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Insights from the Healing American Healthcare Coalition™

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HEALING AMERICAN HEALTHCARE COALITION

From the Editor: This issue's article summaries begin with the consequences of Roe v. Wade being overturned, then updates on Covid boosters, a promising treatment for melanoma, and the puzzling Adderall shortage. Click on the headline to read the full article.

Abortion providers relieved, wary as high court preserves pill access, by Sharon Bernstein, Reuters, 4/21/23

TMR Topline – The US Supreme Court has preserved access to Mifepristone while legal challenges to the drug continue. Abortion opponents are confident the court ultimately would rule in favor of the pill's challengers, who contend that the FDA illegally approved mifepristone and then removed critical safeguards on what they call a dangerous drug. Reproductive rights supporters said they remained concerned about the future risks to access as the case returns to the lower courts that had sought to restrict it.

Texas abortion pill ruling could impact other FDA-approved drugs, vaccinations: HHS secretary, by Stephen Neukam, The HILL, 4/9/23

TMR Topline – HHS Secretary Xavier Becerra said the move by a Texas federal judge to block the approval of a type of abortion medication could have far-reaching effects on the status of other federally-approved medications and vaccinations. *"When you turn upside down the entire FDA approval process, you're not talking about just mifepristone. You're talking about every kind of drug. You're talking about our vaccines. You're talking about insulin. You're talking about the new Alzheimer's drugs that may come on."* The judge argued that the federal government's approval process was rushed, concluding in an unsafe drug being put on the market. *"If a judge decides to substitute his preference, his personal opinion for that of scientists and medical professionals, what drug isn't subject to some kind of legal challenge?"* Becerra said. *"So we have to go to court. And, for America's sake and for women's sake, we have to prevail in this."*

Obstetrics faces declines in residency applicants, services, by Mari Devereaux, Lauren Berryman, Modern Healthcare, 4/18/23

TMR Topline – With a battle over reproductive healthcare and abortion raging, fewer medical school graduates are pursuing obstetrics-gynecology residencies, making the existing shortage worse. The American Association of Medical Colleges reported a 5.2% drop in senior OB-GYN residency applicants. Half of all US counties lack an OB-GYN and more than 89 obstetric units closed in rural hospitals from 2015-2019 according to the American Hospital Association. During the pandemic more than 20 rural communities' lost access to obstetric services.

TMR'S Take: Reproductive rights restrictions already are taking a toll, especially for rural hospitals in red states. The US already ranks last in maternal mortality rates among high-income countries. With fewer OB-GYNs, it's not likely to improve. Mifepristone was developed in 1980, approved by the FDA in 2000 on the World Health Organization's list of essential medicines. It has proven to be safe and effective. Serious complications are rare.

FDA clears extra Covid booster for some high-risk Americans, by Lauran Neergaard, Associated Press, 4/18/23

TMR Topline – The FDA has cleared another booster dose of the Pfizer or Moderna Covid-19 vaccines for older

Americans and people with weak immune systems. Those 65 or older can get the spring booster as long as it's been at least four months since their first dose of the bivalent vaccine targeting omicron strains. FDA vaccine chief Dr. Peter Marks said *"Covid-19 remains a very real risk for many people."* Letting seniors and the immune-compromised get an extra booster dose puts the U.S. in line with Britain and Canada. The FDA will hold a public meeting in June to consider if the vaccine recipe needs more adjusting to better match the latest coronavirus strains — just like it adjusts flu vac-cines every year.

Moderna/Merck cancer vaccine plus Keytruda delays skin cancer return, by Julie Steenhuysen, Reuters, 4/16/23
TMR Topline – Moderna and Merck recently presented the results of their experimental mRNA cancer vaccine at the American Association for Cancer Research meeting in Orlando. They found adding a personalized cancer vaccine based on mRNA technol-ogy to Keytruda could cut the risk of death or recurrence of the most deadly skin cancer by 44% when compared with treating the patient with Keytruda alone. Dr. Ryan Sullivan, a melanoma expert at Mass General Cancer who worked on the study, said "*From a general cancer therapeutic standpoint, this is a potential major break-through*." The vaccine is custom-built based on an analysis of a patient's tumors after surgical removal and are designed to train the immune system to recognize and attack specific mutations in cancer cells. Patients enrolled in this study were at high risk of their melanoma returning. Among 107 study subjects who received both the experimental vaccine, and Keytruda, the cancer returned in 22.4% of the patients within two years of follow-up, compared with 40% of those who received Keytruda alone. Merck's chief medical officer Eliav Barr said it took about eight weeks to design a personalized mRNA vaccine for each patient and that it may take three to four years before the results of the larger trials are known. Moderna's mRNA technology allowed for the inclusion of as many as 34 neoantigens, which Barr called "*astonishing*."

TMR'S Take: After conquering Covid-19, will mRNA technology also conquer cancer? Too soon to tell, but mRNA development may well wind up being the medical miracle of the 21st Century!

The ongoing, unnecessary Adderall shortage, explained, by Dylan Scott, Vox, 4/10/23
TMR Topline – Six months after the FDA announced a shortage of the ADHD drug Adderall , ADHD patients are still struggling to obtain this medication that can be essential for them to lead normal lives. While drug shortages are increasingly common in the US, the persistent Adderall shortage is more compli-cated than most drug shortages because the stimulant amphetamine is an active ingredient. Amphetamine's availability is controlled by the DEA and Adderall is regulated as a controlled substance. The DEA limits its availability for its potential to be abused. The companies that produce Adderall and its generic version have cited both a shortage of the active ingredients and an increase in demand to explain their ongoing shortages

According to the CDC, approximately 6 million children ages 3 to 17 (about 9.8% of children in the US) have been diagnosed with ADHD as of 2019. Boys are about twice as likely to be diagnosed with the condition as girls. According to IQVIA, a health care data and analytics company, about 41.4 million prescriptions for Adderall were dispensed in 2021. This suggests that millions of Americans are relying on the drug to moderate their ADHD symptoms. But that became more difficult when the Adderall shortage began in October of 2022. The DEA approaches its role in regulating Adderall as a law enforcement issue and emphasizes preventing abuse as much as possible. Dr. Max Wiznitzer, who advises the ADHD advocacy group CHADD said in a recent editorial in the Times, *"Perhaps in response to its failure to prevent the rise in prescription opioid misuse, the DEA may be trying to avert a repeat crisis by keeping stimulant manufacturing quotas tight."* Wiznitzer also said that due to this regulatory approach, In the richest country in the world, desperate patients can't get a medicine they need.

TMR'S Take: Healthcare – it's REALLY complicated! Opioids to addict adults abound while Adderall for ADHD kids is scarce. The Covid-19 pandemic exposed lots of flaws in US healthcare delivery. The public health emergency ends May 11. Get a head start on your summer reading by ordering *"Lessons from the Pandemic"* available in both soft-cover and eBook versions. Click here to buy it at a discounted price with coupon **Printbook** or **ebook** at checkout.