront. Serving patients in southwestern Missouri and northwestern Arkansas, it has gone from having about 20 patients a day hospitalized for Covid-19 related illnesses in May to more than 100 by July. In Springfield Missouri, the number of Covid-19 related inpatients jumped from 76 on June 8 to 192 by July 8.



[COVID-19 'is becoming a pandemic of the unvaccinated.'](#) CDC director

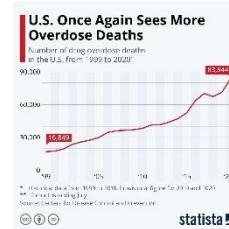
says, by Heather

Hollingsworth and Josh Funk, Associated Press, 7/16/21

TMR Topline™ - The Covid-19 comeback is putting pressure on hospitals at a time when some are busy just trying to catch up on elective procedures that were postponed during the pandemic. Staff members are worn out and finding traveling nurses to boost their ranks can be tough. *"I really think of it as a war and how long can you stay on the front line,"* said Dr. Mark Rosenberg,

president of the American College of Emergency Physicians. *"And how many times do you want to go back for another tour of duty. Eventually you just don't want to do it."* The fear now is that hospitals might have to postpone non-COVID-19-related care again — and risk the potential health consequences for patients. CDC Director Dr. Rochelle Walensky warned that the outbreak in the U.S. is becoming *"a pandemic of the unvaccinated"* because nearly all hospital admissions and deaths are among those who hadn't been immunized.

TMR Take - Dr. Walensky's right! If you haven't done so, *get vaccinated!* The life you save may be your own.



['It's Huge, It's Historic, It's Unheard-of': Drug Overdose Deaths Spike](#), by Josh Katz and Margot Sanger-Katz, New York Times, 7/14/21

TMR Topline™ - As the Covid pandemic raged, drug abuse deaths rose 30% to more than 93,000 in 2020, disproportionately among the young. Deaths rose in every state but New Hampshire and South Dakota, with the greatest increases in the South and West. A Times analysis estimates that the drug deaths represent 3.5 million years of life compared to 5.5 million for the 375,000 Covid deaths. The pandemic's disruption to outreach and treatment facilities and increased social isolation contributed to the increase as did fentanyl becoming entrenched in the nation's drug supply. Fentanyl is easier to manufacture and ship than traditional heroin with higher potency. The pandemic brought some policy changes that may have saved lives such as allowing people enrolled in methadone treatment to take doses home with them, instead of having to visit a clinic each day. Regulators also made it easier for people to seek medical care through telemedicine.



[States Announce \\$26 Billion Settlement to Resolve Opioid Lawsuits](#), by Sarah Randazzo, Wall Street Journal, 7/21/21

TMR Topline™ - The nation's three largest drug distributors— McKesson Corp. , AmerisourceBergen Corp. , and Cardinal Health Inc. —and drugmaker Johnson & Johnson have been negotiating the \$26 billion deal to resolve thousands of opioid-crisis lawsuits for two years. Under the terms of the settlement, states must spend the funds on social services to address the harms of opioid addiction, like treatment programs, education on disposing pills and needles, and funding for first responders. Over an 18-year period, McKesson will pay up to \$7.9 billion, while AmerisourceBergen and Cardinal each agreed to provide up to \$6.4 billion. J&J will pay over nine years, with up to \$3.7 billion paid during the first three years. The agreement needs support from at least 48 states, 98% of litigating local governments and 97% of the jurisdictions that have yet to sue.



[Justice Department Blasts Purdue Pharma's Bankruptcy Plan](#), by Brian Mann, NPR, 7/19/21

TMR Topline™ - The DoJ is condemning a [proposed bankruptcy settlement](#) for Oxycontin maker Purdue Pharma, describing the plan as fatally flawed. Separately, the office of the U.S. Attorney for the SDNY said the plan violated the "constitutional right to due process" for those with potential opioid claims. The company's aggressive marketing of Oxycontin that began in the late 1990s is widely seen as a trigger of the nation's deadly opioid epidemic, which has killed more than a half-million Americans. The plan would allow the Sackler family "third party releases," sheltering them from future opioid lawsuits. In return, would contribute roughly \$4.3 billion from their private fortunes to help compensate people and communities harmed by Oxycontin.

TMR Take – The Sackler family earned over \$10 billion from Oxycontin and would be relieved of civil and criminal liability if Purdue Pharma's bankruptcy plan is approved. Families of victims are appropriately concerned.



[FDA chief Janet Woodcock acknowledges agency may have misstepped in process leading up to Alzheimer's drug approval](#), by Rachel Cohrs, STAT, 7/14/21

TMR Topline™ - Acting FDA Commissioner Janet Woodcock acknowledged her agency may have mis-

stepped in its handling of its [polarizing approval](#) of a new Alzheimer's drug. While defending the therapy and the decision, she said "it's possible that the process could have been handled in a way that would have decreased the amount of controversy involved." The agency already has had to [narrow the patient population](#) for whom the drug is approved; Woodcock also called for an [independent watchdog to investigate](#) the actions that led to the drug's approval. The FDA's approval of Aduhelm has been mired in controversy after controversy since its approval last month amid concerns about a May 2019 off-the-record meeting between an FDA regulator Woodcock supervised and Biogen, the drug's developer.

[Will Medicare Pay For The New Alzheimer's Drug?](#), by Howard Gleckman, Forbes, 7/13/21

TMR Topline™ - Given the FDA approval of Aduhelm, Medicare now must make a National Coverage Determination (NCD) on Biogen's \$56,000 a year drug. [An independent analysis suggests](#) \$3,000-\$8,400 would be a reasonable price range. Medicare must determine whether the drug is "reasonable and necessary for the diagnosis or treatment of illness or injury." Even if only 1 million of the 6 million Americans with Alzheimer's are prescribed the drug, Medicare costs could exceed \$50 billion annually. CMS says it will base its decision on "an assessment of the clinical evidence such as published clinical studies, professional society guidelines, and public comments."

TMR Take – Medicare is not allowed to negotiate drug prices, so Biogen executives and investors will benefit greatly from a positive NCD, even with the narrower approval. Spending at that rate for a drug with unproven effectiveness ultimately could bankrupt Medicare, leaving American taxpayers holding the bag. In a recent issue of Gooznews, Modern Healthcare's Editor Emeritus Merrill Goozner argues that Aduhelm is an opportunity for the Patient-Centered Outcomes Research Institute (PCORI) to conduct comparative effectiveness research. Created by the ACA, PCORI conducts studies that measure the "potential burdens and economic impacts" of health care services and "the full range of clinical and patient-centered outcomes." One arm of the trial would get the unproven drug. Another arm "would receive home care coupled with non-drug interventions like physical and cognitive exercise. And a third arm would get both." **TMR** agrees. Such a trial would measure the impact each approach has on cognitive decline as well as how either affects the financial and emotional patients' families well-being. The third arm would determine if the benefits of the two approaches are additive.