The Three Minute Read™

Insights from the Healing American Healthcare Coalition™

October 2023-1

HEALING AMERICAN HEALTHCARE COALITION

From the Editor: This issue's article summaries include the Nobel Prize in Medicine award for mRNA research, Big Pharma agreeing to negotiate with Medicare, the downsides of Ozempic and pros and cons about the use AI. Click on the headline to read the full article. If you are enjoying **TMR**, please subscribe here.

Nobel Prize Awarded to Covid Vaccine Pioneers, by Benjamin Miller and Gina Kolata, New York Times, 10/2/23

TMR Topline – The Nobel Prize in Physiology or Medicine has been awarded to Katalin Karikó and Drew Weissman whose work on mRNA transformed vaccine technology and enabled potent Covid vaccines to be made in less than a year, averting tens of millions of deaths and helping the world recover from the worst pandemic in a century. Dr. Karikó struggled for years without funding or a permanent academic position, keeping her research afloat only by latching on to more senior scientists at the University of Pennsylvania who let her work with them. Unable to get a grant, she said she was told she was *"not faculty quality"* and was forced to retire from the university a decade ago. She and Dr. Weissman wandered down one dead end after another until making a specific chemical modification to mRNA synthesized in the lab before injecting it into cells.

It worked and the discovery *"fundamentally changed our understanding of how mRNA interacts with our immune system,"* the Nobel Prize panel said, adding that the work *"contributed to the unprecedented rate of vaccine development during one of the greatest threats to human health in modern times."*

TMR's Take: Kudos to Dr. Kariko for her persistence in pursuing the basic research that has produced a 21st century medical miracle on a par with the Salk polio vaccine in the 20th century. Vaccines using mRNA technology are being developed for influenza, malaria and H.I.V.

10 U.S. drugmakers agree to participate in price negotiations with Medicare, by A. L. Lee, UPI, 10/3/23

TMR Topline – The companies electing to participate in the Medicare Drug Price Negotiation Program include Bristol Myers Squibb, Boehringer Ingelheim, Janssen Pharmaceuticals, Merck Sharp Dohme, AstraZeneca, Novartis, Immunex, Pharmacyclics LLC, Jannsen Biotech and Novo Nordisk. According to HHS, the companies' drugs brought in $50.5 billion from prescriptions covered under Part D between June 1, 2022, and May 31, 2023, with consumers paying $3.4 billion in out-of-pocket costs. When negotiations conclude, CMS will announce the prices of the selected drugs on or before September 2024 to go into effect in 2026. Merck and J & J have filed lawsuits in an effort to declare Biden's plan unconstitutional.

You Won't Lose Weight on Ozempic Forever, by Dani Blum, New York Times, 9/18/23

TMR Topline – Diabetes drugs Ozempic and Wegovy now are being widely used for weight loss, but users are finding that they soon hit a weight loss plateau. The human body is built to fight back against weight loss. These medications mimic a naturally occurring hormone and slow the emptying of the stomach. Users feel fuller, faster and for longer. They also target the areas of the brain that regulate appetite, curbing cravings. People with diabetes have tended to lose less weight, less quickly, than people who are not diabetic. Endocrinologist Dr. Andrew Kraftson explained that even if someone still is classified as overweight, their blood pressure and

cholesterol could be under control, and their blood sugar might have dipped because they were taking medication.

FDA updates Ozempic label to acknowledge some users' reports of blocked intestines, by Katherine Dillinger, CNN, 9/28/23

TMR Topline – The FDA has updated the diabetes drug Ozempic's label to acknowledge reports of blocked intestines in some who use the medication. Novo Nordisk, manufacturer of Ozempic and Wegovy, said it is working closely with the FDA *"to continuously monitor the safety profile"* of its medications. Wegovy and Mounjaro labels already acknowledge reports of ileus, or intestinal blockage, in some people who use them. Some people who use Ozempic and Wegovy have also reported developing a condition called gastroparesis, or stomach paralysis.

Contamination Found at Novo Nordisk's Johnson County Plant Report Says, by Zachary Eanes, Axios, 9/25/23

TMR Topline – The FDA visited the Clayton plant in July and found its safety controls were deficient. It makes semaglutide, which has seen demand increase due to surging popularity of Ozempic and Wegovy.

Insight: Big Pharma bets on AI to speed up clinical trials, by Natalie Grover and Martin Coulter, Reuters, 9/22/23

TMR Topline – Major drug-makers are starting to use artificial intelligence (AI) to find patients for clinical trials more quickly or to reduce the number of people needed for clinical trials. Use of AI may accelerate drug development while saving millions. Human studies are the most expensive and time-consuming part of drug development. It can take years to recruit patients to conduct clinical trials - the process can cost over a billion dollars and take 10 years from drug discovery to the finishing line. Companies like Amgen, Bayer and Novartis are training AI to scan billions of public health records, prescription data, medical insurance claims and internal data to find trial patients - in some cases reducing the sign-up time by 50%. From 2016-22, the FDA reported it received about 300 applications that incorporated AI in drug development with over 90% of them submitted in the past 2 years. Amgen's AI tool, ATOMIC, scans internal and public data to identify and rank clinics and doctors based on past performance in recruiting patients for trials. Enrolling patients for a mid-stage trial normally takes up to 18 months, but ATOMIC can cut that time by 50%. Amgen expects that by 2030 AI will have helped take two years off the decade or more it typically takes to develop a drug. A senior principal scientist at Roche subsidiary Flatiron Health Blythe Adamson said the advantage of AI was that it lets scientists examine real-world patient data quickly and at scale. While AI can speed up the clinical trial process, evidentiary standards for a drug's safety and effectiveness will not change.

Feds Rein In Use of Predictive Software That Limits Care for Medicare Advantage Patients, by Susan Jaffe, KFF Health News, 10/5/23

TMR Topline – UnitedHealthcare Group (UHC) , the nation's largest health insurance company, bought naviHealth, a care management company, in 2020. Its proprietary *"nH Predict"* analyzes data to help insurance companies make coverage decisions by analyzing millions of medical records to match patients with similar diagnoses and characteristics, including age, preexisting health conditions, and other factors. Its algorithm anticipates the care a specific patient will need and for how long that care will be needed. However, patients, providers, and patient advocates have noticed a suspicious coincidence: it often predicts a patient's date of discharge that coincides with the date their insurer cuts off coverage, even if the patient needs further treatment that Medicare would provide. "*When an algorithm does not fully consider a patient's needs, there's a glaring mismatch*," said Dr. Rajeev Kumar, president-elect of the Society for Post-Acute and Long-Term Care Medicine. In January, New federal rules for Medicare Advantage plans will rein in their use of algorithms in coverage decisions. Insurance companies using these tools will be expected to "*ensure that they are making medical necessity determinations based on the circumstances of the specific individual, as opposed to using an algorithm or software that doesn't account for an individual's circumstances*."

TMR's Take: AI – blessing or curse? Speeding clinical trials – a potential blessing. Making medical necessity determinations – not without physician input!