Three Minute Read™

Insights from the Healing American Healthcare Coalition™

February 2023-1



From the Editor: The articles summarized include updates on the public health emergency and the latest tactics of drug makers and health insurers to place profits before patients. To read an article, click on its headline.



WHO maintains highest alert over Covid, but sees hope ahead, by Abinaya Vijayaraghavan and Jennifer Rigby, Reuters, 1/30/23

TMR Topline – With uncertainty over the wave of infections in China after it lifted its zero-Covid measures at the end of 2022, Covid-19 continues to constitute a global health emergency. WHO Director-General Ghebreyesus hopes to see an end to the emergency this year given the advent of vaccines and treatments.





Biden to end Covid health emergency declarations in May, by Adam Cancryn, Politico, 1/30/23 TMR Topline – The Biden

administration will end the Covid-19 national and public health emergencies (PHE) on May 11, unwinding a sprawling set of flexibilities put in place nearly three years ago that paved the way for free Covid treatments and tests. De-fending the decision a senior official said, "We're in a pretty good place in the pandemic. We've come through the winter, cases are down dramatically from where they were the past two winters."

TMR's Take: Under the PHE and national emergency declarations, HHS and its agencies were able to <u>waive or</u>

<u>ease</u> many healthcare regulations. An article in <u>Modern</u> Healthcare lays out the policies that will be affected.



How a Drug Company
Made \$114 Billion by
Gaming the U.S. Patent
System, by Rebecca Robins,
New York Times, 1/28/23

TMR Topline – With its key patent scheduled to expire at the end of 2016 and a rival drug approved by regulators, AbbeVie exploited weaknesses in the US patent system to block competitors from entering the market for six years, garnering \$114 billion in revenue from sales of Humira, its anti-inflammatory medication used to treat conditions like arthritis. The drug's list price has increased 60 percent to over \$80,000 a year since the end of 2016. One analysis found that Medicare spent \$2.2 billion more on the drug from 2016-19 than it would have if competetion hadn't been blocked. The article provides a look at the legal tactics AbbeVie used to protect its monopoly. Even now, as competitors enter the market and prices drop, the company will earn royalties from the knockoff products that it blocked and delayed.



Drug companies could have made naloxone more accessible. Why didn't they? by Leana S. Wen, Washington Post, 1/23/23

TMR Topline – Written by Baltimore's former Health Commissioner, the article provides insights into yet another strategy used by Big Pharma to protect its profits. Naloxone, administered as an injection or nasal spray, has been used for decades to treat opioid overdoses. It is safe and extremely effective, and can be administered by bystanders without any medical training. FDA officials asked manufacturers to apply for OTC status at a 2017 conference. It didn't happen until Harm Reduction Therapeutics, a nonprofit company started from scratch, ran a clinical trial for a new intranasal formulation of naloxone and conducted a study to ensure consumers could use the product based on simple instructions.

When HRT submitted its FDA application last year, Emergent BioSolutions filed its application for OTC status. Why the delay? HRT's co-founder Michael Hufford speculated that "they charge a significant premium because they get reimbursed for it as a prescription." Both companies are expected to receive OTC status as early as March.



Appeals court clears the way for more lawsuits over Johnson's Baby Powder, by Scott Horsley and Brian Mann, NPR, 1/30/23

TMR Topline – The 3rd US Circuit Court of Appeals dismissed a bank-

ruptcy filing by a Johnson & Johnson spinoff company, ruling that the company was not in genuine financial distress. The court noted that the spinoff company still has access to J&J's assets, worth an estimated \$61.5 billion. The company was facing some 38,000 lawsuits from people who allege its Johnson's Baby Powder was tainted with asbestos, a substance known to cause cancer and other illnesses. It tried to short-circuit the lawsuits in 2021, using a controversial legal tactic known as the "Texas Two Step." It first assigned liability for the baby powder complaints to a spin-off company, then immediately put that company into bankruptcy. A bankruptcy judge upheld the maneuver, but the appeals court disagreed. A similar case involving Purdue Pharma is pending before a New York federal appeals court.



I wrote about high-priced drugs for years. Then my toddler needed one., by Carolyn Y. Johnson, Washington Post, 1/30/23

TMR Topline – When her 3-year-old son stopped walking and spiked a 104 fever, Ms. Johnson headed for the ER. After several days of testing, he was diagnosed with a rare type of childhood arthritis called systemic onset juvenile idiopathic arthritis, or sJIA, in which the innate immune system, the body's first line of defense against pathogens, goes haywire. Untreated, destructive joint damage can occur. The doctors wanted to try anakinra (trade name Kineret), a biologic that, according to pediatric rheumatologist Randy Cron at UAB, was "Remarkably effective and safe." Her insurer, Aetna, disagreed, and denied the prior authorization request. On appeal the denial was upheld by a team led by a urologist. Like many drugs for rare diseases, anakinra is expensive – about \$4,000 per month. Instead, Aetna

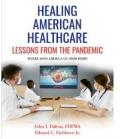
insisted on step therapy, requiring that her son try 30 days on drugs such as naproxen or ibuprofen, or two weeks on a steroid first to see if those worked. They didn't. Ironically, after two months of excruciating effort by Johnson and her medical team, Aetna approved use of a much more expensive drug – and it worked. The full article is disturbing, but well worth reading.



Feds expect to collect \$4.7B in insurance fraud penalties, by Amanda Seitz, Associated Press, 1/30/23 TMR Topline – The Biden

administration has announced it could collect as much as \$4.7 billion from insurance companies with tougher penalties for submitting improper charges for Medicare Advantage subscribers. HHS's Office of the Inspector General has been sounding the alarm for years about questionable charges by claiming members are sicker than they really are to receive inflated payments. A review of 2017 claims alone suggests that about \$6.7 billion may have been paid for patients whose diagnoses were not supported by their medical records. Nearly half of the 60 million seniors enrolled in Medicare belong to MA plans. HHS Secretary Xavier Becerra said, "Today, we are taking some long overdue steps to move us in the direction of accountability," Insurers disagree. AHIP's President Matt Eyles said, "Our view remains unchanged: This rule is unlawful and fatally flawed, and it should have been withdrawn instead of finalized," warning that the move will raise insurance rates.

TMR's Take: American healthcare – it's REALLY complicated, and needlessly so. To quote Cynthia Johnson, "Health care is a battlefield. Patients often become cannon fodder." Modern Healthcare's Editor Emeritus Merrill Goozner did a deep dive into the flaws of the MA plans including an estimate that upcoding overpayments range from \$20-36 billion a year. TMR's next issue is a special edition covering the Commonwealth Fund's latest report on "U.S. Health Care from a Global Perspective,



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