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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 include four pharma updates, a blood test for cancer, United Health's prior authorization demands and the Medicaid purge. Click on the headline to read the full article. If you enjoy this curated newsletter, please subscribe [here](#)



6/6/23

TMR Topline – Merck has sued the Biden administration over [Medicare's](#) new powers to substantially reduce drug prices for seniors under the Inflation Reduction Act, calling the law's drug price [negotiation program](#) a "sham" and "tantamount to extortion." Merck alleges that it is an unconstitutional attempt to take private property for public use without just compensation in violation of the Fifth Amendment and asks the court to block HHS from compelling Merck to participate in the program. Responding, HHS Secretary Becerra said, "We'll vigorously defend the President's drug price negotiation law, which is already lowering health care costs for seniors and people with disabilities. The law is on our side." With nearly 60 million Americans in Medicare, AARP said Medicare's price negotiations will save billions of dollars for seniors, noting that Americans face the highest drug prices in the world. HHS will publish a list of the 10 drugs selected for the first round of price negotiations by Sept. 1. The negotiations end on Aug. 1, 2024, and CMS will publish a list of the reduced prices the following month. Those prices go into effect on Jan. 1, 2026.

[Merck sues Biden administration over Medicare drug price negotiations](#), by Spencer Kimball, CNBC,



[A landmark appeals court ruling clears way for Purdue Pharma-Sackler bankruptcy deal](#), by Brian Mann, NPR, 5/30/23

TMR Topline – A New York federal appeals court cleared the way for a bankruptcy deal for opioid manufacturer Purdue Pharma that will shield members of the Sackler family, who own the company, from future lawsuits. The ruling overturns a [lower court's December 2021 decision](#) and clears the way for a deal hashed out with [thousands of state and local governments](#). As part of the bankruptcy settlement, the Sacklers are [expected to pay roughly \\$5 to \\$6 billion and give up control of Purdue Pharma](#). Under the Sackler family's ownership, the company's aggressive marketing of OxyContin is widely seen as a spur to the national opioid crisis that has killed hundreds of thousands of Americans. About \$750 million will go to individuals across the US who became addicted to OxyContin and to the families of those who died from overdoses.

TMR'S Take: A [Rand Corporation](#) analysis found that in 2018, prescription drug prices averaged 2.56 times higher in the US than in 32 other OECD countries. Merck hasn't turned down business from those countries even though they negotiate aggressively for lower prices. Purdue Pharma and the Sacklers take a financial hit, but like the bankers who foisted sub-prime mortgages on unqualified buyers triggering the Great Recession, none went to jail. It's time for Big Pharma to put patients before profits!



[Coming up short: Why drug shortages are occurring](#), by Alex Kacik, Modern Healthcare, 5/30/23

TMR Topline – A shortage of chemotherapy drugs is leading to dose rationing and delayed care. Erin Fox, senior pharmacy director at University of Utah Health, noting similar issues with chemo drugs in 2011, said, "It feels a little like Groundhog Day. We are not seeing pro-gress because we haven't done the work to incentivize quality." Providers are constantly managing a rotating list of dozens of pharmaceuticals in short supply.

Many shortages are driven by manufacturing quality issues and financial considerations. Often, there are only one or two manufacturers of drugs like [epinephrine](#) and [saline](#), that require specialized production for relatively inexpensive products. If hospitals don't have saline to stabilize patients during surgery, they may have to postpone elective procedures. Drug manufacturer Teva Said it will "*pivot to growth*" by focusing on "*high-value*" drugs, consolidating its manufacturing network and trimming some low-margin generics. Unanticipated demand spikes can also spur shortages. During the Covid-19 pandemic, demand for Asthma drugs and sedatives soared. Proposed solutions range from increasing US production to rewarding high-quality manufacturers. Fox and other industry experts have recommended that Congress implement a rating system for pharmaceutical manufacturers. CMS then could give hospitals an add-on payment when they purchase high-quality drugs.



[FDA seeks to ease cancer drug shortage with China-made imports](#), by Ken Alltucker, USA TODAY, 6/5/23

TMR Topline – The FDA will temporarily allow overseas drug manufacturers to import some chemotherapy drugs to alleviate shortages, including the injectable chemotherapy drug cisplatin from China. India-based Intas Pharmaceuticals supplied about half the US market share when it had to pause production to fix quality issues. The National Cancer Institute said cisplatin and similar drugs are prescribed for 10-20% of all cancer patients. The FDA has sent a [letter](#) to Intas allowing the drugmaker to resume shipping cisplatin, and 15 other types of injectable medications to the US, subject to completing a third-party review and testing of any imported products.



[Multi-cancer blood test shows real promise in NHS study](#), by Michelle Roberts, BBC News, 6/2/23

TMR Topline – The Gallen blood test developed by California company Grail has shown real promise for detecting more than 50 types of cancer in [a major NHS trial](#). The test correctly revealed two out of every three cancers among 5,000 people with suspected symptoms. In 85% of those cases, it also pinpointed the original site of cancer. This test looks for distinct changes in bits of genetic code that leak from different cancers.

Spotting treatable cancer early can save lives. The test remains very much a "*work in progress*", the researchers from Oxford University said. About 75% of those testing positive with the blood test were found to have cancer and 2.5% of those testing negative were also found to have cancer. The test is very good at finding hard-to-spot cancers such as head and neck, bowel, lung, pancreatic, and throat cancers. The findings will be presented at the American Society of Clinical Oncology



[UnitedHealth backs off contentious prior authorization plan](#), by Arielle Dreher, Axios, 6/1/23

TMR Topline – The US's largest health insurer, UnitedHealth, has backed off its plan to require prior authorizations (PAs) for colonoscopies and other endoscopic procedures. However, the debate over insurer required sign-offs for these procedures will likely continue. While PAs are supposed to ensure that health services are medically necessary, critics say they can create barriers to care and drown the health system in red tape. The company had planned to require PAs starting June 1st for most endoscopic procedures, but sharp pushback from physician groups led it to substitute an alternative advance notification process that would require clinicians to collect and submit patient data before performing a procedure. Providers must participate in this program if they want to qualify for a [gold card program](#) set to roll out next year that will further streamline the process. Three provider groups rejected this new process, saying it would require essentially the same amount of documentation as PA, noting that staffing shortages would leave many practices with no one to pull the necessary information. They worry that PA delays may make patients skip or miss screenings.



[As Medicaid Purge Begins, 'Staggering Numbers' of Americans Lose Coverage](#), by Hannah Recht, KFF Health

News, 6/1/23

TMR Topline – Since pandemic protections ended April 1, more than 600,000 Americans have lost coverage. In most states the vast majority were dropped because of technicalities, not because state officials determined they no longer meet Medicaid income limits. The CBO [projects](#) that the under 65 uninsured rate will increase from its historic low of 8.3% to 9.3% next year. Medicaid or CHIP covered 93 million Americans before the unwinding.