## Three Minute Read™

## Insights from the Healing American Healthcare Coalition™

July 2023-2



**From the Editor:** This issue's article summaries begin with two drug updates and conclude with the Covid pandemic's conclusion and **TMR's** plea for paid subscriptions. Click on the headline to read the full article.



First over-the-counter birth control pill gets FDA approval, by Matthew Perrone, Associated Press, 7/13/23
TMR Topline – The FDA has

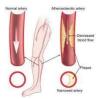
approved the nation's first over-the-counter birth control pill. Manufactured by Ireland-based Perrigo, once-a-day Opill can be sold without a prescription. Shipping will begin early next year, and there will be no age restrictions on sales. Until now, birth control pills required a prescription. Medical societies and women's health groups have pushed for wider access for decades, noting that an estimated 45% of the 6 million annual US pregnancies are unintended. Perrigo submitted years of research to the FDA to show that women could understand and follow instructions for using the pill. They warn that women with a history of breast cancer should not take the pill because it could spur tumor growth. Common side effects include irregular vaginal bleeding, headaches, dizziness and cramps. Certain drugs can interfere with Opill's effectiveness, including medications for seizures, HIV and hypertension. Opill should be in stores by early next year.



Chamber of Commerce files
motion for preliminary injunction
on Medicare drug negotiation, by
Joseph Choi, The HILL, 7/12/23
TMR Topline – The US Chamber of

Commerce filed a preliminary injunction to block imple-

mentation of Medicare's Drug Price Negotiation program established by the Inflation Reduction Act (IRA), joining suits filed by PhRMA, Merck and Bristol Myers Squibb. The suit challenges the constitutionality of the program claiming it violates the First, Fifth and Eighth Amendments. Chamber spokesperson Anthony Varcoe said "We're seeking timely relief before the government can further implement its illegal and arbitrary price control scheme. If allowed to go into effect, the scheme would harm not only US businesses but US patients - limiting access to medicine, deterring needed investment, and stifling innovation." The first 10 drugs eligible for price negotiation will be announced in September and negotiations will continue in 2024. The CBO estimated the program could reduce the budget deficit by \$25 billion in 2031. A KFF analysis found that Medicare Part D's 10 top-selling prescription drugs accounted for 1% of its covered drugs in 2021 but 22% (\$48 billion) of its drug spending. They include products like Eliquis and Ozempic. "While the drug price negotiations begin modestly with 10 drugs in the first year, KFF's research shows that even a relatively small number of drugs can command a substantial share of spending in Medicare," KFF said.



Patients Lost Limbs as Doctors and Health Care Giants Prospered, by Katie Thomas, Jessica Silver-Greenberg and Robert Gebeloff, New York Times, 7/16/23

TMR Topline – About 12 million Americans have peripheral artery disease (PAD), in which plaque accumulates in the arteries of the legs. The <u>vast majority of people</u> with PAD have mild or no symptoms and don't require treatment, aside from getting more exercise and taking medication. Many also have heart disease or diabetes, which present serious risks. Some doctors insert metal stents or nylon balloons to push plaque to the sides of arteries. Others perform more risky atherectomies, in which a wire armed with a tiny blade or laser is deployed inside arteries to blast away plaque. Medicare's 2008 decision to pay doctors for procedures performed outside of hospitals led to a proliferation of specialized outpatient clinics, including vascular.

The Times investigation found that when surgeons opened vascular clinics, medical device companies were there to provide loans, training and billing tips. Medicare payments ballooned from \$86 million in 2011 to \$612 million in 2021...and so did complications, including amputations. It's a long and troubling read.

**TMR's Take:** If ever there were a procedure that required prior authorization (and, perhaps, a second opinion), atherectomy belongs at the top of the list.



White House taking aim at surprise medical bills, 'junk' insurance, by Andrew Cass, Becker's Hospital Review, 7/7/23

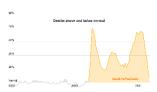
TMR Topline - President Biden announced a series of actions to address surprise medical billing, unfair medical debt and "junk" short-term insurance plans. The administration is issuing guidance to end health plans abuse of the "in-network" designation. Some plans contract with hospitals, then try to claim that they are not technically innetwork. Under federal law they are either out-of-network and subject to the surprise billing protections, or in-network and subject to the ACA's annual limitation on costsharing, further protecting consumers from excessive outof-pocket costs. Health plans and providers also must make information about facility fees available to consumers. Nonparticipating providers and emergency facilities cannot evade the protections of the No Surprises Act by renaming charges otherwise prohibited under the Act as "facility fees."

The Consumer Financial Protection Bureau (CFPB) has reported that patients often do not understand medical credit card terms and end up with more credit than they can afford. The industry has grown significantly in the past few years (e.g., Care Credit grew from 4.4 million cardholders in 2013 to 11.7 million in 2023). The CFPB and Treasury are releasing a request for information to learn more about the emerging practice and solicit comments on potential policy actions. Short-term health plans don't have to cover preexisting provisions or the ACA's essential health benefits. The Trump administration had extended the allowable coverage period from three months to as much as three years. Under the newly proposed rules, short-term plans would be limited to three months, or a maximum of four months, if extended.



Excessive Drinking During
the Pandemic Increased
Alcoholic Liver Disease
Death Rates, by Phillip Reese,
KFF Health News, 7/12/23

**TMR Topline** – The pandemic lockdowns made people feel isolated, depressed, and anxious, leading some to increase their alcohol intake. CDC data show that the number of Californians dying from alcoholic liver disease during the last three years was 25% higher than in the three years before the pandemic, with most deaths between 55 to 74 years old.



A Positive Covid Milestone, by David Leonhardt, New York Times, 7/17/23 TMR Topline –The number of Americans dying each day

from any cause is no longer historically abnormal. The excess deaths number has been an important measure of Covid deaths because it does not depend on the specific cause of death. The improvement is mostly due to three factors: 1. about three quarters of US adults have received at least one vaccine shot; 2. more than three quarters of Americans have been infected with Covid, providing natural immunity; and 3. post-infection treatments like Paxlovid, that can reduce the severity of symptoms, became widely available last year.

Chief infection control officer at Tufts Medicine Dr. Shira Doron said "age is clearly the most substantial risk factor. Covid's victims are both older and disproportion-ately unvaccinated. Given the politics of vaccination, the recent victims are also disproportionately Republican and white." President Biden angered some public health ex-perts last year when he declared, "The pandemic is over." His declaration may have been premature, but excess-deaths data suggest it's true now: It is finally over.

TMR's Take: TMR first published in March 2020 to provide brief updates on emerging healthcare issues to colleagues coping with the Covid-19 pandemic. 95 issues and 575 article summaries from nearly 100 sources later, TMR must face the economic reality that it needs more paid subscribers to keep publishing. If you enjoy this twice-monthly curated newsletter and would like to continue receiving it, please upgrade to a paid subscription <a href="here">here</a>.